



Collaboration of the Health IT Policy and Standards Committees

Consumer Task Force

Final Transcript

October 17, 2016

Presentation

Operator

All lines are now bridged.

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

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a joint meeting of the Health IT Policy and Health IT Standards Committee's Consumer Task Force. This is a public call and there will be time for public comment at the end of today's call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll; Donna Cryer?

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Here.

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

Hi, Donna.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Hello.

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

Patty, I know you're on.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Yup, I'm here.

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

Hi, Patty.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Hey.

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

Andrea Hartzler?

Andrea Hartzler, PhD – Assistant Investigator – Group Health Research Institute

Here.

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

Hi, Andrea.

Andrea Hartzler, PhD – Assistant Investigator – Group Health Research Institute

Hello.

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

Angela Kennedy? Brian Ahier? Carolyn Kerrigan?

Carolyn Kerrigan, MSc, MD – Professor of Surgery – Dartmouth-Hitchcock Medical Center

Here.

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

Hi, Carolyn. George Mathew?

George Mathew, MD, MBA, FACP, CMQ – Chief Medical Officer, Clinical Analytics – Hewlett Packard Enterprise

Here.

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

Hi, George. Jenna Marquard? John Derr?

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

Here.

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

Hi, John.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

Hi.

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

Kevin Fowler – Consultant – Kidney Health Initiative

Here.

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

Hi, Kevin. Leslie Kelly Hall?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Here.

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

Hi, Leslie. Mark Savage?

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Hi Michelle.

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

Hi, Mark. Susan Brown? And Susie Hull? And from ONC on the line I believe we have Elise Anthony and Margeaux Akazawa; is there anyone else from ONC on the line?

Michelle Murray, MS, MBA – Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Yes, Michelle Murray.

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

Hi, Michelle.

Caroline Coy, MPH – Health IT Program Analyst, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology

Caroline Coy.

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

Hi, Caroline.

Lana Moriarty, MPH – Director for Consumer e-Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

And Lana Moriarty.

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

Hi, Lana. And with that I'm going to turn it over to our Chairs, Donna and Patty.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

All right, excellent. Thank you everybody for joining us today. We have...we're jumping into something I think is really exciting. So you know, we've all talked about and heard about patient-generated health data, but I'm excited to hear what ONC and their team have been working on to see how this group can participate as we have done with other things in the past. I mean it's something that everybody, and I love Leslie your example and hopefully you'll be sharing more with us, of how we're starting to really use patient-generated health data to improve clinical outcomes for our patients.

So, we'll be primarily Donna and I, who are usually very chatty, I don't think she and I are going to be talking much today, except for maybe opening us as I am and then Donna will help to facilitate some questions at the end. But we're going to be talking about or the groups going to be talking about the important of patient-generated health data. We'll have one of our team members from ONC opening with that and then we'll have a presentation of...overview of the PGHD Policy Framework Project, Emily Mitchell from Accenture.

Margeaux, I think you're going to lead us through the kind of the task force role, what you need us to do and we'll have some presentations from our members that will help to really drive it home and talk more about you know the importance and some examples of this. And then we'll have some discussion. We have some questions at the end that will drive our discussion. So next slide.

So I think at this point in time, people are aware of who's on this group...

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

Actually Patty, we invited two new folks to join.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Oh, well thank you for reminding me.

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

It didn't sound like Jenna was on, but Andrea is and maybe we can give her a quick minute to introduce herself. We asked Jenna and Andrea to join as we talk about patient-generated health data. So maybe Andrea, could you just give a quick introduction for the group?

Andrea Hartzler, PhD – Assistant Investigator – Group Health Research Institute

Sure, yeah thanks so much. My name is Andrea Hartzler; I'm an Assistant Investigator at Group Health Research Institute in Seattle. My background is in health informatics and my work largely focuses on integrating innovative forms of data into clinical care and I'm really excited about patient-generated health data and have looked from a patient's perspective at their use of data and sharing data with clinicians for gosh probably the last 10 years or so from a research perspective. So I'm really excited to join this group and I'm excited to participate. Thanks.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Excellent, thank you Andrea; we need your brain. We're so...we are glad you're here. And I guess Jenna, we'll have Jenna introduce herself the next time that we get together, unless she's joined us just recently; Jenna, are you with us? No, okay, but we will have Jenna introduce herself next time. So

Andrea, we're a fun group. We are, you know we've looked at several things already that ONC has prepared and I think you'll enjoy being with this group.

