# HIT Policy Committee
# Consumer Empowerment Workgroup
# Transcript
# July 16, 2013

## Presentation

**Operator**
Ms. Robertson, all lines are bridged.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thank you. Good morning everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. Welcome to the HIT Policy Committee's Consumer Empowerment Workgroup meeting. This is a public call and there is time for public comment or there will be at the end of the agenda. This call is also being recorded so please make sure you identify yourself when speaking. And just for the record, there are several other workgroups who were invited to participate – or to listen in today, the Consumer Technology Workgroup, the Meaningful Use Workgroup, the Information Exchange Workgroup and the NwHIN Power Team, but I'm just going to go through the roll call of the Consumer Empowerment Workgroup. So, Christine Bechtel?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Good morning.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Good morning Christine. Korey Capozza? Jim Cartreine? Scott Fannin? Leslie Kelly Hall? Katherine Kim?

**Katherine Kim, MPH, MBA – Health Equity Institute Professor in Residence – San Francisco State University**
Good morning.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks Katherine. Sarah Krug?

**Sarah Krug – CEO, Cancer101 – President, Society for Participatory Medicine**
I am here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks Sarah. Rita Kukafka? Patricia MacTaggert? Beth Morrow? Jan Oldenburg?

**Jan Oldenburg – Vice President, Patient Engagement – Aetna**
Jan's here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks Jan. Casey Quinlan? Clarke Ross? Mark Savage?

**Mark Savage, JD – Consumers Union of United States, Inc.**
Mark's here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Ah, great Mark. MaryAnne Sterling?

**MaryAnne Sterling – CEO – Sterling Health IT Consulting, LLC**
I'm here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks MaryAnne. Ann Waldo? Ryan Witt? Terry Adirim? Cynthia Baur? Bradford Hesse?

**Bradford W. Hesse, PhD – Chief, Health Communication & Informatics Research Branch (HCIRB) – National Institute of Health**
I'm here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Ah, thanks Brad. Kim Nazi?

**Kim Nazi, PhD, FACHE – Management Analyst – Veterans Health Administration**
I'm here thank you.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks Kim. Danielle Tarino? Teresa Zyas Caban? And any ONC staff members on the line, if you could please identify yourself?

**Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator**
Mary Jo Deering.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks Mary Jo.

**Michelle Consolazio – Office of the National Coordinator**
Michelle Consolazio.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks Michelle. And if there are any workgroup members that joined a little bit after the roll call, Christine I'll try and send an email and let you know. So with that, I'll turn the agenda back – sorry, who is that?

**Mohit Kaushal, MD, MBA – Partner – Aberdare Ventures/National Venture Capital Association**
Good morning, it's Mo here as well, Mo Kaushal.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Ah, thanks Mo.

**Patricia MacTaggert, MBA, MMA – Lead Research Scientist/Associate Professorial Lecturer – George Washington University**
Yeah, and Patricia MacTaggert, I got disconnected and reconnected.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks Patricia.

**Paul Egerman – Businessman/Software Entrepreneur**
And Paul Egerman is –

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Sorry, was there one more?

**Paul Egerman – Businessman/Software Entrepreneur**
Paul Egerman is here.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Ah great, thanks Paul. With that, I will turn the agenda back to you Christine.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great, thanks. So welcome everybody and thank you for joining us. This is a terrific listening session that we have planned for the day. We actually have online participating members from three different workgroups; one is the Consumer Empowerment Workgroup of the Health IT Policy Committee. One is Consumer Technology Workgroup, which is sort of our sister workgroup from the Standards Committee. And then the third are members of the Meaningful Use Workgroup of the Health IT Policy Committee. And we really wanted to bring these three groups together today to begin to talk with more detail about policy implications for patient-generated health data. For those of you who aren't members of the Consumer Empowerment Workgroup, we've done a fair amount of discussing the implications of patient-generated health data, given the fact that view, download, transmit, and actually, if Altarum could back up a slide, I'll get to that in a moment, that'd be great. Thank you.

So, given the fact that the view, download, transmit criteria for Stage 2 of Meaningful Use will go live later this year for hospitals and beginning in January for physician practices. So, given that fact, we realized that there will be many questions and opportunities as consumers begin to download their health information. They'll be seeing some errors in the record, they will see some missing information they think is crucial and we wanted to make sure that coming into that context, we are prepared and have the policies in place that we need, in order to support and accommodate their participation and engagement, as full partners with clinicians in managing their health information and their care. So that's the broad context for today. But as you know, we've had a lot of discussion, both in this workgroup and recently over email, there was quite a lively discussion on email about patient-generated health data. There are some great examples of how providers around the country are really leveraging it and using it to improve care and to engage patients. And so what we've got in front of us today are four really terrific speakers to help us look at the different dimensions, both from a policy viewpoint and from a practice viewpoint when it comes to patient-generated health data.

So first we're going to hear from David Holtzman, from the Office of Civil Rights, and he's going to focus on the HIPAA right to amend the record. Because that is a form of patient-generated health data and so we need to start by understanding really what the essential policy framework that is already in place is, which may or may not be able to be leveraged. I suspect it will. The second is Prashila Dullabh from the National Opinion Research Center, and she's going to talk about a pilot study that NORC helped to facilitate, where patients were putting information into their record. Third we're going to hear from Joy Pritts, she's the Chief Privacy Officer with the Office of the National Coordinator and she's going to talk about a data provenance project that's in process, and talk about where they're at with that. And then finally we're going to hear from Jonathan Wald from RTI. As many of you know, ONC has established a technical expert panel on patient-generated health data that's really looking at best practices or promising practices and workflow around PGHD. So we've set up a very nice listening session and what we will do is take – I'll ask you guys on the phone, if you've got questions that are questions and not comments, but really questions, after each presenter we'll go ahead and do those questions after each presenter. But let's hold the discussion until the end, we've got about 45 minutes or so built into the agenda to have a discussion at the end. So maybe take good notes as you go as well.

So I'm going to give some kind of brief context, so, going to the next slide. As I mentioned, the Stage 3 of Meaningful Use, so Altarum, can you go to the next slide please? Thanks. So Stage 3 of Meaningful Use would – is currently being discussed by the Meaningful Use Workgroup of the Health IT Policy Committee, and we have some members with us today. And at this point we haven't gone back to the full Policy Committee or even to ONC yet, so what I'm going to show you on the next two slides are very much drafts. But just to remind you that there is – the function of view, download and transmit your health information is something that indeed is on the slate to at least be preserved and continued through Stage 3 and it would have a kind of one new addition, which is – or two really that I wanted to point out.

The first is providing patients with an easy way to request an amendment to their record online. So this would become part of view download, so that electronic records are capable of offering that information – or that ability. And obviously that has workflow implications for providers as well, although it's currently same workflow implications as are under the law today. The second piece that is an addition here is there has been a lot of exploration around the Automated Blue Button. And so the current proposal is to have a menu objective that is part of Meaningful Use, where patients would have the ability to designate who, and under what circumstances a care summary would be sent to a patient designated recipient. And that could be another provider or it could be my personal health record or my family caregiver, for example. And so, there'll be some work to kind of capture some preferences, etcetera. So that's been under discussion.

The second thing contextually on the next slide that you will see is a proposal to support opening the door for patient-generated health data in Stage 3. The way that the workgroup has currently structured that objective would simply be to provide a small percent of patients with the ability to electronically submit patient-generated health information through semi-structured or structured questionnaires. The objective here is really to create the capacity within the EHR to do that, but to allow providers the flexibility to decide what patient-generated health information is most useful to them. So for one provider that could be functional status, for another it could be blood pressure readings, etcetera, or it could be a depression screening or a pain questionnaire, for example. So again, meaningful use applies to a very broad range of providers, so the idea here is just to create the capacity, but allow it to be really flexible so that it is applicable to various provider types.

So, with that, what we want to do today, on the next slide you will see is really think around two dimensions. So the first is, what policies do we really need or have in place to support the use of patient-generated health data by providers? How would they accept the information into the record? What are the expectations for provider review, etcetera? Are there policy issues around that, again, particularly given the context that I outlined just now around using structured or semi-structured questionnaires that are broadly applicable. And so the second piece is, so how do we best support the inclusion of patient-generated health data for Stage 3 of Meaningful Use? Now for members of the Consumer Empowerment Workgroup, you know that meaningful use is out of scope for us, but in this case the Meaningful Use Workgroup would like to get some input from this group on that objective that I just described. So those will be the discussion questions that we will focus on toward the end. All right. So with that, we're going to jump right in and I'm going to hand it over to David Holtzman from OCR to talk about the right to amend the record. David, take it away.

