

**HIT Policy Committee's
Consumer Empowerment Workgroup
Transcript
June 17, 2013**

Presentation

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thank you. Good afternoon everybody, this is MacKenzie Robertson in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Policy Committee's Consumer Empowerment Workgroup. This is a public call and there is time for public comment built into the agenda. The call is also being recorded so please make sure you identify yourself for the transcript. I'll now go through the roll call. Christine Bechtel?

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

I'm here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Christine. Korey Capozza?

Korey Capozza, MPH – Consumer Engagement Director, HealthInsight

I'm also here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Great. Thanks Korey. James Cartreine?

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

I believe he's on he may be on mute.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Yeah. Scott Fannin? Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Leslie. Katherine Kim? Katherine, I believe you're on as well. Sarah Krug?

Sarah Krug – CEO, Cancer101 – President, Society for Participatory Medicine

I am here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Sarah. Rita Kukafka? Patricia MacTaggart?

Patricia MacTaggart, MBA, MMA – Lead Research Scientist/Associate Professorial Lecturer – George Washington University

I am here thank you.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Patricia. Beth Morrow? Jan Oldenburg? Casey Quinlan? Clarke Ross?

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup, the National Quality Forum

Hello, I'm here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Clarke. Mark Savage?

Mark Savage, JD – Consumers Union of United States, Inc.

Mark Savage here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Mark. MaryAnne Sterling?

MaryAnne Sterling – CEO, Sterling Health IT Consulting, LLC

I am here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks MaryAnne. Ann Waldo? Ryan Witt?

Ryan Witt – H4Y Corp

I am here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Ryan. Terry Adirim? Cynthia Baur? Brad Hesse?

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

I'm here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Great, thanks. Kim Nazi?

Kim Nazi, PhD, FACHE – Management Analyst – Veterans Health Administration

I'm here thank you.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Kim. Danielle Tarino?

Danielle Tarino – Lead for Consumer Education, Health Information Technology Team – SAMHSA

I'm here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Danielle. And Teresa Zyas Caban?

Teresa Zayas Caban, MS, PhD – Agency for Healthcare Research and Quality

I'm here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks. And any ONC staff members on the line, if you could please identify yourself?

Erin Poetter Siminerio, MPH – Policy Analyst – Office of Consumer e-Health – Office of the National Coordinator for Health Information Technology

Hey MacKenzie, it's Erin Siminerio.

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Mary Jo Deering.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Mary Jo.

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

Also, this is Kathy Kim I am on.

James A. Cartreine PhD – Instructor in Psychiatry – Brigham & Women’s Hospital – Harvard Medical School

And Jim Cartreine is on.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

Thanks Kathy and thanks Jim. Okay...

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC

And Casey Quinlan was late dialing in, but she’s here.

MacKenzie Robertson – Office of the National Coordinator for Health Information Technology

All right, thanks Casey. Any other members join in later. Okay, I’ll turn it back to you Christine.

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

Great, thanks MacKenzie and thank you all for joining us this afternoon for our third call, actually. And thank you also to those of you who sent feedback about what we think are the most pressing issues to address or issues that could be immediately impactful. Our agenda today, which I’ll go in...actually, I’ll go into that in a minute. So let’s forward the slides please. One more, thank you. So you can see on the slide that is on the screen now, that our charge, just as a reminder, is to provide recommendations to ONC through the Policy Committee on policy issues and opportunities for strengthening the ability of consumers, patients and lay caregivers to manage health and healthcare. So I’ll just start with that as a reminder for our framing. It’s a pretty broad charge, but we had a very good discussion last meeting about some of the issues that are coming down the pike and the landscape, particularly with respect to the changes that we expect to see as a result of the new view, download and transmit function that will be coming, beginning to go live in October for hospitals and then in January for physician practices.

So what we’ll do today, on the next slide, is we’re going to really focus pretty much on the first issue that many of us identified, which is thinking about the question of a policy framework for patient-generated health data. It’s a big, hot topic; we’re going to talk a little bit about what’s happening in the environment, just to level set for folks. But the purpose of today’s call is to really have a discussion among workgroup members about whether we think a policy framework is necessary. We did some advance work around existing policy frameworks that might simply be applicable; we want to get your reaction to that. And then raise any other policy issues that may be coming down the pike as a result of patient generated data.

Once we come through that stream of work, we will start to think about shared care plans. So we talked about this previously, but there’s not really an agreed upon template for what a care plan might be. But it raises also a lot of policy issues around consumers as authors and contributors to care plans, how those plans...the policies governing them when they’re shared across multiple members of the care team, including of course family caregivers and patients themselves, etcetera. So, we will do a deeper dive into that next. But today we’re really going to dive into a policy framework for patient-generated data, again focused on do we have what we need or are there other key policy recommendations that we want to put forward. And what are the key policy issues. It might be good for folks to put themselves on mute because I’m getting some background noise.

Okay, so with that, I’m going to dive in and talk for a few minutes about some of the background work that we did over the last six weeks to help provide a starting point for the group. So first I’m going to dive into some context around patient generated health data, what is it and what’s happening in the draft Stage 3 Meaningful Use criteria. And also I’m going to ask Mary Jo Deering to talk briefly about a technical expert panel that ONC has convened on patient generated health data, given all the interest that there is in it at this time. So on the next slide, you will see a definition that came from a white paper that was commissioned by ONC and crafted by RTI. Many of you will be familiar with that definition, but you can see it on your screen.