Andrea Hartzler, PhD – Assistant Investigator – Group Health Research Institute

Great, thanks.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

So we can go to the...we'll go to the next slide.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Patty may...just for a moment, this is Donna.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Hey Donna.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Wanted to welcome Andrea and to all of our guests for this call, but also just take a moment to just give the background of the composition of this task force. As you can see from the diversity just amongst the Co-Chairs with Patty coming from a nursing informatics background in a clinical setting and me coming from a patient and patient advocacy setting, you'll see that diversity demonstrated throughout, very deliberately as we had pulled the task force together to have both direct patient, patient and consumer advocacy and clinical perspectives of variety of sizes and types, and so just wanted you to be aware of that diversity of expertise and perspectives among the task force members as we go through this process together, so, thank you.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Excellent. Thank you, Donna.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Absolutely.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

So just a quick blurb on our charge; you see this slide in each of our presentations, just reminding everyone that this group is pulled together on an as needed or ad hoc basis to provide insight to ONC on their various projects with a consumer focus. So we've been looking at...we first looked at the Blue Button Connectors, then we looked at the Patient Engagement Playbook. We provided some input on the Model Privacy Notice and now we're diving into patient-generated health data. You can go to the next slide.

So at this point I believe I'm going to turn this over to one of our colleagues at ONC to start to just give the background of PGHD and why we're even having this discussion, why it's so important. So I'll turn it over to you guys.

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

Hi everyone, this is Elise Sweeney Anthony, the Director of Policy at ONC. So we thought that we would start out today by talking a little bit about ONC's kind of perspective and interest in PGHD and why we continue to kind of work in this space from a policy perspective, but also from thinking about certification criteria in support of that, which you'll see as I discuss the 2015 edition. And that I think kind of builds into the next part of the workgroup's charge to look at the PGHD White Paper, which we'll talk about in a bit. So next slide, please.

So here you see kind of the delivery system reform, kind of HHS quick shot, quick look, and this talks about the incentives, it talks about care delivery and it talks about the information. And all of those things together come together to help improve the state of the delivery system, and that's in terms of, as you guys have heard probably many a times, better care, spending dollars more wisely and of course healthier people.

Also in information you see it says support consumer and clinician decision-making and among the other bullets on this slide, we think that PGHD is an important component in that equation. Care coordination is not just coordination between clinicians, but it's also thinking about how the patient can help inform and be part of the care continuum that affects them. So this is something that we've thought of...thought about many times and we have worked on in different ways, including through our Patient at the Center Initiative and most recently, in our 2015 edition.

So this is an ongoing piece of our work, I would say it's a thread that kind of weaves its way throughout many of the different offices of ONC, whether it's in terms of the care transformation work that happens in terms of the standards and development, and of course here in the policy shop. So what is PGHD? Next slide.

So how do we think about PGHD? So we think of it in terms of health-related data that's created, recorded or gathered by or from patients, and that's to help address a health concern. Now one of the key parts of that is patient-generated health data often causes people to think only of the patient as part of that, but we also think about the family members or other caregivers that are involved and speak on behalf or with the consent, approval or input of the patient.

So, it's not just the patient, but it's also others in their care realm that can help provide data that can provide more of a complete look at the patient generally. And the type of data that is included in PGHD is diverse and I think it depends upon the care setting and the care needs, but it includes things such as the health history, treatment history, biometric data, symptoms and even lifestyle choices. And all of those things together again help to pro...to create a whole picture of the patient and provide clinicians with additional information that can help to inform the care.

In the case of PGHD you think of a situation where the patient is the pri...is primarily responsible for capturing and recording that data. And then the patients also decide on how it is shared. And part of what we want to do here at ONC is to understand the landscape of PGHD, what's happening in the field and on the ground and if we go to the next slide, we'll talk a little bit about that.