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**

Thank you very much Christine, and thank you for that kind introduction and on behalf of the Office of Civil Rights, we are happy to support the work of the FACAs of our sister agency, sister office, the Office of the National Coordinator. And would like us to change gears a little bit and put our HIPAA hats on. The – if we could bring up my slide please – slide deck; thank you. So the patient's right to amend is one of a number of individual patient rights that are contained in the original Privacy Rule. You'll recall in the Individual Privacy Rule, in addition to the Rules requirements on covered entities regarding their use and disclosure of protected health information, they can only use it and disclose it as permitted or required or authorized by the rule. And then there were a number of individual consumer rights, for example, the right to have a Notice of Privacy Practices, a right to request restrictions in certain circumstances, and one of those other foundational rights is the Right to Amend.

So recalling that the Privacy Rule is – sets a floor, a national floor of standards for individual rights as well as usage and disclosure, so covered entities are permitted to employ or have more permissive or put in place policies that help consumers control and be a partner in their healthcare in the use and awareness of their health information. So one of the provisions, there's a standard, a right to amend, but not correct the protected health information or record about an individual in the designated record set. And we're going to discuss what is a designated record set in just a few minutes. So this obligation extends to a covered entity, and again, putting our old HIPAA hats on, a covered entity is a health plan, which could be a group health plan or a health payer or health insurance issuer, as well as a healthcare clearinghouse and those healthcare providers and facilities that engage in certain electronic transactions. In other words, the basic standard transactions that are defined under the HIPAA Administrative Simplification Rule.

Generally those providers who participate in meaningful use and use the certified electronic health records technology, generally those providers and facilities are covered entities. However, this standard does not apply directly to a business associate and it only applies to the protected health information or the record created by the covered entity. It doesn't – the rule or the standard doesn't automatically apply to records that were created that are held by one covered entity when the record or the PHI was created by another covered entity. And this is – and the right to amend was not one of those provisions that was expanded or modified to include business associates under the recently modified Privacy Rule that was issued under the Omnibus Rule. In fact, this right to amend, this standard, has – underwent no changes, no modifications and is unaffected by the Omnibus Rule. Next slide please.

So, in addition to the standard, there are a number of implementation specifications, which essentially set minimum processes that covered entities must put in place in order to implement the right to amend by an individual. So the covered entity must have a process in place that allows for the request for the amendments to be received by the individual patients. And a covered entity can have in place a requirement that such requests be made in writing, but they have to provide – they have to lay that requirement out in some prior notice to the patient, and it's usually found in the Notice of Privacy Practices. And there are timelines for the receipt and action that would take place once a request for amendment was received, and that's a 60-day timeline, but the rule does provide that there can be a 30-day extension if there is a written notice to the patient, as well as an explanation why the extra time is needed. And a covered entity must act on notifications from other covered entities, amendments to records that were created by the covered entity were made. Moving on to the next slide.

There is no – there are provisions that provide for the covered entity to deny a request for amendment. So, there are – one of the reasons why – there are several reasons why a request could be denied. For example, the information in the record is correct and it accurately reflects the treatment or the decision-making of the provider – but there is a process for the denial of the amendment request. And you have to provide the response in writing within 60 days. But the individual – if the request is denied, the individual has the right to have a statement of disagreement included with their health record. And in addition, the covered entity can have a rebuttal to the statement of disagreement. And then thereafter, those – the denial, the statement of disagreement and any rebuttal is included and made a part of the designated record set and is included in all disclosures or they're – if the statement of disagreement is long and involved, the covered entity is permitted to have an accurate summary of what the statement of disagreement is. Moving on to the next slide.

So, what's important in the electronic health record – in the use of electronic health records is that these amendments apply to the entire designated record set. And so a designated record set is defined as all of the information that is held by a covered entity about the patient. So includes the medical and billing records, the enrollment, payment, claims adjudication and case or case management record systems and any information that's used in whole or in part by or for the covered entity to make decisions about individuals. And I think it's important to point out here that this applies across the universe of covered entities, so the records that are maintained by a health plan are going to maybe different and much more extensive or of different decision-making than that held by a provider. And the same holds true with a healthcare clearinghouse. And the definition of a designated record set is included in 164.501. Moving on.

So covered entities that use electronic health records must be cognizant that the right to amend applies regardless of whether the information is stored electronically, it's in a paper format, or it's a film image. And that the term or the definition of the designated record set is not limited to only that information which is included in the electronic record. Last slide please. And that the obligation to notify and maintain the amendments and the statements of disagreement and the rebuttals, once a covered entity has accepted an amendment or has received a statement of disagreement. All that documentation must be included in the designated record set maintained by the covered entity, and the covered entity must then notify, going forward, those other covered entities and business associates identified by the patient as having received the protected health information and whose own records need to be updated. And the covered entity has to make sure that if they use a business associate to maintain its electronic health record, that the BA is obligated to include any amendment request, denial, disagreement or rebuttal statements in those records that are maintained by the business associate. And this would be the – and this same principle will hold true if the information is held by an HIO or a Health Information Network, if they are a business associate.

So with that, that's the end of my slides. Sorry about the halting way I've kind of gone through it, and I'll be happy to take any questions.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Thank you so much David. I did have just a quick question or two. The first is, what constitutes an amendment, can you only correct something that is incorrect or can you add missing information?

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
So an amendment, excuse me, an amendment is a change to information in the designated record set that is objectionable to the patient, so – and it is distinct from a correction. So, I think it's important to make a distinction between a correction of demographic information and a correction or a disagreement with the professional judgment and decision-making or evaluation of a healthcare provider. Corrections of demographic information is not meant to be covered in this particular section. This is more an amendment of information relating to a decision made by a covered entity or whether or not care was provided in the manner that is described in the record. Or, in some cases, we have found – we have heard – we've all heard of treatment records in which inadvertently a record or an item in another individual's record is misplaced into another patient's record, and this is the mechanism by which a patient brings that information to the attention of the covered entity. And the covered entity has an opportunity to either accept the amendment to the record or the patient is able to provide their own statement as to why the designated record set is not correct.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So David, where is it that you might have the right to correct demographic information, is that covered elsewhere?

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
That is not specifically covered elsewhere. There is nothing in the Rule, which prohibits an individual from requesting amendment of their demographic record, and often times covered entities do this above and beyond what the requirements of the Privacy Rule require. Recalling that the Privacy Rule is a floor, it is not the ceiling.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Right.

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
So, as we know in common practice, covered entities whether they be healthcare providers or health plans, they strive to maintain correct information. And in fact, if a covered entity is put on notice that the demographic information is not correct, and then thereafter there is an unauthorized disclosure. For example, an address is not updated or a name is not updated and then the covered entity then goes on to transmit or send information to the wrong place that may be an unauthorized disclosure under the Privacy Rule. But we trust that covered entities can take care of that simple stuff without the federal government setting standards on how they're to accomplish those basic business activities.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So David, I'm just going to give you one last quick question or I hope it's quick, and it's two case examples. So let's say I'm the patient, I'm looking at my record and my record online says I am allergic to Penicillin, but I'm not and I want to correct that. Is that covered by this?

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
Well, it's very difficult for us to say specific use cases, but so assuming you are a patient and you're presented with this information. You would contact the covered entity and utilize their request – their process to request an amendment of that information. That request would go to the covered entity, if the covered entity requires it be in writing, it would be done so in writing and I wish to add, just a real quick aside, when we say in writing, electronic means of accomplishing something satisfies the requirements of in writing. So, the individual has made that request for an amendment to the covered entity, the covered entity accepts that request for an amendment, they notify the individual that they've – a request for amendment has been accepted and the covered entity does whatever process it's going to do to amend the record. And then it has to then go on and notify those other covered entities and business associates who maintain the record or they've transmitted the information to. If, for example, the covered entity chooses not to accept the amendment, they have to notify the individual that well, our records indicate you are allergic to Penicillin and we believe the record is correct and therefore we're not going to accept your request, but you have the right to have a statement of disagreement.

And that statement of disagreement could be as simple as my record says I am allergic to Penicillin, I am not allergic to Penicillin. And then therefore that statement would then be included as a part of the designated record set, which would be transmitted or made a part of the record that is sent to covered entities in the future. And then to carry that process on even further, the covered entity could put a statement of rebuttal that says words to the effect, even though the individual says that they are not allergic to Penicillin, we have – we've conducted laboratory tests and we have found that the individual is, in fact, allergic to Penicillin. And that too would be included in the individuals designated record set. And I'm sorry the answer was so long.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
No, that helped. And I assume the process is the same if the situation was reversed where I see my med list, my medication allergy list and I am allergic to Penicillin, but it's not on there. I would simply use the same process and –

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
Yes the same process would apply and the same results would apply. But I want to point out that this does not presume that covered entities, and particularly healthcare providers, are not going to accept the statements or requests of their patients to update and assure that the record of care or the statements about the individual are not, in fact, correct and accurate. We find in our experience, that these matters become more sensitive and controversial when a patient seeks to make changes or has issue with the professional judgment or analysis that's provided in treatment by a healthcare provider. Or in the case of a health plan, decisions that are made in utilization management determinations.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Okay. Thanks you so much David. Are there – I know I've got us a little behind schedule already, but are there any pressing questions for David before we move on, and hopefully David you're able to stay for the discussion at the end as well.