So first of all, patient-generated health data are health-related data, things like health history, symptoms, biometric data, treatment history, lifestyle choices and other information that are created, recorded, gathered or inferred by or from patients or their designees, in other words, their informal caregivers, to help them address a health concern. So PGHD is distinct from data generated in clinical settings and through encounters with providers in two ways. One, it's actually patients that are primarily responsible for capturing, recording and probably transmitting these data. And number two, that patients direct the sharing or distributing of the data to healthcare providers and other stakeholders. So it completes or complements provider-directed capture and flow of health related data, across the healthcare system. So hopefully that is fairly clear to folks, we can certainly get into some Q&A in a moment here.

So that paper came out in April, about a year ago, and it was a great help to the field because I know the Policy Committee has been really thinking about how to create the electronic infrastructure for supporting patient-generated health data. One of the ways that the Policy Committee has focused on it is through meaningful use. So, on the next slide you will see the latest draft definition for a Stage 3 objective in Meaningful Use. Again, we're early in the process for Stage 3, Stage 2 is currently active and Stage 3 is being working on by the Policy Committee this summer. So that definition you see before you or draft objective, the goal is for providers to give 10% of patients the ability to electronically submit patient-generated health data that can be reviewed and then selectively incorporated by EPs and EHs into their certified EHR. We included some sort of here's what we meant by that, e.g. pre-visit information, problem history questionnaires, home med updates, functional status, patient created health goals, advance directives, etcetera, to allow patients to contribute information needed for visits, etcetera.

So this could be accomplished through a variety of channels such as structured or semi-structured questionnaires or through secure email. And then EPs and EHs can be able to review and incorporate what they need into their EHR. So that's the second kind of big environmental piece that's happening. So number three, I'm going to ask Mary Jo to talk on, which is the next slide, about ONC's technical expert panel. Mary Jo?

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Yeah, thank you very much Christine. As Christine mentioned, we commissioned that white paper way back at the end of 2011, and it was produced in 2012 because we were very interested in seeing how this emerging trend could be clarified and enhanced. And so after the white paper was published, and by the way, I'd be happy to share a copy of that with...or at least a link to it, with the entire workgroup, and I'll take that as an action item to send that out to you, so you'll have it. And then we were very happy that the Meaningful Use Workgroup began to take it up. But we wanted to also see if we could make some additional contributions by understanding, well, how this is currently happening right now. Are there any sort of good practices out there?

We know it's too early for anything to be called a Best Practice with a capital B and a capital P, so, we asked our grantee, the National eHealth Collaborative to convene what's called a technical expert panel. And we charged them with giving us input on how patient-generated health data could be successfully incorporated by a provider into their medical practice, and specifically to identify some use cases. And as I mentioned, you can see the small b and small p, best practices for how you could actually get it into the clinical workflow. What we're hoping this will provide is almost like perhaps a...it's a policy framework but not a big P policy framework, it's more like an operational level policy framework so that the concerns of both patients and providers could be reduced, that the information could flow a little bit more easily and this mutual...setting of mutual expectations on both sides of what this is, what information's going to be collected, how it would be handled when it came in. So the TEP, as it's called, will be presenting its findings from having reviewed a variety of activities that are going on across multiple providers and it will be summarizing them and trying to identify what indeed do seem to be promising practices for safely, effectively and most valuably using patient-generated health data. So, I'll stop there.

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

Thanks Mary Jo. So I would imagine that some of these best practices or promising practices are ones that might be disseminated, for example, through like the regional extension centers at some point.

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Absolutely, absolutely.

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

Okay. So if we step back a level, what I'd like to do at this point is I want to open it up for any questions that you guys may have around patient-generated health data or any of these kinds of environmental trends. But before I do that, I'll just try to pull these three pieces altogether by saying if we think about view, download, transmit coming online later this year and early next, it will begin to really change patients expectations for how they interact with their health information and their healthcare providers. We've already seen that in Meaningful Use Stage 1 simply now the vast majority of providers have adopted and implemented an electronic record and so consumers are really beginning to expect the presence of an EHR in their healthcare experiences. And I think that something very similar will happen in terms of expecting online access to patients own health information and functionalities like secure messaging.

And so when we think about consumers downloading their health information from let's say the three different doctors that they are seeing, we can imagine that they will have a need to do a couple of things. One would be to correct or amend some health information that's inaccurate. Two would be to share that back with their providers whose records reflect those inaccuracies and three would be to add missing or incomplete information. All of those are forms of patient-generated health data. So we've got the technical expert panel that ONC has convened thinking about how to do this in practice. We've got the potential for meaningful use to really accelerate the opportunity for patients to contribute health information. So the question for us is really, okay, what's the policy framework, do we need a policy framework to support effective implementation. So let me stop there and ask folks if you have basic questions about patient-generated health data or these environmental trends, and then I'll go into the tech...the kind of policy framework opportunities that we think are potential for looking at. So, questions?

Ryan Witt – H4Y Corp

This is Ryan Witt, I have a question. Are you guys including in patient-generated health data, data generated from apps that might connect with an EHR and feed into it?