So here at ONC we continue to be at a learning stage to understand, like I said how PGHD is being used currently. What are things that are being...that are successful? What are the things that have not worked maybe as well? How can health IT help to better inform or improve the use of PGHD across the landscape? And it's not only at ONC are we thinking about that, but also at CMS in terms of some of the

work that they're doing; we'll talk about that in a bit as well. But it's across HHS, we recognize obviously the importance of the patient in the care continuum.

So as we are at this learning stage, we think about what PGHD can do, but we also think about the potential opportunities and just to highlight those, increase patient engagement, cost savings such as by avoiding readmissions. And then improvements to the quality and like I said, care coordination which is my buzz word I guess as it was when it comes to PGHD because it's such a crucial part of care coordination is really thinking about information that can come in through different means; and then also patient safety. Next slide.

So is this the first time that we've said PGHD or we're thinking about PGHD, and the answer is no. It really weaves across the activities that we've done at ONC recently, including in the strategic plan, in the interoperability roadmap, in the 2015 edition. Also from our partners at CMS, in terms of Stage 3 and the Meaningful Use criteria, and then also these slides were developed before Friday and for those who are...who have spent a fair amount of the weekend reading, MACRA was act...the MACRA Rule was actually released on Friday, and there's also PGHD components in there. So I would add that to this slide as well. And then the Precision Medicine Initiative is another example of how PGHD plays an important part. Next slide.

So just to talk a little about one of the tangible ways that you see PGHD come to bear in the work of ONC is in our 2015 edition, and just a quick background. The 2015 edition is the latest iteration of the kind of list of certification criteria that ONC has established that that certification criteria can be used by a number of different settings and vendors can come to us and be certified to those certification criteria. We then list them on CHPL and at that point purchasers of technology whether providers, clinicians, others, can purchase certified technology and that provides a reliable way for them to understand what the technology does.

CMS requires the use of certified EHR technology for a number of its programs including the EHR Incentive Programs and most recently in MACRA as well. So the 2015 edition in many ways provides the foundation for a number of different payment programs, but it also provides a foundation for interoperability in our minds, right? So the more that you have a standardized and formatted way of receiving, capturing information and also sending it out, the better situation you are in in terms of getting to an interoperable state where information can be used across providers to benefit the care of a single patient, for example.

So in this latest iteration, the 2015 edition, we included a new criterion called patient health information capture, E3 as we affectionately call it. And E3 enables...calls for a user to be able to identify, record, access information directly and electronically shared by a patient or authorized representative. Again you see that authorized representative there in terms of the extended patient as it were, so the caregivers and so forth who are working with or speaking on behalf of the patient.

And then the second thing that the criterion calls for is the ability to reference and link to patient health information documents. And this would...how this might work, for example, and we...I note that this is a very broad criterion and it's broad for a reason, because we recognize that PGHD can come into a system, can come into the care equation in many different ways.

So what we did in the...in E3 is we thought about including a functionality requirement that allowed for diverse types of PGHD to be included in systems and that allows for vendors as well as clinicians to think about what type of PGHD is critical for the patients I serve and what type of information do patients want to share with me as well. So we want to encourage those types of conversations to happen

outside, but at the same time, provide kind of an arena in which to think of them, and that's how E3 basically operates.

So referencing and linking to patient health information documents, what could that be? So that could be things such as advanced directive forms, for example. It could even be a birth plan I suppose, it's a very broad criterion and depending upon the specialty and the type of patients you serve, all of that can be considered as this criterion, the technology for this criterion is included in different systems.

One other thing I would note here is that the purpose of the criterion again is to make sure that the information can be accepted into the system, right? So we want an environment in which the clinician for example, who has purchased a system that has been certified to E3 is able to say that this type of information can come into the system in a usable way. Next slide.

So that's...so E3 is just one example of how we're thinking about PGHD. But we also recognize that there's a lot of learning to be done in terms of PGHD, and there's a lot of exciting things that are happening on the ground. So in that vein, we've been working through a PCOR project on a policy framework activity, and the goal of this is for us to think about a policy framework through which to think about PGHD.