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
I'll try hard.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great. Thank you very much.

**Rita Kukafka, DrPH, MSPH, FACMI – Columbia University**
It's Rita Kukafka, I have one quick question. It seems that there is potential for disagreement, is there any statement or do you think there's a need for a statement that says that a patient's statement of objection would not negatively impact their care?

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
I'm so sorry, I didn't, could you help me with that question once more?

**Rita Kukafka, DrPH, MSPH, FACMI – Columbia University**
Sure. So, it just seems that there's potential for disagreement between the patient and the provider and given the power relationship that exists, it seems that a patient might have concern that objection might negatively impact their treatment or their care. And I'm wondering how that's addressed?

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
Well the Privacy Rule in another section of the rule, prohibits a covered entity, which would include a healthcare provider, from retaliating or in any way – retaliating against an individual because they exercised their rights under the Privacy Rule. And that's in section 530, I can – I don't have it exactly in front of me, I don't have the Rule in front of me, but it's in section 530, 164.530.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Okay, great. Thank you so much David.

**David Holtzman, JD, CIPP/G – Senior Health Information Technology & Privacy Policy Specialist – US Department of Health & Human Services, Office for Civil Rights**
You're very welcome.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
All right, so let's move on to NORC. We're going to hear from Prashila Dullabh on findings from their pilot study. Prashila.

**Prashila Dullabh, MD – Health IT Program Area Director, NORC – University of Chicago**
Thank you Christine. This is Prashila and I guess thank you for opportunity to present today. Before I get started, I just wanted to acknowledge my co-collaborators in the study, Ethan Katsh, Norman Sondheimer and of course, Geisinger Health. So, next slide please. So this project that I'm going to talk about today was funded in 2010 under ONC's Consumer Health Program. And at that time, I think there was pretty much this recognition that once EHR adoption ramps up and patients get access to their data, one natural sort of consequence of this will be that patients would see information that was incomplete, that needed updating or in some cases, simply incorrect. So it was in this context that NORC was funded by ONC basically to do four things.

One was to try and see what type of data quality problems may come to light once patients get access to their health information. And there was pretty much recognition that there are data quality issues and there are various examples in the literature around that of health records, both paper and electronic. We were also asked to assess the current state of the field in looking at what some of the organizations are doing to make information available to their patients, as well as to obtain patient feedback. As part of this, we also looked outside of the healthcare industry to see what other industries were doing and there were some interesting examples from eBay and PayPal that I think we've talked about in some of our prior discussions on this topic. And then finally, as part of the scope of work, we were asked to test a prototype feedback mechanism and I think at the time, there was very much this notion that we would do it in some kind of lab setting. And so today I'm here to report that good progress is being made and I'm going to sort of get into that in the next couple of slides.

Next slide please. Okay, so just by way of background, we conducted this environmental scan where we reviewed the literature, had a series of expert discussions and then very carefully looked at eight organizations that had patient portals and were making information available to their patients. Next slide please. I'm going to give you sort of just a few highlights from our sort of environmental scan. In a study that Markle conducted in 2008 and then again repeated in 2010, the results showed that 87% of patients would use a PHR to check for errors or mistakes in their medical record. Similarly, in 2010, the California Healthcare Foundation also conducted a survey and when users were asked, what would be most useful – what would be most useful in a personal health record, what was ranked highest by patients in terms of usefulness, was making sure that information would be correct. So there's sort of validation in terms of other data sources here as well. Next slide please.

So very briefly, in looking at sort of these eight patient portals that we reviewed. So I just want to remind everyone that we did this in 2010, so three years ago, and at that time, we found that there seemed to be general consensus on what type of information was being made available to patients. You will see the areas that are most commonly shared, which include medications, allergies, lab results, immunizations, clinical care summaries and problem lists sort of slightly lower down the list. For each of these organizations, we also looked to see to what extent they encouraged or facilitated patient feedback.

So I just want to clarify these terms. In terms of encouragement, we reviewed if they had an acknowledgement summary on the website that said that there may be some issues with the content in the medical record, and this is a way to get in touch with the provider. And then moving beyond that, we also looked to see to what extent patient feedback was facilitated. In other words, was there some kind of feedback button or online form patients could submit to request changes or ask a question. And at that time, there was subset of organizations already going down the path. And if you look at the last column here, in terms of facilitated feedback, you will see from the areas that are – some of these leading entities had started looking at, in terms of where patient input could be received and how they could be processed. And what we found was that the processes varied in terms of how information was being gathered from the patient and how that was triaged within the healthcare organizations. In some places there was sort of free text fields that patients would use and in other cases there was slightly more structured form. Next slide please.

So now I'm going to sort of shift you away from the environmental scan and really talk about sort of this – talk about the pilot study that we did at Geisinger. And again, here the intention was initially to sort of see if there was some kind of prototype feedback process. So what we did was as part of our environmental scan, we had engaged with Geisinger and at that time, they were getting started with a project where patients were being encouraged to provide feedback on their medication list. So we had this amazing opportunity to test this intervention not in a pilot setting, but actually in a real clinical setting in some of their clinics, which I think was a very exciting part of the study. Next slide please.

Okay, so I'm not going to belabor this slide, I think it's sort of more research and evaluation focused, but I just wanted to give a context to everyone in terms of what we were trying to accomplish and what type of information we had to sort of inform the key questions we were asking. So first we wanted to determine the interest of patients in becoming engaged to improve the accuracy of information in their medical records. So what would motivate the patients to provide updates and will they actually go through this process. The second major aim was really to see what type of workflow could be used to obtain and process the patient feedback. So in other words, once updates were received, how would they be triaged, who would receive the input, how would it be processed and then how would the medical record be updated if that was indeed necessary.

And then thirdly, to assess the impact of the patient input. So here we sought to understand how accurate the input was that was provided by the patient, what was the impact of the patient input on the provider and how did it affect provider workflows, and then ultimately trying to assess rather qualitatively, what was the impact on patient engagement. I would say that given the time and budget constraints, we did not do a very comprehensive impact analysis, but I think there are some interesting findings to share. Next slide, please.

Okay, so just very briefly about the pilot. The pilot was – this was conducted in an ambulatory care setting, just important to know that as part of this broader medication reconciliation effort, Geisinger had initiated a pilot where patients with upcoming medical appointments were invited to complete a medication feedback form before their scheduled doctor's visit. So they would receive a form online saying that you have an upcoming appointment, this is all your information on your medications that is in your current active MyGeisinger medication list. The pilot was initiated in November 2011 at two clinics in rural Pennsylvania, and so to be included in the study, patients had to have at least one chronic condition such as asthma, hypertension, diabetes or heart failure. In addition, patients had to be active users of MyGeisinger and by active users, we defined that as a patient that had logged in at least once into the system. And then just by way – just for context, MyGeisinger is really the – personal health record that Geisinger uses.

Okay, so I guess just very briefly then, as of June 2012, which is pretty much when we ended our study, a total of 1500 patient forms had been received. Just very briefly about this form, I think it's important for context in terms of what Christine had talked about early on, the form had both structured and free text fields and offered patients the ability to update the medication list. And by this we mean, patients were given the option to indicate whether they were taking the medication as it had been prescribed, had stopped taking the medication or note if there were changes in dosages and frequencies, and this feedback was obtained through the use of a structured form. Patients were also given an opportunity to provide a reason why they were not taking a medication as prescribed and they could select from a list of various choices or they could key in a free text field. They were given a separate form if they were taking prescribed medications that were not on the list and they could also add any over the counter medications. And then finally, there were some general questions asked of the patient about feedback on their medications. Once the form was submitted, it was actually received and processed by a trained medical therapist. Next slide please.

Okay, so just in terms of key findings, so now you have the background, you have the context of the pilot study itself, and I have to say that as we went into the study, the NORC team as well as the Geisinger team, I think there was some skepticism about what we would learn. So I think we were all, in some ways, pleasantly surprised. Next slide please. So just very briefly from some of the qualitative work that we did, so we did a number of focus groups and talked to a number of providers and pharmacists that were part of the study. What we learned was that patients like the opportunity to communicate with their providers outside the office. Anecdotally we heard in some cases the form avoided or made it more convenient for the patient to communicate and they did not even have to go in for the office visit, so was clearly seen as something that was convenient for the patient.