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

If you mean...I would probably say yes, but I would rephrase it a little bit and focus on the information that is contained within those apps. So if that information, for example, comes from a home monitoring device, right, that's patient-generated health information because the source is the patient, it's something that I create and direct the sharing of. The vehicle may be an app, but it's...we're really talking about the data contained in it.

Ryan Witt – H4Y Corp

Cool.

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

Thanks Ryan. Other questions?

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

Yeah, this is Kathy Kim. My question relates to the use or patient access to the information that they are contributing, especially when we are in the context of multiple providers, multiple conditions. It sounds like it was focused on getting patient generated data into an EHR, but then if you're with multiple providers and accessing multiple EHRs or PHRs, is there thought in the framework as to how to make that access easier for consumers?

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

That's very interesting. So, let's hold that, because that's, I think, an additional policy issue that we should talk about with the group that we need to think about. So I just made a note of it, if you don't mind, and we'll hang onto that and then get in...and let's think about that as we get into the policy framework that I'm going to review.

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

Great.

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC

This is Casey raising her hand because I'm going to just...I'm going to ask that as we talk about this, we do have to look at policy that will cover everything from Athena Health to EPIC and the policy that will drive the actual interoperability of this. Because it's still...we still don't have interop and adding patient upload is going to...I mean, as much as that's what I want, and what I think we need to concentrate on, that road is not even paved yet and its...that's going to get very exciting.

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

And by interoperability do you mean the ability to share that across...

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC

Yeah, in other words to upload it to something that will talk to my primary care provider who's using Athena and that will also be able to strap across to the hospital should I be in line for surgery that is using EPIC or Cerner. The cross-platform issues are huge, so I'll sit down and shut up now, but I just wanted to raise my hand on that.

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

Okay Casey, thanks. And we also have a sister group chaired by Leslie Kelly Hall who's on the phone, that does deal with standards and I would say that it depends on what kind of patient-generated health data we're talking about, because I think for some of it, like clinical summary, there are standards that would support the movement of that information. But then for others, what about pre-visit information, gee wouldn't it be nice to not have to fill out the same forms over and over again with your family health history and your medical history, etcetera, and how do we support the movement of that information, which has standards again to some degree, but probably not to all. So what we'll do in this group is focus on the framework of policy, and then when we get to the point where the standards and interoperability components come into play, that's when we hand off to our technical experts on the Standards Committee. So, Leslie...

Jan Oldenburg – Vice President, Patient Engagement – Aetna

This is...go ahead...sorry.

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

I was just going to ask Leslie if she wanted to add anything to that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

No, I think that that's great. We're starting to see a lot of work in this area, so I'm eager to get on and support this team's efforts.

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

Great, thanks Leslie. Someone else was trying to speak?

Jan Oldenburg – Vice President, Patient Engagement – Aetna

Yeah, this is Jan Oldenburg and I have a question about whether when we're talking about patient-generated health data whether we're also talking about the data that might be generated from devices that they are...on the one hand there's data that's from devices they might choose to wear and then there's data from devices that might be implanted in their bodies. And so are we incorporating that into our roadmap, because that's certainly got a lot of interesting policy implications?

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

Yeah, I think that's right. I would say yes, I don't know what other groups think, but I would say yes. I mean I think again, if it's patient generated, so if we can go back to slide 5, so if it's health related data that is created, recorded, gathered or inferred by or from patients or their designees.

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Christine, this is Mary Jo from ONC. There is another workgroup that was created in response to the requirement to move patient safety forward and medical devices that are implanted fall under the FDA's authority...

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

Um hmm.

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

...and so that other workgroup will actually be looking at least at the safety issues and possibly other policy related issues of these devices that are FDA regulated. So, I do think while if...we would do best to think of policy issues broadly and then to the extent that they are also relevant and important for FDA regulated devices, we would certainly want to include them. But again, we would certainly not start from that direction, because we do have another whole workgroup that's looking specifically at that.

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

Yeah, so I think...and I completely agree and understand it from a safety and a regulatory perspective, I do think it's a question we should keep track of in terms of if you think about some of the policy issues and actually that got raised earlier on the call in terms of patient access to information they're contributing, it's...in some ways the regulation of the device is...in all ways that's not part of our scope. However, in some ways consumer access to that information I think is a policy issue that there are some challenges around that we may want to...may or may not want to include in our discussions here. Does that sound okay to you Mary Jo? I don't want to step on...

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Oh yes, and I'm not trying to a priori necessarily exclude things, but I did want to make sure that people understood that there is a lot of deep work going on around medically regulated...I mean FDA regulated devices, so just in terms of even keeping...given our limited time and attention, but I do agree Jan, that was an important thing to raise and I also agree with Christine's answer that there are undoubtedly policy issues that this group should touch on.

Jan Oldenburg – Vice President, Patient Engagement – Aetna

Great.

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

Okay, great.