But before we get to that point, we've been working with Accenture to put together a white paper, so they're putting together a white paper that will provide additional learning information that we can use as we think about PGHD going forward. So the project is a two-year project and the goal, as I stated is to develop a white paper. It also includes pilots, and I think Accenture will talk a little bit more about that. But what I wanted to note here is that the white paper, which is part of...which is the activity that the workgroup will be looking at and helping to inform will then come to ONC and that will also help us think about the policy framework that will eventually be worked on at ONC.

So all of this is part of our learning activity and the work that you would be doing as the workgroup is crucial because you in many ways are on the ground, as Donna talked about, in many different formats and many different settings whether it's hospital or patient perspective. All of those perspectives, as always with the work of the FACAs, of the Federal Advisory Committees, really helps us to think through these issues.

So more than anything else, I do want to say thank you for taking on this task, for taking a look at the white paper, for helping to inform it and providing us with additional information that can help us think through this important area of kind of the care continuum and with that I think I'll turn it over to Accenture.

Emily Mitchell – Program, Project and Service Senior Manager - Accenture Federal Services

Great, thank you Elise; this is Emily Mitchell from Accenture Federal Services and I'm the Program Manager for the Patient-Generated Health Data Project. I think we need to jump forward a slide or two. Yeah, great. Thank you.

So as Elise introduced, our team has been investigating best practices, opportunities and gaps in the use of PGHD in care delivery and research. We've conducted industry outreach to individuals and organizations familiar with PGHD, and that's actually included several of the members of this Task Force.

And we've conducted environmental scans and literature reviews to develop our understanding of PGHD, building up to our white paper.

Our research was structured around 7 key topics requested by ONC, which you see on the slide. The first is collection and validation of data and tools, which focuses on the existing and emerging tools for capturing PGHD. It also considers the types of PGHD that clinicians and researchers collect and how they validate the data and tools.

The second is the ability to combine PGHD with medical record data, and that examines the opportunities for combining PGHD with clinical data for analysis and for patient care. It also included methods for combining data from multiple sources, as well as the standards and technology needed to support it.

Third we have data interoperability, which examines the benefits of and the barriers to increased interoperability between the health IT system and the devices that are used to capture PGHD. And that included a review of some of the cultural and workflow barriers as well related to interoperability.

The fourth topic assesses the technical and cultural challenges related to using PGHD in big data analysis. As we shift from daily or occasional measurements towards using devices that take measurements every few seconds, we need to consider how to store that volume of data. And there's also a need to access a broader variety of data types quickly and efficiently in real-time in order to support clinical decisions.

Fifth we have data donation, which explores patient expectations for sharing data with clinicians and researchers. We also examined existing and emerging methods of data donation for research and how to encourage and sustain data donation over time.

The regulatory overview discussed the current federal statutory and regulatory paradigms relevant to PGHD, including the tools and technologies used to capture PGHD. And finally we have patient recruitment for research studies and trials, which focuses on the ways PGHD could be used to identify patients for research studies and trials and to connect the patients directly with the researchers. Next slide, please.

So in looking at those seven topics, some of the initial observations and trends we learned from our research indicates that the use of PGHD can have a positive impact on patient satisfaction. This of course is dependent on a number of variables such as how comfortable the patients are with the technology they're using and what sort of feedback loops they have with their clinicians. But when those features are in place, there were, you know we've heard a lot of stories of very positive satisfaction there.

And from the organizations we spoke to, those that are seeing benefits from their implementations of PGHD tend to be focused on a specific disease or population segment for now. They've also used some form of data analytics and simplified user interfaces such as dashboards or data visualization that can draw attention to key data points, such as biometric values that exceed certain thresholds.

And we've also heard that it's important for clinicians and researchers to implement a well-defined workflow, such as determining who will review the data and what steps they'll take with the data. In some cases they're assigning specific members of the care team to triage the data and taking steps to minimize the burden on physicians.

Our research also indicates there are many opportunities where use of PGHD is beneficial. For example, PGHD can help patients engage in healthier behaviors, increase treatment adherence and improve and improve...potentially improve their health outcomes. PGHD also provides clinicians with a broader range

of data, helping clinicians make timelier and better informed decisions. And the use of PGHD can also help improve collaborations between clinicians and patients to develop a personalized care plan and to engage in joint decision making to foster better outcomes.