In the patient focus groups we heard that most patients find that online access to their medication list offers them an opportunity to dialogue with their patients and to track their medications more easily. And once they go for their office visit, they're that much more equipped to actually have a meaningful conversation about the medications. And from the provider side, we heard anecdotally that there was definitely a sense that this was improving the patient provider communication. We heard often that – like patients go for a doctor's visit and just as they come out, they realize, oh I forgot to tell my doctor something about my medication, and then they wait for the next visit. So we heard these kinds of anecdotal comments in the qualitative work that we did. Next slide please.

So what did we learn. That patients are eager to provide feedback, 30% of the forms were returned where patients made requests for certain updates to be made within the medication record. And when you sort of look further down, in terms of what was actually happening, when we analyzed the feedback forms that patients provided, we noted that in the majority of the cases, so 89% of cases, patients requested updates to the medication list. So this would include changes to frequency and/or dosages of existing medications and request for new medications to be added, and this would be both prescription and over the counter medications. Next slide please.

Okay, so I guess I should also note that for our study, the average patient had at least ten medications and on the far end there were some patients that had like forty medications, so these were a lot of medications for patients to actually sort of review and keep track of. All right, so when we sort of analyzed the patient feedback that had been received in these forms, we actually looked at 281 forms and in that we saw that of those 281 forms, there were 616 requests for medications to be changed. So on average, every form that was submitted had at least two requests for changes. And this number is actually an undercount because what we were specifically looking at was requests for discontinuations or changes in the frequency or dosage of medications, what is not represented in those numbers are changes for new meds to be added, either prescription or over the counter. And the reason why those numbers are not included was they were obtained by free text fields, so we actually had to do a manual count and that was sort of outside the scope of what we were able to do at that time. Next slide please.

Okay, so in order to assess the accuracy of the patient feedback, we also looked at the pharmacist's response. Hello –

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Sorry, this is MacKenzie, we can still hear you but can I just ask all the members to put your phones on mute, because we're getting background noise. Thanks.

**Prashila Dullabh, MD – Health IT Program Area Director, NORC – University of Chicago**
So in order to assess the accuracy of the patient responses, in other words to assess to what extent the patient feedback actually resulted in changes in the medication record, we conducted a subsample analysis of 116 forms. And so what we did was, in these cases once the forms were received, the pharmacist reviewed the forms and in our subsample analysis, and I'm sure you see sort of the results in front of you, in 56% of cases, the pharmacist actually accepted the input that the patient had received and made changes in the medication record. And all of these changes in the medication record were sort of logged as made by the pharmacist. So, again from the sort of limited study, what we concluded was that patients can provide accurate and reliable feedback as validated by the pharmacist in this case. Okay, next slide please.

So I'm sort of getting to the end of the formal discussion. So to understand what factors would get patients to provide updates on their medication record, we also looked at usage – for patients and here what we – here we noticed was that in general, the patients who complete the medication feedback forms log into MyGeisinger at least twice as often as those that are not. And then findings from our focus group also showed that most patients expressed great satisfaction when using MyGeisinger to conduct a variety of functions. Which really goes to show that in some ways, having sort of the supportive, online environment is an important component in making sure that when patients are using these kinds of tools to give information to the healthcare system, that the healthcare system then responds using this rich, online environment. Okay, next slide please.

So in putting what we learned from the Geisinger pilot in the context of the deliberations around the upcoming stages of meaningful use, where we're discussing patients should have the ability online to request changes, I'm going to just anchor this in what our study showed. Providing outpatients the ability to request updates to their record online for medications through VDT, using some kind of structured form is what we had seen in the Geisinger context. In the Geisinger study the forms were prepopulated and patients used drop-down lists, and again, the study was limited to medications only. They were able to notify their doctor when medications had changed and this was done in a pretty expeditious manner. In terms of the measures for the pilot, there was a 30% response rate, which I had talked about, and 85% of the requests that were received from the patients were processed within four business days. This may offer some broad guidelines in thinking about what would be the parameters around the measures. And then in terms of other work that we did on the project, our survey of the patient portals and discussions with thought leaders show that there are other promising areas, so medication allergies was brought up as well as immunization and demographics. We were cautioned that in the case of medication allergies that it would be important to sort of unpack the term allergy, because there could be sort of various interpretations of what that actually means, so that should be given some thought. And then finally, other promising areas for patient sourced information include smoking status, advanced directives and family health history. Last slide please.

So in conclusion, patients from our study – the results from our study show that patients can provide accurate and reliable feedback, that there are effective ways to process patient feedback that is less disruptive to the provider workflows and that giving patients access to their medical information is important for patient engagement. But providing opportunities for patients to contribute to the content of their record is equally important because I think what we saw as part of this is providing these opportunities rightly acknowledges that patient feedback can enhance the accuracy and completeness of the medical record. And I guess with that, I will end my formal presentation.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great. Thank you very much Prashila, I really appreciate it. That was really instructive. I think at this point, since we're a little bit behind, I'd like to ask folks to write down their questions and then we can get to them in the discussion portion of our agenda. And if any of our speakers are not able to stay on, we can follow up with them offline. So thank you again Prashila. Do we have Joy on the line? MacKenzie, do you know if we have Joy Pritts on the line?

**Michelle Consolazio – Office of the National Coordinator**
Christine, this is Michelle. It doesn't look like she's on the line yet.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Okay. Then why don't we – and we have Jonathan, yes?

**Jonathan Wald, MD, MPH, FACMI – Director of Patient-Centered Technologies – Center for the Advancement of Health IT, RTI International**
Yes, I'm here.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Okay. So if the Altarum folks can work a little bit of slide magic and maybe take us to Jonathan's presentation, that would be terrific.

**Rebecca Armendariz – Project Coordinator, Altarum Institute**
We're there.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great. Thank you. So Jonathan, welcome and I will turn it over to you

**Jonathan Wald, MD, MPH, FACMI – Director of Patient-Centered Technologies, Center for the Advancement of Health IT - RTI International**

Okay, thank you Christine. So my name is Jonathan Wald, I'm from RTI International and I'm going to present this report to the HIT Policy Committee Consumer Empowerment Workgroup. And it's really from the Technical Expert Panel convened by the National eHealth Collaborative on behalf of the ONC. We worked with a talented group of panel members who are shown on the next slide, slide 2, representing vendors, providers, advocacy groups, patients and families, government, other stakeholders and it's been an active and participatory group and we're really thankful for their contributions to the work. So I wanted to acknowledge everybody on this slide. Our goal in this work was to identify good practices for the use of technology to enhance patient input to their care. And the approach that we used was a technical expert panel that was formed in January of this year, as well as a focused environmental scan to inform our learning in this area. So as part of that, the – we extracted good practices and challenges from a number of sources. The ONC patient-generated health data white paper, PGHD hearings that were conducted last year, available case studies and especially studies that showed high value for those who have incorporated PGHD into the clinical record or into the care process or care decisions.

And the deliverable for this work, the first deliverable is a report on good practices and policy guidance and heading towards recommendations or considerations for Meaningful Use Stage 3. And that's this slide deck and this presentation. The goal was really to identify information of value to providers, to patients and to focus on what might be a priority subset of information that's nearly always valued and could be used in various ways, possibly in a kind of a menu-driven way. The initial work focuses on Meaningful Use Stage 3 draft recommendations and how practices can get started, and the group is still together and will continue its work, focusing on how practices can prepare and prioritize information and incorporate PGHD into the practice. So really the focus will move beyond meaningful use. And I want to call your attention, in the slide deck there's a background section that has much more detail than I'll be able to have time to present in this portion.

So, going to the next slide, the way that we defined patient-generated health data, it's health related data that was created, recorded, gathered or inferred by or from patients or their designees, to help address a health concern. And throughout the presentation, patient is really a shorthand, it includes patients, family, personal caregivers, designees and in some care settings, the language changes, they may be known as consumers or clients or recipients of care. So it's a very broad group that's represented by the word patient. The types of information that we're talking about for patient-generated health data are pretty broad and the uses are – continue to evolve. So information could be an observation, it could be a result, a confirmation of some information that's in a record, a change or correction or addition, it's very broad. And we also wanted to recognize that the idea of information being contributed by patients into the care process and into the chart and into events that are occurring, is really not new, but it hasn't always been labeled as PGHD. So in reality, many patients are recording and sharing information on health and wellness with their provider and healthcare team, they're doing that a lot, it's just that now we're taking a look at it, especially from the vantage point of how do EHRs and how does Health IT come into play to support that.

We identified a number of concerns both from patients and providers that we wanted to sort of put right on the table. From a patient point of view, the concerns surround the idea of how well and what expectations are there – are reasonable around communication, around information sharing, and how does this support the doctor patient relationship. So, questions when processes are unclear that come up among patients are things like, who saw the information I sent, what's the next step in the process, will I be receiving a reply, is the information being saved or shared and things like that. The provider concerns were also very clear, both from the expert panel and from the supporting materials, primarily in three areas. Concerns about a time burden and a work burden, about the risk of liability being raised and about concerns about financial impact.