Ann B. Waldo, JD – Wittie, Letsche & Waldo LLP

If I can ask one more scope question...this is Ann Waldo. I think that from what you're saying both of these scenarios would be in scope, but I just want to confirm. So one area would be a consumer-facing app that I download on my Smartphone and let's say it measures my various cardiac data, and that's clearly patient-generated health data, the way I've described it so far, it's not subject to HIPAA when you think of privacy, it's the land of consumer protection privacy laws. But then there are the flip-side of that that are also developing where it's pushed by the provider, a whole bunch of different apps out there that are in startup mode where, for example, when you get physical therapy, you will be given an app that will show you how to do it properly over time, and may even be able to correct you. And then that data can flow back into the EHR, so that second category is clearly subject to HIPAA, the first category's not, but for our purposes, we're going to consider both of them as patient-generated health data.

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

Yes, I would. But I think that's part of what we want to begin a discussion with this group about. I would consider that patient-generated health data, now the framework governing it is a real question mark and we're really glad you're on the phone Ann, because that's actually a pretty good segue into one potential starting point for thinking about a regulatory...not a regulatory, a policy approach here. But I will say all the issues that folks have raised are really critical. So what we want to do today is think about these things that are...that may not be covered by the approach that we're going to describe and make sure we catalog them and think through what some recommendations might be. So very good, everybody's raised some really good stuff. Any other questions before I jump in.

Mark Savage, JD – Consumers Union of United States, Inc.

Christine, it's Mark Savage with two questions.

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

Yup.

Mark Savage, JD – Consumers Union of United States, Inc.

Looking at the definition would...I've always thought of family history data as being patient-generated health data, it often gets incorporated. I just want to make sure that...it's not...the patient is not necessarily directing after it flows into the provider's office, so I just wanted to make sure that that's within our definition of patient-generated health data.

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

Yeah, absolutely, because it's the...it is essentially the data is coming from the patient and it makes its way into the EHR. But the original source is the patient, because it's really the patient that's responsible for sharing that, if you will. So I think in that first line, that's what's meant by health history, would include family health history.

Mark Savage, JD – Consumers Union of United States, Inc.

Second example, the...in view, download, transmit, would the transmit portion be patient-generated health data if the patient's doing the transmitting?

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

Yes, that's exactly why we want to have this conversation, yes.

Mark Savage, JD – Consumers Union of United States, Inc.

Thank you.

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

Thank you.

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup, the National Quality Forum

Christine, this is Clarke.

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

Hi Clarke.

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup, The National Quality Forum

I had two elements I wanted to suggest for addition to the definition of health data, is that a later conversation or should I do that now?

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

I think you can do it now. This isn't our definition, the workgroup's, this came from a white paper, but I think in terms...so it's a good starting point for us, but we're not limited to it. So why don't you go ahead now.

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup, The National Quality Forum

Okay, thank you. So for persons with severe disabilities striving to live a meaningful life in the community, consistent with the Olmstead Supreme Court Decision, the two elements I would suggest adding are housing stability and access to community services and supports, and these would be non-medical services and supports, things like transportation and social supports.

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

And Clarke, do you mean by access to it, you mean the patient is reporting or their caregiver is reporting their level of access or what community supports they're using, for example?

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup, The National Quality Forum

Yes and probably the number one...well, I don't want to say it's the number one barrier, a major barrier is lack of transportation and people can't get where they need to go, so that would be an example.

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

Okay, I see what you're saying. Thank you. Okay, so let's continue and go back to slide, it looks like 9. Thank you. So, as we thought about the feedback from the workgroup and the needs that ONC has and the environment that we just described, we actually thought a lot about the right under HIPAA to not only view your record, but the right to request an amendment. And so we of course thought about the fact that we have these rights and we need to make it easy for patients to exercise them and easy for providers to comply with them; and we want to think about technology, of course, as a way to do that and the concomitant policy issues it might raise. Next slide please.

So under HIPAA, right, there is something called the correction principle, and Ann can enlighten us all about it, but the correction principle says that individuals should be provided with timely means to dispute the accuracy or integrity of their individually identifiable health information and have erroneous information corrected, or have a dispute documented if they're requests are denied. So meaning, you've got to have a timely way to say, hey, this piece of information isn't accurate. At the end of the day, the provider has the ability to say, okay yup I agree and I'll make that change. Or if they disagree with you, then you do have the right, as a patient, to append the record with what I would describe almost as a note or a flag to say, well, it's supposed to travel with the record, to say well this piece of information the provider thinks is "X" and the consumer says is "Y."

So, on the next slide you have a right to request that a healthcare provider or plan amend your health information, either change wrong information or add information to your file that is missing or incomplete. So in our view, I think that provides a pretty interesting starting point for thinking about patient-generated health data because you've got the right to request an amendment. It turns out that Meaningful Use, as you'll see on the next slide, also has a draft recommendation that would provide...that would...it would require providers through their EHR to provide patient's with the ability to request an amendment to their record online. And it would happen through view, download, transmit and be done in some way that is fairly obvious and easy for the consumer.

So to the next slide. So I want to open it up for discussion and Erin and Mary Jo and I will take good notes here. But let's think about what you guys reaction to that as a potential policy framework? Do we need more than that, which simply guarantees the right? And it sounds like we do, I think there are some other issues that folks have raised on the call, but there are some other issues that I also thought about in terms of, well, if I'm sending data to my provider, and then is there any requirement, or should there be, for responding or acknowledging its receipt? Does that information need to be essentially flagged as from the patient, we hear about that one a lot. How do consumers exercise their rights electronically? Are we ready for this, etcetera? So, I'll open up the floor and get you guys reactions and see...and what I'd like to do here is get your reaction to both the potential framework as a starting point and also to continue hearing from you guys other policy issues that you see, that might need some attention from this group.