And there are significant opportunities for researchers. PGHD can provide vast amounts of data and give researchers a more complete view of patients' health. Compared to traditional research approaches, the use of PGHD provides opportunities for researchers to access more data spanning broader timeframes and for more...from more patients from a broader geography. Next slide, please.

So based on our research to date, we're synthesizing our key findings into the draft PGHD White Paper and the white paper discusses emerging trends that enable PGHD and provides a vision for the future of the capture, use and sharing of PGHD. And the white paper is being structured around stakeholders. To align with scope of our project, our white paper is primarily focused on patients, clinicians and researchers as the key stakeholders. For each of the three we're discussing opportunities, challenges and enabling actions that each stakeholder can take to support or benefit from PGHD.

And while the paper focuses primarily on those three stakeholders, we also discuss other stakeholders that will play significant roles in supporting PGHD. Those include technology stakeholders, government, and payers, health plans and employers. And we see all of these players as being critical components that must collaborate with each other to realize the future vision of PGHD.

So the white paper is in its final stages of editing and review now, and I want to emphasize that it's the draft version and the intent of our project is to update it next year based not only on the feedback we get from this task force, but also based on findings from our two pilot demonstrations.

So earlier this summer Accenture conducted an RFP to identify two pilots that would test the application of PGHD in real world clinical care and research. And the intention is that those pilots will help us further understand the benefits of PGHD use and test solutions to some of those challenges. So based on their findings, we'll be updating the white paper next year. So if you could jump to the next slide, please.

As the two pilots, we selected Validic working with Sutter Health and TapCloud working with AMITA Health as the two pilot demonstrations. Both pilots kicked off over a month ago and will run until next spring. Key findings from these demonstrations will be incorporated into the white paper, as I mentioned earlier.

For the Validic and Sutter Health demonstration, Validic will test personalized care using remotely collected PGHD from devices. Their pilot will focus on diabetes care, but builds on knowledge that they gained from their previous pilots with patients with other chronic conditions. The pilot will be researching the infrastructure and workflows needed to implement and scale PGHD initiatives and will include ethnography to identify ways to improve patient and provider engagement.

For the TapCloud and AMITA Health demonstration, they are gathering PGHD and associated clinical results across several medical areas. Through the use of the TapCloud App and the associated platforms, this pilot will connect patients and clinicians outside the clinical setting with the goal of identifying how patients feel rather than focusing on biometric data.

And I think these two pilots really complement each other and I'm very excited to hear the outcomes from their studies and definitely look forward to sharing further updates with this group later on. And I think that is it for my slides. Actually if you jump to the next slide, that just has my contact information in case there's any questions.

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

Thanks Emily. Margeaux, if you want...

M

Thank you.

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

Can we go to the next slide? Margeaux, did you want to walk through the task force's role?

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Probably on mute?

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Margeaux, are you on mute?

Jenna Marquard, PhD – Associate Professor – University of Massachusetts Amherst

And I'll just jump in quick, this is Jenna Marquard; my speaker wasn't quite working at the start, so I've been on the call and listening intently. Just wanted to let you know I'm here.

(Two speakers talking over one another).

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

Actually while we try to find Margeaux, Jenna do you want to...introduce yourself?

Jenna Marquard, PhD – Associate Professor – University of Massachusetts Amherst

Yeah, no problem. So Jenna Marquard; I am faculty at the University of Massachusetts in Industrial Engineering, so actually think about more on the patient and clinician decision-making and sort of behavioral side, how these patient-generated data can be included in effective care processes in a way that supports decision-making and effective clinical care.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Excellent. Well Jenna, this is Patty Sengstack, one of the Co-Chairs, just wanted to officially welcome you to the group, we're glad you're here.

Jenna Marquard, PhD – Associate Professor – University of Massachusetts Amherst

Thanks so much, glad to be here.

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

And thank you for that because I think we found Margeaux now, I think she may have hung up instead of unmuting, which we've all done at some point or another.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Yeah.