So for example, people would ask, well, if there are large amounts of data that have to be reviewed, or if there are new or additional streams of information containing patient data, will that be a burden. Will handling this data disrupt workflow or cause interruptions. Around risk, the ideas and the concerns were again with a large amount of information, making it possibly harder to review and to manage that information, creating risk. Or the timing of the information, if it wasn't received in a timely manner or if there was some missing critical information or if there were differences in expectations, patients believing one thing and providers not having seen information perhaps that they were expected to see or act upon. Things like that were concerns that were expressed from the provider point of view. Also that patients might be sending information that's urgent in a way that would be difficult to respond to in a very, very quick timeframe.

And then in terms of financial impact, the questions and the concerns were around kind of what kind of compensation might there be if there's extra work involved. How do you really gain efficiency and/or save money? And if this takes valuable staff or physician time, where's that time coming from, what else is not happening? Overall what we found in the expert panel in the background material that we looked at is that when PGHD is implemented appropriately, and when these concerns are surfaced and addressed, the patient-generated health data use really can become routine, and organizations that are doing this well have addressed these concerns.

One of the most important ways to plan for PGHD is through appropriate policies and procedures. And these are critical in order to manage burden and to manage risk. They're relevant really at every step. And in the background materials, we talk a little bit about the steps where PGHD is received in an organization, is processed and then there may be follow up steps, documenting the information or sometimes generating more questions with a patient. But those steps need to be thought through and policies and procedures around those steps thought through in order to manage the process well. Patients and something like a patient family advisory council has been prominent in a number of organizations to assist with planning for policies and procedures.

And some examples of this are listed as well, where when patients, family and other personal caregivers understand policies and procedures, they have a better idea of what information to share and when and how and why. They generally want to understand how and when information that they send will be received and acted upon. It's helpful for all users of systems that allow sharing of patient-generated data to be reminded that for example, urgent and time-sensitive matters should be communicated directly and separately to ensure that they are communicated well. And similarly, policies and procedures for provider staff and provider organizations are critical in defining responsibilities and processes to make sure that receiving information, reviewing it, responding to it, recording information are done in a consistent way and in a way that's been thought through by the organization.

That said, the policies and procedures are just part of the picture and individual judgment often comes into play and should be factored into designing processes for handling PGHD. So, we also understand that policies and procedures are evolving and input at every level is important because the issues on the frontline say in a clinic are very important and they need to marry up with other areas of an organization, folks who are responsible for medical information handling or medical records or service policies. So, these policies and procedures are really important and help to set the mutual expectations for patients, physicians and for staff.

This slide shows examples that were among the most common examples as we talked and looked at material in this work. So for example, sharing home blood pressure, glucose or weight information because it's being monitored, provided value as input to understanding treatment response and how a care plan might be working. Similarly information such as changes in medications or the medication or list or similarly for the medication allergy list, serve as input to really most treatment decisions, certainly to medication prescribing decisions, and can be helpful for error prevention. And the same for other kinds of allergies and intolerances. They're very important for treatment decisions, for orders and for error prevention. And so these were some of the most common examples that were discussed in the technical expert panel.

Continuing the examples, the ability for a patient to share that a procedure or an event happened and a date was also felt to be very useful, such as when a colonoscopy occurred or immunizations and their dates or getting a mammogram or the presence of advanced directives. That these were important inputs to quality reporting, to clinical decisions that were being made and to clinical decision support. They helped with updates when screening was being considered and they helped with documentation. And similarly, another area, which is changes in symptom or symptom intensity, functional status and changes in treatment such as from a different provider, were valuable in that they could reassure that a current treatment plan was going as expected, or they could prompt for action that a change was needed or review was needed in a treatment plan. The next example is more about concerns that a patient or family or caregiver may have or behavioral changes that were noted by somebody, and those can be valuable for helping to engage these trusted observers in providing information that's relevant for care decisions. And some of the examples below are listed, especially around symptom intensity and functional status.

This slide highlights the importance of the patient-generated health data in response to EHR data. So with expanding use of patient portals and ways that organizations are sharing information from the electronic health record, it creates a lot of opportunity for beneficial PGHD. So for example, when radiology reports are shared and findings are noticed by say patients or family members that weren't fully explained, or lab results are seen that don't seem to fit, or medical history seems to be missing or misstated, or maybe there's an abnormal lab result that wasn't addressed. Those can lead to or those can prompt patients and others involved in their care to potentially avoid something being missed by a provider or incorrect in the record or just not understood clearly by the patient. Similarly, it may be administrative information that they're looking at, whether it's old insurance information or old address or contact information or other more administrative information, and correcting those or notifying someone or asking about those can really help to make critical and useful information accessible at the time and the place that it's needed.

This next slide is just kind of a high-level summary of some of the prominent organizations and work that they're doing related to PGHD. So for example, in the first row, receiving patient-generated information through secure messaging, it's happening at virtually all organizations that we're aware of that are using secure messaging. Similarly, many organizations in some way, sometimes in a pilot project, sometimes in a limited way, sometimes more broadly, are receiving biometric data such as blood pressure or glucose levels or weight information from at least some of their patients. All of these organizations are also using questionnaires in some way, to capture information from their patients. And it may be related to pain or activities of daily living or well-being, depression, etcetera, but some work is going on using questionnaires. And the next row just reinforces the idea that these organizations are each committed to sharing their EHR data, which serves as a prompt for patients to send patient-generated health data and a growing number of organizations are sharing even more of the medical chart in the form of provider notes. Hmm, I'm hearing a loud noise.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
There we go.

**Jonathan Wald, MD, MPH, FACMI – Director of Patient-Centered Technologies, Center for the Advancement of Health IT – RTI International**
Okay, we'll keep on going. The next slide is titled a process view of patient-generated health data flow, and the point of this slide is that if you look across many organizations and many types of information, you can extrapolate more or less some general steps or processes that take place. Starting with patients having some information, sharing that information with providers, and that's the circle at the top, and then as the information moves sort of into a provider organization, its received, its processed, it may be documented. And it may generate additional requests for information, which can also be the starting point, a provider request for information then leading to a patient response. A couple of points from this diagram, one is that all of the policies and procedures that I talked about earlier come into play as organizations figure out how they want to design this flow. Security policies are very important for any information that's held by an organization or is being provided electronically by a patient. And the group has spent time going into detail around a number of these steps, and that's provided in the background material.

So getting to the specific examples of valued patient-generated health data, we start with safety related information and treatment plan related information. And there are a number of examples relating to the medication list, to the allergy list. And then for treatment plan related information, it could be information the provider has requested or it could be changes that might prompt a change or reconsideration of the treatment plan. And all of the examples that were listed in previous slides. In the next slide of examples, we wanted to highlight a new patient concern as being an important example of PGHD, especially if there are unexpected worsening symptoms or just information that's really felt to be of importance by patients or families or caregivers. As well as administrative information that's important because it may have a high impact on the care process, such as key demographic information or preferred facilities or locations where – that the care team needs to be aware of, it could be insurance information. It could be information about who is on the caregiver or the care team and what role they're in and what contact information is available for them. It could be about communication preferences, such as sort of whether folks prefer to be called or using secure messaging to contact them or some other way. And other information that can inform or impact communication.

So wrapping up, we wanted to summarize a couple of conclusions and then talk about considerations for Stage 3. The first slide of conclusions highlights the fact that PGHD really is an opportunity to capture needed information for use during care. That there is great potential for cost savings, for improvements in quality, for improvements in care coordination and patient engagement and the organizations that we've highlighted in our work are really focused on PGHD for all of those reasons. It fosters patient learning, self-monitoring and self-management. It also enables activities to shift from provider-driven to patient-led and it really facilitates partnering between patients and providers. It encourages and allows the patients family and other caregivers to better assist in care. It reduces information gaps and coordination gaps among multiple care team members, it can improve the accuracy of information, can improve access to information.

This point is really important that PGHD while it's collected and used in many organizations and care settings, the priorities in any particular setting are almost entirely contextual. We felt that context really was everything and it was very challenging among this sort of broad technical expert panel to get agreement about the top three types of information let's say – the most important patient-generated health data, it all depends is what we heard over and over. We also heard that this information comes through multiple channels, it may come through secure messaging, it may come through specific applications that have been developed to collect and transfer information, it may come through questionnaires and it often – in many cases it comes through multiple channels, not just one. That – the hallmark is that it has to be beneficial, beneficial for patients, beneficial for providers.

And as we look at different context for implementing patient-generated health data, different organizations approach it differently. In many cases they focus on patients who have a common ailment or condition, or perhaps patients who are already users of online services, or patients who have a pre-existing relationship with a care provider. It may be pre-visit focus, either for existing patients or for new patients. So there are many, many different contexts that come into play.