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup, The National Quality Forum

This is Clarke. I can...I'd love this and I can give you an example of not only the importance of this policy, but the acknowledged receipt, and that's in the area of serious mental illness and psychiatric advanced directives. And despite having state laws requiring psychiatric advanced directives and specifying the conditions that providers and consumers must follow, many professionals, particularly psychiatrists, refuse to acknowledge, even though it's the law. So this would be a great mechanism to reinforce something that's happening. SAMHSA, the national Substance Abuse and Mental Health Services Administration actually have suggested guidelines on psychiatric advanced directives. And a number of states have statutory provisions, so this is a great consumer protection and a consumer empowerment vehicle and the example of serious mental illness and advanced psychiatric directive would be one.

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

Thanks Clarke. So in that case, we can think about the one sort of potential issue might be that with an advanced directive, if we use the policy framework that I just described around correct, amend and add to your record, which is already guaranteed right under HIPAA, then the provider would have to review and accept your advanced directive. It's hard to imagine that they wouldn't do that, but I just want to flag that if we apply that policy framework to that situation, I think that's how it would work.

Clarke Ross, DPA – Consortium for Citizens with Disabilities Workgroup, The National Quality Forum

Right and that would be great.

MaryAnne Sterling – CEO, Sterling Health IT Consulting, LLC

Christine, this is MaryAnne Sterling and I want to jump in with a quick addendum here to your previous slide, and that is, for millions of us who are caring for those who cannot speak for themselves, I would love to see a provision in here saying for patient or designated personal caregiver...

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

And are you talking about the Meaningful Use Stage 3 draft recommendation?

MaryAnne Sterling – CEO, Sterling Health IT Consulting, LLC

The definition you had on your previous slide, so this is 13, slide 12.

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

Okay, so yeah, that's the Meaningful Use Stage 3 draft recommendation and that's a good catch and I'll take that forward.

MaryAnne Sterling – CEO, Sterling Health IT Consulting, LLC

Yeah, because I...those of us again, just a small example here, but those of us dealing with parent with Alzheimer's disease, they're not going to be the ones requesting a change in their medical...so...

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

Right, yeah, and I agree with that and actually we had this discussion probably a couple of months ago where we needed to go back through Meaningful Use and say everywhere provider...I mean patients or their designated caregiver, we needed to say that everywhere, so that's a good catch here.

Jan Oldenburg – Vice President, Patient Engagement – Aetna

A note also about, and this is reflecting I think on Mark's question about whether data that already...

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

I'm sorry, who's talking?

Jan Oldenburg – Vice President, Patient Engagement – Aetna

Sorry, this is Jan Oldenburg.

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

Thanks Jan.

Jan Oldenburg – Vice President, Patient Engagement – Aetna

So this is about the data that a patient transmits would be considered patient-entered data. And I just want to create a context in terms of a larger framework that seems to me that it means that we actually have to do a much better job of tracing provenance of data all the way through the system. So if I transmit data unchanged, that was originally generated by another doctor should it really be considered data generated by me, or should it still be tagged with the original facility or physician who put it in their medical record? So, I think that that actually has broader implications, but I think it's going to be very important as we start building this framework where data comes from all sources and you may want to be able divide and see where things come from and their history.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Jan, this is Leslie and I think that's a great point. And in the standards we really designate differently the author versus the sender, so those kinds of provenance questions come up and are being discussed right now, so it's a good reminder. Thank you.

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

Kathy Kim...

Ryan Witt – H4Y Corp

This is Ryan...oh, I'm sorry, go ahead.

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

This is Kathy Kim. I wanted to react to the bullet that says consumers exercise their rights electronically and related to the previous comment, when consumers generate their own data and submit it to a provider, will it have the same sort of protections based on the content of that. So if they're submitting something around mental health, will the providers, once they receive it, have it become HIPAA protected and have the same obligations to protect sensitive health information separately from other health information? How those sorts of consents and authorizations would be managed at that granular level, because we don't have those systems in place today.

Ryan Witt – H4Y Corp

This is Ryan, from an EHR perspective. I think that a lot of the questions that are being brought up, working at an EHR and seeing the implementation of Meaningful Use there, if it were...if EHRs, a lot of meaningful use really clamps down on EHRs to actually build features and make things happen. And if we had a list of all these different areas and we said that an EHR to be Meaningful Use certified had to integrate with at least six of these applications that fit these categories, a lot of the answers to the questions as far as the details, will be driven by doctors, because doctors will want to see, well who entered this data, was it the patient, and they'll want to confirm it. So I'm not quite sure that we need to have that in a policy, but more just have the EHR integrate, and then the rest of the things would be driven by the market, in my opinion.

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC

This is Casey Quinlan speaking up. As a writer, I struggle a little bit with the language...the ability to request an amendment to their record, and I don't have a great suggestion right now, I will ideate on it and share it when something comes to me. But I really would like to see language that was less, we are allowed to make an amendment to, we are allowed to enter data. Because requesting an amendment is like please can I have you fix this, whereas actually uploading data and adding to our records with data that we generate is not...that's not a request, that's a statement. And I do think that Ryan's point about certifying or check listing or white listing six or seven commonly used health data collection apps on the patient side with EHR technology, would be a really elegant way of solving that issue. But again the language, I'm struggling with this language a little bit.