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

So welcome back Margeaux.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Thanks everyone, sorry about that. And actually right before I jump into this slide, I believe Elise Anthony has something else to add regarding PGHD and MACRA I believe. So why don't you go over and turn it over to her for a second.

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

Sorry, I was on mute myself. So I did want to encourage folks to take a look at MACRA. There are...there's a wonderful website that they put together, they as in CMS, and its qpp.cms.gov; that's Q-P-P-dot-cms-dot-gov and that website gives kind of a ton of communications related, easy to read and access information about the final rule.

The other thing I wanted to note is, many folks know that MACRA relates to eligible clinicians and there is also still the EHR Incentive Program as it relates to hospitals and Medicaid providers. So both of...all of those together includes some PGHD elements to them, so we can talk about those probably a little bit later when the workgroup actually starts to look at the white paper, but I did want to highlight the qpp.cms.gov website as well, in terms of some of the provisions that it includes.

And just a quick touch, the EHR Incentive Program, the 2015 editi...not edition, sorry; the 2015 Rule, you can obviously see that I do a lot of work on the 2015 edition, but the 2015 EHR Incentive Program's final rule includes a measure with a 5% threshold for PGHD as an option, for data coming in from a non-clinician setting. So, non-clinician setting would include PGHD type data.

In addition, MACRA, through the Quality Payment Program Final Rule component of that rule includes a measure related to PGHD and data from a non-clinical setting. And the structure for how MACRA sets up the advancing care information category is a little bit different from how the measures and objectives are set up for the traditional EHR Incentive Program structure that folks know, but we can...we'll talk about that a little bit later, but in the review of the white paper. But I did want to just highlight that those are two resources that I think would be helpful for folks to look at generally.

Kevin Fowler – Consultant – Kidney Health Initiative

And Margeaux...said...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Elise, this is Leslie. Oh, I'm sorry.

Kevin Fowler – Consultant – Kidney Health Initiative

This is Kevin, just to...yeah, just to follow on that point. So the website you said was, I'm on it right now, qpp.cms.gov and then was there another one, too? I just want to make sure I didn't miss that.

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

No, no, no; it's just that one and that is kind of...

Kevin Fowler – Consultant – Kidney Health Initiative

Okay.

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

...I guess a one-stop shop as it were for all things MACRA rule related.

Kevin Fowler – Consultant – Kidney Health Initiative

Thanks very much.

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

The other thing that folks...sure. The other thing that folks might be interested in knowing is that the MACRA Rule is a Final Rule with comments, and there's a comment period attached to it, so folks should also feel free to provide additional comment on this...on PGHD or any other area of interest to them during the public comment process.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Elise, this is Leslie, I just wanted to congratulate whoever worked on this, that website, it is really easy to understand. It's very well-designed and I'm sure it took a lot of work, but to make something so complex readable is much appreciated.

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

Actually I will definitely pass that on because a lot of work went into that. I will definitely pass that message; thank you.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Great, thank you so much Elise. And I also want to say thank you to Accenture as well for presenting today and providing such a great overview on the PGHD work that they're doing. I know it's a lot of information that just was presented right now, so we just wanted to provide a little infograph...a little graphic to show really where the Consumer Task Force fits into all the work that ONC is doing.

So again there's going to be this draft white paper that we are working with Accenture on that is really sort of a landscape, really identifies those best practices, gaps and opportunities for progress in the collection and use of PGHD. And then...so it's really that white paper that we're asking the Consumer Task Force to review, and you will be receiving it very soon and...just like your other assignments that we have given you, we'll be providing a lot of questions, homework questions for you to follow to guide your review of that white paper once we have it.

That white...the findings from that white paper and again incorporating all of your comments and thoughtful feedback will then play into...to inform the pilot demonstrations. So again we have those two pilot sites that were announced by Accenture on this...in their presentation. And so the best practices that are defined in that white paper are going to then be tested and refined through real world application through those pilots.