The final slide is to share some thoughts about considerations for PGHD information to start with for Meaningful Use Stage 3. And the first bullet, non-specified, is the idea that because of the multiple contexts and the difficulty picking one over another, that one way to approach this may be to identify a threshold and say that any patient-generated health data that's shared in an organization, whether it's using secure messaging or questionnaires or some other channel, should count and should reflect the organizations participation in encouraging this from patients. And we know from hearing from ONC and CMS repeatedly that sometimes with very low thresholds, organizations get started in an area and then they exceed those thresholds. So we're wondering whether that might be a possibility if this approach was taken.

The second bullet, specified, is the idea that one could approach this by picking different areas of information to focus on. They might be current meaningful use elements such as information that's already identified in treatment summaries that are shared or somehow identified as important for quality and safety and meaningful use already; problems, medication lists, allergies and so on. It could be information that's really defined by an organization to be relevant to their site-specific purposes and context. It could be information that meets some criteria of value to a patient group, to a provider group, or to an organization, and what we've observed from all the examples is that sometimes PGHD has broad value across these different stakeholders and sometimes it's more valuable to one or more than one, but not all of them.

So, I just wanted to wrap up to say that our work with the technical expert panel and this project will continue, to refer you also to the background materials that are – that follow in this slide deck and to say that we wanted to thank, again, the TEP for all their work and would welcome any questions or discussion. Thanks very much.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Thank you so much Jonathan. That was really helpful, it's great to get a sense of what's going on big picture on the ground, so I appreciate that. So let's go directly to Joy Pritts, who I think is on the line now.

**Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator**
Yes, I am on the line. Thank you.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great, thanks Joy, welcome, take it away.

**Joy Pritts, JD – Chief Privacy Officer – Office of the National Coordinator**
I apologize for my tardiness, I am having technical difficulties these days, but I'm hoping to overcome them. I was asked to speak to your group about some work that we have been doing through our office on data provenance. Next slide please. We use the term data provenance in our context for describing what the origin of clinical information is when it was first created. So it's information about the source of the data and it can be information about processing and the transitions of the data that the data has undergone. Why is this important? Well first, from – we undertook the project because we are also working on the ability to be able to mark data and send it or not send it and otherwise address it, based on the source of the information.

So there are certain privacy laws that say if – state and federal, that if information is generated by a specific type of provider, that the informa – that privacy protections follow that information wherever it flows. And in order to enable people to follow those rules, you need to be able to know what the source of that data is as it moves through the system. It also enables providers trust in the information being exchanged between providers, so when you have a provider to provider exchange, it's important for many providers to know what the source of that information was and they will attribute various levels of trust in that information, depending on who the source is – the provider source. We've heard this repeatedly, for example, that some providers trust certain laboratories much more than others, that's just one example. The issue that's most relevant for this group, however, is that it can enhance – knowing the source of information can enhance the provider trust in the information it receives from a patient.

For example, my data it receives from a personal health record, now I know this is a little bit different than many of the use cases that have been described in this meeting earlier, but it is – the general principle remains the same. And that is, that we have heard repeatedly through many workgroups that have been held – workgroup meetings that have been held that providers want to know what the source of the information is if they have incor – when they're deciding how they're going to rely on it and how they're going to use that information. Next slide please.

We undertook our project to explore three use cases that had been proposed to us. First is how an EHR marks information, the source of the information and sends it on to the next EHR and how the receiving EHR handles the data – the provenance of the data, how does it know what the source of that information was. We also looked at how that works within the context of health information exchanges and how they handle data provenance, as well as personal health records, the information that comes into them and how they aggregate that – potentially aggregate that information and then send it out. We focused on how this information was marked and retained as the information is aggregated from different sources. And that was our primary focus on here, because that was one of those use cases that were presented to us, all involve this common element was, if you receive information from multiple sources and you aggregate it into an EHR, for example, or into an HIE database, how do you know where that information came from.

The focus of our project was on provenance within CDA documents, because that is the primary method that the EHRs and the health information exchanges have proposed at this point. And it includes a landscape analysis and a gap analysis. Next slide please.

Some of the key provenance considerations that came out – what we did here is, just to give you a little bit of how this was conducted. We interviewed in very non-structured ways, we asked some questions to vendors, to some provider organizations and other entities as to – including like PHR vendors and things of that nature, what were their practices currently with regard to provenance, data provenance. What were their issues? What were the things that they needed to know? From that, some of the key considerations that came out were, they wanted to know who or what was listed as a source, is it the organization, the provider, the data entry staff, the device and details of the device.

When you're talking about a CDA, the question was, all right, so you've now decided that you're going to mark where this information came from. If it's a document, is the entire document listed as having the same source, can it be the section, can it be an individual data element, and how to you update or – the source when you import it or export it. Do you list the organization as a sou – the receiving organization as a source or the original creator as the source? This last piece was fairly interesting to us because frankly as a lawyer, it had not occurred to me that when somebody would import information from another source, that they would then declare it as being their own. But that is exactly what happens in some circumstances. Next slide please.

So overall, a very large overview of what is going on today is that there is a lot of variability in how the source of the data is marked and retained in all of these different models for facilitating electronic health information exchange, from EHRs to PHRs to health information exchange organizations. Some of them mark the data at the document level, some to at the section level, some do at the data element level. There are different practices regarding the source, again all these different layers of where they mark it, and there are different practices when they import or export it, whether they retain the original source of the information or they modify it to list themselves as being the source of that information. Next slide please.

A common response to this variability is, and this primarily applies to the CDA, is to utilize what they call the "flow down" of provenance data, so they mark it at the document level only and then that docu – that provenance data is inherited at all the data elements within that. What this means is that it creates some integrity issues because you might have information listed in a CDA that was created by organization "A," but now it looks like it was created by organization "B." Next slide please.

Some of the implications for patient-generated data are generally that provenance at the data element level is lacking, as records are shared with providers. EHRs often export with sending organizations listed as the source on the document level only. PHRs my import with provenance of the document or of these other levels, but when they export the information from the PHR, they list the PHR as the source of the information at the document level. And health information exchange organizations can export with documentation at the data element level, but there's often not sufficient information available at that level. So the resulting flow down of the document level provenance may not meet provider need for granular detail. And one of the ways that – from listening to this group and some of the proposals for how information – patient generated information would be directly provided to an EHR.

So the implications for that that come from this work is that in some areas the solution to this has been to create almost the equivalent of two separate databases I would say. Where one portion – or a segmented database where one portion is this is where we put all the patient generated data and this is where we put all the electronic health record and the provider-generated data. And we think that the goal here is to eventually integrate all this data and the conclusion is right now that there aren't standard ways of doing that and it may be difficult, that is an area that actually needs further work. Next slide please.

Some of the work that needs to be done is not only looking at harmonizing how its handled within the HIT community from a work process flow, but also the standards that are in place. And there is some work being done on this through the HL7 Data Provenance and Privacy Support for the CDA, but I don't know how useful that work is going to be for the patient generated data that is submitted directly through a portal. But the conclusion is that it really doesn't – what is going on right now where the data is marked at a document level and it flows down and it doesn't tell you well maybe the pa – particularly from a PHR, what data from that PHR came from a provider, what data was entered by the patient. That level of granularity is just not happening on a very wide basis right now. Next slide please. And that is the brief summary of the work that we did.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Terrific. Thank you so much Joy and I appreciate you making the time for talking with us today. So we have just had a crash course in patient-generated health data with lots of really important insights around processes and policies and workflow and technology. So I want to open it up to the group now to talk and give any reactions or questions, keeping in mind that we want to focus on whether the approach that's proposed in Meaningful Use is a good one. And I'll remind you that that is – there actually, if I think about Jonathan's presentation, it would – Meaningful Use Stage 3 would have structured and semi-structured questionnaires, would have secure messaging and would have the ability to submit amendments to the record. So the only thing I think that was on Jonathan's loop that's not on a meaningful use loop would be something around biometric data. So that would be one. And then the second piece is to really identify any policy issues that we think we need to take up in order to facilitate the more widespread use of patient-generated health data. So I'll open it up to you guys for questions and comments.

**Mark Savage, JD – Consumers Union of United States, Inc.**
Christine, this is Mark.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Hi Mark.