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

So, I do want to come back to Ryan's point. But I think on this, and I'll lean on Ann here if she's willing to jump in. This is an existing policy, and so while I agree and share like it's not ideal in some ways, because it would just be nice if I as a patient could say, hey, this is wrong and you need to change it. But that's not what the law says and we don't have the authority to make a change in the law or that...I mean even ONC or OCR would have to go through the regulatory process.

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC

Yeah.

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

So what I'm looking for here is, is there enough in the existing right to either change wrong information or add information that will cover the idea of patient-generated health data, because we are talking about the provider's EHR, it is a legal medical record, they are responsible for its content. So, as much as I want to say, you should just take my amendments, I understand the legal requirements around the medical legal record that might make a provider hesitant to do that and therefore want to review. So we also actually heard today about a patient who in her health history described her previous health history as having several strokes, when in fact that wasn't the case, she had some other neurological issues and in a conversation, the provider and the patient agreed, oh yeah, so that's not quite right, it was really this other thing. And so rather than repeating incorrect information, even though it was sourced by the patient, it was able to be more accurately represented through a conversation. And that review process is what I think generated that. Ann, I don't know if you have anything to add here.

Ann B. Waldo, JD – Wittie, Letsche & Waldo LLP

Sure, happy to try. Yeah, just to clarify that correction principle, of course, is already in law, as Christine said, and it's deliberately pretty narrow I think for the same reasons that you identified. Because this is the caregivers professional record and they need to be in control over it and it is definitely best practices that if there is a disagreement between the provider and patient about the content, then the provider should put the patient's comment in the record and annotate that this information came from the patient. I'm trying to think of a good example, but let's say you have a positive antibody to an STD and so the doctor is quite sure scientifically that you have had that STD, and the patient says, no, I haven't. Well, the appropriate thing would be for the patient to go ahead and record the information accurately and his own conclusion and then say, patient denies any knowledge of this, or whatever.

So that's existing law. I think the really fascinating thing that you're raising Christine is whether we want to take that existing law, which obviously we're not going to change, and try to piggyback onto that a new right...new rights with respect to patient-generated health data. So, you're really talking about using the amendment and correction right as an analog I think is a fascinating one and kudos to you guys for thinking about it. I think...I mean a couple of con...I definitely hear Casey too saying it's not enough, we want to be able to upload our own information, and I share that in patients. I'm working with a number of startup companies that are building cool ways to do that.

The one cautionary note I want to add though is, that if there are 500 apps in 2014 and 5 million health care apps ten years later, and you can't give every patient the right to submit all their content into an EHR without some limits on it. And the entire system will crash and I can understand why doctors would be horrified at that thought. So, I like the idea of really standardized interfaces so that you can send your data...so that the EHRs can accept data from a whole lot of standard APIs that the developers will understand. But then it's probably going to need to be a market serving solution in the long run as to which apps are permitted to send data to which EHRs.

Ryan Witt – H4Y Corp

This is Ryan. I think from a policy perspective it will really help if EHRs are forced through Meaningful Use, so they're driven through Meaningful Use to actually integrate, because right now, there's no real motive for an EHR, from what I've seen, to integrate with outside apps. And without the motive to integrate, then there's no really motive to create some sort of a standard API, because nobody's really...there's no motive to integrate anyway.

Ann B. Waldo, JD – Wittie, Letsche & Waldo LLP

Yeah.

Patricia MacTaggart, MBA, MMA – Lead Research Scientist/Associate Professorial Lecturer – George Washington University

Christine, this is Patricia, can I jump in, because just two sub-comments to the comments that are going back and forth. Because it is a legal document, I think it's going to be really important and that we do a disservice of the policy if we don't add some clarity that says, this does not mean you get to submit everything you want and this does not mean you get to require something to be deleted. I mean, those...have the clarifications so we don't build expectations that leave everybody frustrated because it has an expanded scope, but it's not an unlimited scope. And then a comment to give the EHRs six options to pick from, that's becoming problematic, I think for providers and consumers because if your EHR, and again, not all the providers or the consumers understand which ones the EHR has chosen versus the provider has chosen. It may not be the right ones for the provider or it may not be the applicable ones, so options, unless you require "and" instead of "or," or to be effective have to become ands or they just build an expectation that's not met. So I would just suggest that in our policy we kind of make sure we deal with expectations and being very clear of what can't be as well as what can be, at yet a very high level.

Sarah Krug – CEO, Cancer101 – President, Society for Participatory Medicine

And this is Sarah Krug. I'm not really sure that this is necessarily a policy issue, but that's where patient education is so critical, as we start to roll things of this sort out. I mean I know that in our cancer world, when we have many of our patients completing symptom trackers and things of that source that they're sharing with their clinicians, but when we do a deep dive, we find out that a lot of patients don't know how to identify their symptoms. And they haven't necessarily been taught how to identify their symptoms. And when they think a particular symptom means one thing, it actually means another. And so again, this is not a policy issue, but this is where again patient education plays such an important role, because as you're starting to empower engaged patients in tracking their data. Unless the clinician, whether it is a doctor, a nurse or a patient educator at that institution or practice is taking the time to further engage that patient and teach that patient, the data that you're going to receive may not be what you want it to be.