**Mark Savage, JD – Consumers Union of United States, Inc.**
Hi. So, it strikes me that we sort of heard things at two levels and I just want to say that it sounds like there's a lot of work beyond Stage 3 that we could be doing to support. I know that's not for this call, but I'm going to lift that up as something to think about for future agenda. For Stage 3, the one thing I heard from the presentations, looking back at the language and the proposed criteria, was whether to just limit it to semi-structured questionnaires. I mean, we've just heard about a whole range of things that are being used and I wonder if we want to recommend some flexibility in those uses. I think the semi-structured part remains important but are there other things besides questionnaires that we might want to add. The last question that occurs to me, given how much is happening, is – and how important and effective it's been, is whether this is a menu requirement. I don't know what the standards are in place, but it would sure be nice to see this being used widely as a core requirement.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great, thanks Mark.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**
Christine, this is Wes Rishel.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Hi Wes.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**
Hi. I'm one of those invitees for this meeting. I think I understood from the way you described it just a moment ago that you'd had some discussion on biometric data and had decided to exclude it in version 3, or at least not specifically mention it. I'm just impressed with the amount of biometric data that I and other people are accumulating in the cloud now, blood pressures and blood sugar readings and things like that. And cognizant that its capable of being, although we're not there exactly in terms of standards, its capable of being ingested without a person doing a translation from the semi-structured representation to the structured representation. So I'm wondering, given the growth of the consumer market for these devices, whether it is worth considering that data in this context. Thanks.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Thanks Wes, that's really helpful. You're right, it's not in there because of the standards issue, so if we could get your thinking on how best to structure that, I know the workgroups always been interested in that that would be great.

**Paul Egerman – Businessman/Software Entrepreneur**
And this is Paul.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Hi Paul, how are you?

**Paul Egerman – Businessman/Software Entrepreneur**
Yeah, it's Paul Egerman. I just wanted to agree with what Wes said and take the issue one step further. One of the challenges is that there is the quantity of data that is coming from these devices. So there are people who are tracking their – the number of steps, the number of calories burned every day, their weight, their sleep activities, every single day. And you could have a large quantity of information as a result, which could be a challenge. I do think – but basically, I'm agreeing with Wes, this is an area that really should be talked about and explored, because it is a significant area and a growing area of patient involvement.

**Wes Rishel – Vice President & Distinguished Analyst – Gartner, Incorporated**
This is Wes again, if I could reply. One of the important themes I heard in several of the presentations today was patient-generated data in context and I think for many reasons, there's good reason to be concerned about sort of an unthrottled flow of patient-generated health data if only because of the variability in how different patients will use it. But I think that many of the measures, not all of them, I don't know for example, how well the sleep data matches up with what clinicians like to look at, but many of the data items, O2 sat and so forth, have analogs in LOINC codes that are already measured using other devices. And in the context of a care plan for treating a diabetic or a COPD patient, I think there is the opportunity to use this data in context, rather than just a total blast of data.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Right, I agree. Thank you. Other comments or questions on our presentation.

**Kim Nazi, PhD, FACHE – Management Analyst – Veterans Health Administration**
Hi, this is Kim. And thank you to the group for a really rich set of presentations, I think it was very helpful. Building on the previous comment, I just would like to also offer that perhaps part of this has a time dimension, so it may be that a certain set of data's more appropriate for a closer focus for a certain part of the patient trajectory, and that may change over time. So thinking about the tools, but also considering an opportunity for customization within those tools, so that for a given patient for a certain period of time which may change, there's opportunities to adjust the flow rather than seeing it as kind of an on off switch.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Thank you.

**Katherine Kim, MPH, MBA – Health Equity Institute Professor in Residence – San Francisco State University**
Hi, this is Kathy Kim. I really appreciated these presentations and I was particularly struck by the one from NORC saying that patient input really does improve the accuracy, and I wanted to comment on what kind of data is important to have in the EHR from patients. That questionnaire data, if it's instruments that are actually gathering clinical measures so they're validated instruments for clinical measures that seems to be important to be in the EHR. But if it is more self-monitoring data, where patients are tracking calories and tracking steps, potentially tracking other things, that's really more relevant for them. Then all of that doesn't need to be in the EHR and what needs to be in the EHR is really a summary or a trend analysis so that a clinician can make a decision based on that. And so part of that throttling is the type of data, the frequency of the data and who it's relevant for so that we get around these issues of thinking it has to be all or nothing.

The second comment that I wanted to make was that it really strikes me that the semi – unstructured data, we already know that there's a problem with having unstructured data in an EHR. And so, if we're going to focus on meaningful use in the next stage or the next two stages, that we really have to move towards structured data, because clinicians won't be able to do anything – won't be – will have limited ability to do something with unstructured data. So maybe the focus should be on those things that can be structured, where there is a data model for doing that and that the requirements for the next phase should be focused on that.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So just to give you a quick piece of info on that, and we struggled with that because there is a vocabulary to structure the data. And so if you think about a depression assessment tool or a pain assessment tool, you've got the PQ tool, things like that, but there aren't data standards for those and it became very challenging to look at the broad array of providers and say, oh, let's just create standards for everything under the sun. So, the structure – it should actually say structured or semi-structured so that you can have some free text to capture information needed. And that was really designed to make it very flexible so providers could really focus in on what was meaningful and useful to them and material to the patient's care and that way avoid a huge data stream that they don't know what to do with because they've selected it. So I hope that helps and open to more input on that. Other folks want to weigh in.

**Jan Oldenburg – Vice President, Patient Engagement – Aetna**
This is Jan Oldenburg, can you hear me?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yes, hi Jan.

**Jan Oldenburg – Vice President, Patient Engagement – Aetna**
Okay, hi. I've got a couple of things. One, first of all, thank you for organizing this, it's been a great kind of overall look at all of the kind of issues that are coming up here, and a great set of comments. I would particularly like to agree with discussion around the question of whether the requirements should be limited to getting data via structured questionnaires and email, since I think it really does, as those speakers have spoken to, reduce the potential impact of tracking devices which may have some of the most meaningful data for providers to be using.

And in that context, I would also want to suggest that the policy considerations around this whole issue of the provenance of information and how provenance is preserved as data is sent through the system, does that really warrant our consideration, I was so happy to hear Joy's presentation, because this has been one of my issues. And I think if we're going to make consumer entered data meaningful, especially in an era of interoperability, we really have to devote some policy time to those issues and that issue of provenance at a granular level may deserve to be incorporated into the Meaningful Use requirements.

And last, but not least, in relation to Prashila's presentation. I think it's really suggestive about the level of engagement of people who were presenting their feedback on their information. And while it was hard to tell whether it was because they were already the engaged users, the possibility that this providing input back has a potential for engaging people more deeply around their health, should be something that we are really exploring and encouraging. Because that's kind of the bottom line of, I think, at least one thing that we're all trying to do. Thank you.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Thank you Jan. Others?

**Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System**
So hi, this is Mike Zaroukian, can you hear me?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Hi Mike.

**Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System**
Hi, yeah, so these were great presentations, thanks so much for organizing it. I'm actually seeing patients this morning, jumping back and forth and so I missed a little of the amendment request conversation, and I love the idea of amending. I'm concerned a little about the lack of clarity around some of the use cases, I was really glad to hear the use case that was described and it was important to hear that it's tough to know how to handle those. I would not have expected necessarily to have to be so elaborate in how I handled them. What I would love to be able to do as a primary care provider myself, who does this all the time, is to simply take any amendment requests that I get, process them, try to decrease the paperwork burden, electronic or otherwise, for the processing of them.

And I guess my biggest concern is how are we going to support the ability to identify anybody else who may need to hear about this update of information and communicate it to them. I'd like to live in an environment where sort of any of those kinds of updates can be part of a system where you can see if something's been updated, but not to have each of the providers or organizations have to figure out all the places they've shared information with before to be able to share this updated information. If I heard it right, that's what I was hearing might be what is required of the provider or organization.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
So Mike, my suggestion on that, this is Christine, would be that perhaps you meet with some folks in Joy's office at ONC because the requirements around amend and correct and sharing well predate meaningful use. That they're – so I think those are things that it's – hopefully the technology makes it easier to comply with but those were pre-existing, so you might want to sort of chat with them about those.

**Michael H. Zaroukian, MD, PhD, FACP, FHIMSS – Vice President & Chief Medical Officer – Sparrow Health System**
Okay. Will do, thank you.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Thank you. Okay, we've got about 5 or 6 minutes, so other thoughts and then I'll try to summarize.

**Rita Kukafka, DrPH, MSPH, FACMI – Columbia University**
It's Rita Kukafka, could you hear me?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yeah. Hi Rita.

**Rita Kukafka, DrPH, MSPH, FACMI – Columbia University**
Hi. So I keep on bringing this up and I'm not sure if there's policy around it or I'd be interested in some of the speakers who have been doing work on the ground have a comment about it, but I continue to have concerns with this exasperating disparities. It seems like a fairly high bar for several subgroups to reach without some provisions. So I would be interested in feedback from the speakers or any general comments.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Do you mean that under-served populations would have a hard time entering their – the data that a provider might request from them?

**Rita Kukafka, DrPH, MSPH, FACMI – Columbia University**
Well I think it's – yeah, that would be one from a logistical perspective, but also from a – I mean at many different levels, logistically entering the data for low literacy populations, and also culturally. And that was a – is it – there's this inherent – there are several things that would have to be addressed for, I think, certain subpopulations to participate in this potential for being empowered.