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

So I actually think that...this is Christine again, is something that potentially the PGHD technical expert panel has probably been looking at, because they are looking at more implementation best practices, which I think also would have to do with setting expectations, etcetera. So I think it might be helpful, Mary Jo, do you think that the technical expert panel may be ready to present some of their thinking already to this group next month?

Mary Jo Deering, PhD – Senior Policy Advisor, Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Oh absolutely, I know you're next meeting's on the 18th and I think it sounds like that would be...I'm sure they would be happy to, so I think if you confirm that that's what you'd like, why we'll certainly make it happen.

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

I think that would be terrific, any disagreement with that? Okay. So I want to come back a little bit...this is all really helpful and good information. So we've got about 12 minutes left, and there are lots of issues around the volume of data, the provider's responsibility for reviewing the data, etcetera. But I want to come back to what I think is sort of a persistent theme, and articulate it and have...see what folks think, I'll just say that. Which is, we talk about the role of the provider in reviewing and approving, we talk about data provenance, so you know whether this piece of information that you want in your record at some point, or you've decided at some point you want in your record, whether it came from another doctor or the patient. And I think I want to step back and ask people why is it important...why is it so important to flag things as coming from patients versus knowing...trusting the information because it came from another clinician.

And the reason I say that is because Leslie and I and maybe some of you attended a White House Summit last week on patient access to their health information. And we had a number of patients in the room who described their experience with their health information, and much of the time, it was their dogged work in trying to correct errors in the provider's record that really generated some major safety wins for them. And so, it just made me really think that we...I keep...I hear a lot of, not in this group, but a lot of policy discussions in Washington talking about the importance of making sure you know that this is patient-generated health data and flagging that, but yet it's okay if it comes from another doctor. So I wanted to just raise that and see what people thought.

Korey Capozza, MPH – Consumer Engagement Director, HealthInsight

Christine this is Korey at HealthInsight.

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

Hi Korey.

Korey Capozza, MPH – Consumer Engagement Director, HealthInsight

Hi, I had a...I'd like to offer a comment on your question, but just back up for just one second and say that I think a big problem here is by and large patients probably don't know that they have that right to correct information...

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

Um hmm.

Korey Capozza, MPH – Consumer Engagement Director, HealthInsight

...so as a kind of policy goal, perhaps it's worth sort of calling that out a bit, so maybe the next thing is to say that providers need to alert patients to the fact that they have this right, and then provide the sort of technical capability to make it happen. Because here in Utah, about two years ago we did statewide focus groups related to consenting for our clinical health information exchange and I can say that this issue of inaccurate data in the record came up in every group. And there was such a high degree of frustration about that and almost nobody mentioned that they knew how to address it. So I think that not even knowing that right is there and that they have the ability to do that is a big piece.

And then with regard to the issue of why it matters that we identify something as patient generated. We just recently came off doing a pilot with a two-way text-messaging tool that gathered data related to blood sugar readings. So on a daily basis, patients were logging their blood sugar readings and what we heard from providers was that, what are they supposed to do with that information if it comes to them...

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

Um hmm.

Korey Capozza, MPH – Consumer Engagement Director, HealthInsight

...what's their liability there, how are they respond to it, and so, just some uncertainty, I think, about really understanding the provider connection to that data, from a legal perspective and from a care treatment perspective. So, just some initial thoughts.

Mark Savage, JD – Consumers Union of United States, Inc.

Christine, this is Mark...

Patricia MacTaggart, MBA, MMA – Lead Research Scientist/Associate Professorial Lecturer – George Washington University

This is Patricia...

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

Mark...

Mark Savage, JD – Consumers Union of United States, Inc.

Christine, could I pick up on that and say, I think as we get more and more patients monitoring data generated by the patient the tracking that it...that that's the real data, that's coming directly from monitoring something is actually going to be helpful. So I hear you, and it's been my experience as well that sometimes patient generated data is not valued as much, but I flip it around as well and say that is the most valuable data, in many respects. And that it...the good provider will actually appreciate having that and knowing that it came from a monitoring device or something.

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

Um hmm.

Patricia MacTaggart, MBA, MMA – Lead Research Scientist/Associate Professorial Lecturer – George Washington University

Christine, this is Patricia. I think the clarification though that needs to come down, and you said it earlier, it's the definition of patient-generated. If it's from an electronic monitor that is doing a reading on my body, yes, obviously that would be. But if you're equating me taking my blood pressure versus a nurse or a doctor taking it, there are some that are very good at it, better than the nurses taking it, but that doesn't relate to all the constituents out there. So, I think it's going to be really important to say, when we say patient generated, which patient generated maybe has the same status.

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

This is Cynthia. So maybe this is a naïve question, but wouldn't we want the source of every piece of information identified?

Woman

Yes.

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC

Yeah.

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

So it sounds like part of the issue is that patient generated data gets labeled and other things do not. But isn't the real issue that all data should be sourced so it's very clear where it came from and if you need to track it back, how you do that?