**Cynthia Baur, PhD – Senior Advisor, Health Literacy, Office of Communications – Centers for Disease Control and Prevention**
Hi, this is Cynthia Baur and I just wanted to endorse what Rita was saying, because I expressed some concerns earlier this week on email about the role of plain language not being sort of adequately addressed yet. And I think even this discussion about what kinds of questions, how those questions are posed, how the answers are received and processed. I think all of those have to do with this issue of clarity of communication and how well different groups are able to engage in that dialog.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Agree.

**Prashila Dullabh, MD – Health IT Program Area Director, NORC – University of Chicago**
Hello, this is Prashila. If I may comment very briefly. So I can't address sort of all of the disparities sort of issue, given that it's a rather large community, but certainly in our study, these patients were rural, the term that was used, they call them the coal-crackers of Pennsylvania. And these were exactly the kind of individuals we talked to in our focus groups, and I think in thinking through this, and we also did some usability studies on the forms that we used. And I think that these are consideration that they are designed in a simple way that they are easily understandable. But from our own study, that issue was not something that these patients had brought up in the sense that I think the forms, for the most part, were made pretty simple, they had their medication bottles, they look at them, they had this information from the provider organizations. So on the whole, that issue was not brought up in this particular population of like sort of rural Pennsylvania, but the ease of context in terms of making sure that the information that is put forward is usable, and I think there are examples out in the field where some – is happening.

**Cynthia Baur, PhD – Senior Advisor, Health Literacy, Office of Communications – Centers for Disease Control and Prevention**
And I think that's a really important point, I mean I was pleased to see that 56% of the information that patients had provided pharmacists did validate, but I was really curious about the 44% in terms of what were the characteristics of the information that the pharmacists didn't accept and did health literacy issues potentially come into play there?

**Prashila Dullabh, MD – Health IT Program Area Director, NORC – University of Chicago**
Sure. So again the focus of this study was not so much as sort of looking at it from the disparities angle, so I don't have like sort of a complete breakdown. But the reasons why the feedback in some cases was not accepted was in a very small percentage, the patient actually ended up at the provider office before the interaction with the pharmacist. In some cases the pharmacist made a determination that this would be something that would be better handled through the provider patient direct communication and a message to that effect was sent to the provider. And then in some cases, and Geisinger has their own sort of peer decision support, if there was some type of scheduled medications with certain types of changes, were being requested, there's a separate process of contacting the pharmacies that prescribe, the providers that prescribe, so there's another workflow that takes place. So all of those, in some ways, factor in to those that were not accepted by Geisinger.

**Susan Woods, MD, MPH – Director of Patient Experience, Connected Health Office – Veterans Health Administration**
This is Sue Woods, can I just make a follow up comment to the questions and answers.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Yeah, but very briefly because we're at the end of the hour, so if you can be very brief.

**Susan Woods, MD, MPH – Director of Patient Experience, Connected Health Office – Veterans Health Administration**
Just as Jonathan has brought up how important the context is in consuming the data, I think it is important to identify the context of how the data is collected from the user capability standpoint and I just have two comments. We have a tremendous amount of data that we collected at the Portland VA on patient commenting about their medications almost 100% identified inconsistencies or errors, even higher than what was shown in the data. And I think there are two important things, one is that data can be collected at the point of care and through assistance of clinical team members for people who can't be doing this or may not be capable. And also second, it brings up the dependency of how important a caregiver user is in doing this.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great. Thank you. All right, so I'm going to take a quick shot at summarizing what I heard and then we'll go to public comment. So I think we heard that context is everything and we heard three distinct contexts at least and they were sort of a safety context of where amendments and corrections would be important. We heard a care enhancement context, so sharing information like functional status and symptoms and changes. And we heard a context for creating efficiencies, which might be admin data. We also heard about some functions that need to be able to happen with patient-generated health data, needs to be received, reviewed, responded to and recorded. And I think there's some work we need to do to make sure that we have the capability, through meaningful use and certification to do that. We certainly have the receiving end, right, so questionnaires, secure messaging, amendments and the group brought up taking another look at other ways we might be able to facilitate connection with biometric data, at least at a summary level. There remain some issues within I think policy and technology, but particularly around provenance and also around some of the workflow and implementations, particularly with respect to vulnerable populations. And there's I think probably a greater need to understand what is happening in the field there and how individuals are addressing engaging underserved populations, because we know it is happening.

So that's what I heard. I think the process from here is that we – I will go back and work with the ONC staff to come up with a pathway forward. Our next meeting as a Consumer Empowerment Workgroup is, I think it's August 21st. We may need to have a quick discussion in the interim, but I think at least do some work offline and we will turn – I will take the feedback also back to the Meaningful Use Workgroup in terms of the support for how it might be done in Meaningful Use as well. So with that, MacKenzie, let's go to public comment.

## Public Comment

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Sure. Operator, can you please open the lines for public comment?

**Rebecca Armendariz – Altarum Institute**
If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue. We do have a comment from Anna McCollister-Slipp.

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Great, go ahead.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Go ahead Anna.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**
Hi, this is Anna McCollister-Slipp and my company is Galileo Analytics, but I'm speaking today as a Type 1 diabetes patient and patient advocate. I want to speak on behalf and urging this workgroup and the ONC and the other agencies to include the incorporation of patient-generated data into Meaningful Use Stage 3. It's critically, critically important for those of us who have chronic disease, specifically those of us with diabetes, that this data is – that we collect on a regular basis is incorporated into the electronic health record through this process. For those of us with diabetes, we may see our endocrinologist four times a year to get a three month check on our hemoglobin A1c. That's sort of like – it's very much a sna – it's an average of what happens over a three month period and it's a general reflection of our overall glucose control. But it doesn't come anywhere close to capturing the level of granularity that we're now collecting on an outpatient basis, not just through blood glucose measures four to ten times a day, but through continuous glucose monitors, which generate data every three minutes 24/7. This is absolutely critical data that provides a much better understanding of what's happening in the outpatient setting and without that context, the physician is not able to provide meaningful advice consulting on how to control glucose in the outpatient setting.

Currently what's happening is it's – for the most part, a lot of this data is being completely unused. Many of the device manufacturers do not provide it in standardized data formats. I think including it in Meaningful Use would encourage that to happen, make it more usable both for the patient in the outpatient setting as well as the physician. In addition, for those who do download their data – or whose physician is interested in seeing the data, in some cases patients are now forced to pay an additional cost to their physician of $75-100 per visit per download, because of the time it takes for the physician or one of their staff to actually download the data.

Diabetes is kind of on the leading edge of patient-generated data, just because we have so many devices that generate data and have been for years. But I think there are lots of other – there are definitely lots of other diseases and chronic diseases that are being treated with new technology that either currently or will be generating data. I serve on the steering committee for MDEpiNet, which is the FDAs – basically it's the medical device version of Sentinel. And I was talking about the need for more patient advocacy and activism on these issues, and specifically around diabetes and some of the people on the committee said, well we've got orthopedic devices that are now beginning to generate data. They're not on the market yet, but they will be soon.

And as we think about where all of this is going from meaningful use and EHRs to patient generated data to patient reported outcomes, mobile applications, etcetera. All of this is really building up to what's being called in the Public Health nomenclature as the learning health system, where you take all of this data that's being generated, you put an application on top of it that creates the ability for everybody to contribute data, everybody within the health system is donating data and then they have the ability to extract knowledge from that.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Anna, sorry, this is MacKenzie, if you can just conclude your comment, we've already hit the three minute mark.

**Anna McCollister-Slipp – Co-Founder – Galileo Analytics**
Oh, I'm sorry, I didn't realize there was a limit, but thanks for the heads up. Anyway, it's absolutely critical if we're going to do true outcomes research to – if we're building towards a learning health system, that we include this. And I really applaud some of the comments that were made today and some of the work that's been done to facilitate this. So thank you, sorry for being so verbose.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks a lot Anna. Are there any other public comments?

**Rebecca Armendariz – Altarum Institute**
We have no other comment at this time.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Okay, Christine did you have any other closing remarks?

**Christine Bechtel, MA – Vice President – National Partnership for Women & Families**
Just to say thank you to all of our speakers and our participants today. This was a really rich discussion and we've got a lot that we will follow up about. Thanks again everybody.

**MacKenzie Robertson – Federal Advisory Committee Act Program Lead – Office of the National Coordinator**
Thanks everybody.

## Public Comment Submitted During the Meeting

1. Question for David. Please restate implication for data amendments through a community portal within an HIE, where data is coming from multiple locations of care. Can consumer amenda at community portal level, or does the patient have to go back to each provider/location of care to amend?

2. Where were the patient concerns collected from? Are these data published or did you get this from patients on your panel?