Jan Oldenburg – Vice President, Patient Engagement – Aetna

This is Jan Oldenburg, sorry, go ahead.

Casey Quinlan – Chief Message Officer – Mighty Casey Media, LLC

Casey was going to weigh in that there really should just be an author tag on all of it, so that if it's Dr. X, Y, Z, and he's the one who put it there, and if it's patient A, B, C, she's the one that stuck it in there. And then at that point, everybody knows where it came from; there really should be some kind of an author tagging system in there.

Jan Oldenburg – Vice President, Patient Engagement – Aetna

Yeah, this is Jan Oldenburg, and I think that that's exactly right. As you start thinking about big data, sensor data, external monitoring data, observations done by the patient, done by a caregiver, done by one physician or another. As we start to try to analytics using all of that data, I think it's a matter that the source of it, where it came from and possibly even the transitions it passed through, is going to be really important to being able to normalize it and make sense out of it. So, I think that Casey is exactly right.

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

Great, there's a lot of agreement on that point.

Ryan Witt – H4Y Corp

This is Ryan. I think that one of the points to just highlight again is, I've heard this a lot from doctors, doctors definitely have to have...they don't know their liability when they're getting data from outside sources, and that's definitely something that was touched on once...but definitely needs to be there because doctors are just...they're scared.

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

Okay. Great. All right, so we've got a lot to go on here. I'll work with the staff to kind of condense it into a set of issues that we want to talk about and think about, either making some recommendations on or learning more about. I think the provider liability issue is real and I don't know if that lives in another workgroup or if we ought to take that on, but we need to certainly understand it before we would do anything. So we will consolidate all that, but we've got about four minutes left and we need to do public comment, so I just wanted to open it up for anybody who's got burning thoughts or ideas. Okay. All right.

So, trying to summarize a very good and wide-ranging conversation I heard issues around patient access to the information that they're contributing, especially when it's across multiple providers. I heard issues around the interoperability of patient generated data, so that patients can see it across platform issues. We talked a little bit about device data, talked a fair amount about device data and information that goes through apps that aren't covered by HIPAA, that's definitely I think a policy issue we need to look at see if the Tiger Team on Privacy & Security has done any work on that. We talked about provenance of data. We talked about what happens to patient-generated health data when the provider receives it, what if it's sensitive health information, will HIPAA protection still apply to those data? We talked about EHR integration with apps and standardized interfaces. We also talked about needing to kind of understand best practices around patient education and expectations, with respect to submitting information, but also correcting or changing information in the record.

And I wonder if we ought to ask OCR next time to maybe give us a five or ten minute overview of what they're doing on that front, because I know that the Stimulus Law gave them some funding to do consumer education about privacy, and they have developed some tools. I'd love to understand where they're at in that process. Let's see, we also talked about the fact that...and I think there was broad agreement that there's high value in patient-generated health data although sometimes it tends to get labeled specially, but all data needs to be sourced, so that we know its author. And then, of course, we talked about provider liability and data volume. So that's my summary, did I miss anything important that you guys want to add?

Rita Kukafka, DrPH, MSPH, FACMI – Columbia University

Yeah, this is Rita Kukafka, just wanted to raise one point. When I listened to this discussion it reminds me of people who are enabled to correct their credit reports and there has been a huge business surrounding just managing those responses with a lot of frustrations. So I think having this policy is sort of necessary, but not sufficient. I think we need to really make sure that we don't step into that same space of an overwhelming amount, the system being unable to manage it and really think about a system that would ensure that it doesn't result in a similar catastrophe, I would say, as people trying to correct their credit reports.

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

Yeah that's great, actually, that's a really great analogy and it bridges the policy and the technology together, so that's a really nice way to think about it. Thank you.

Woman

There was one other issue that we raised, which was the management...the sort of electronic management of consent and authorization for what happens to this information, because we have that issue now in managing, at a detailed level, patient consent and authorizations.

Danielle Tarino – Lead for Consumer Education, Health Information Technology Team – SAMHSA

Yeah, and this is Danielle Tarino from SAMHSA and just a quick comment on that, the authorization and management is going to be an extremely sensitive issue for people that are using mental health or behavioral health patient facing apps, and submitting personal data about themselves all day long to their providers. Especially information that, while it would be great for research in the future to track people's patterns on their roads to recovery, it's also highly sensitive information that they're submitting.

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

Right, and we would, I think, ideally want the ability for...I mean this...patient-generated means patient-generated, so they...so in that case we would want the patient's to be able to submit only that which they were comfortable sharing with their provider, so I think that's right. Okay great, you guys this was a terrific call. Let's open it up for public comment.

Public Comment

Rebecca Armendariz – Project Coordinator, 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 are listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

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

Okay. Great, well thank you again everybody. If you have more thoughts or things you'd like to add, feel free to send them to...

Rebecca Armendariz – Project Coordinator, Altarum Institute

I'm sorry, this is Rebecca from...oh, sorry, excuse me.

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

Oh, she's probably jumping on another call.

Rebecca Armendariz – Project Coordinator, Altarum Institute

Sorry.

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

That's alright. So, anyway, feel free to send those in to Erin and we will work on a summary and an agenda for next month that keeps us plowing forward through these great issues. So thanks everybody. Have a good one.