That will then...all of that will then lead to a finalized white paper from all of those findings and real world applications, that will then...all of that will then inform the ONC Policy Framework that will be coming later. So again, your role is going to be focusing in on the draft white paper, but this is really, we

feel that your feedback is going to be very invaluable given that not only do you have a...does the membership of this task force have such a wide breadth of experience in various different areas, but also all of you bring that consumer focus and emphasis on all the things that you review, which will be really greatly appreciated as we review this white paper.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

This is Mark, is this an okay time for a question?

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Certainly, yeah, if you have any questions on this, we can definitely open up for questions before we jump into discussion.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

The...there have been some previous white papers from ONC on PGHD, I wondered if you could just let us know briefly what's different about this one?

Michelle Murray, MS, MBA – Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

This is Michelle Murray at ONC. A lot of that work was done back in 2012, 2013 and it led an issue brief at the time, which was kind of an early version of a, I wouldn't say framework, but a direction from ONC and then since then a lot has happened. So the industry has changed and there are a couple of rules now that we're working with, there are a lot more policy levers in place and more to come. The industry has picked up speed and it keeps going faster and faster. So I just think there's a lot changing and ONC wanted to go deeper and broader with our guidance on this topic.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Okay, thank you.

Emily Mitchell – Program, Project and Service Senior Manager - Accenture Federal Services

And this is Emily Mitchell, if I could elaborate on Michelle's comments. I think an additional factor here is that we have the pilots that we'll be testing, I don't think that's happened in previous white papers whereas this one will be updated to demonstrate, or to reflect what was demonstrated in the real world.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

This is John Derr, is there any benefit for us getting copies or reference of where we can get copies of those past papers?

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

John, you were asking about where to find those previous white papers that were conducted; I'm going to turn it over to Michelle Murray. I believe they should be on healthit.gov, but we'll turn it over to her to...

Michelle Murray, MS, MBA – Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

They are. So there is a web page at healthit.gov; you can search for patient-generated health data or PGHD or go to healthit.gov/policy-researchers-implementers/patient-generated-health-data.

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

This is Michelle Consolazio, we'll grab that link and send it out to everybody.

Michelle Murray, MS, MBA – Office of Policy and Planning – Office of the National Coordinator for Health Information Technology

Yes, sorry about that.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Thank you.

W

Thank you.

M

Thank you.

Kevin Fowler – Consultant – Kidney Health Initiative

This is Kevin, just if I could, if right now's the appropriate time to comment, I'd just like to you know, make a comment. I mean just from a patient, someone who's gone through a transplant experience, there certainly was room for patient-generated data the...at that time and now, 12 years later, there's a huge need for that because that's a dimension of care that really is overlooked. So, I'll share that with you.

And just also for full disclosure, you know I have done some work with TapCloud in the past where I was working with them to help explore the need for their services in kidney disease across the spectrum of care. And I'll just tell you, my big experience was is that as much as you may look at this as improving the patient, trying to think about how we're going to make it better for the patient, the challenge is making sure that we're talking in a language that the providers receive the benefit. So, I just wanted to share that and disclose that as well.

W

Thank you, Kevin.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

Yeah, this is John Derr again, just to build on what Kevin just said. One of my experiences was after having two stents, I went to my cardiologist and she said to me she's going to give me an anti-hypertensive pharmaceutical. And I said, well I don't have high blood pressure. And she says, well it showed that you did in the office and I said, I take it every morning and every night and I don't have high blood pressure, but I just got it in here because I just had the stents and you probably excited me somewhat.

And she said, well I want to give you a beta...I said, you're going to give me a beta...I'm a pharmacist so, I said you're going to give me an ACE inhibitor or a beta blocker and all the side effects that go along with that for what reason? And she said, oh boy, it's nice to talk to somebody that knows what they're talking about and I said, I'll show you my graphs and that, and she says well if you would do that, then I won't really advise that you take a prescription drug.

So I influenced her in two ways, one for myself that she didn't give me a prescription I wasn't going to take anyway or then also got her because she really excited me when she said, it's nice to know somebody who knows what they're talking about, because I thought in my mind, how many people had you prescribed an anti-hypertensive to that probably didn't need it, but wasn't smart enough to say something. So I think we'll help train the physicians a little bit as well as the patients; that was my main point.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

John, I think that's a very important point and one question I have for the ONC team as well as the Accenture team is, as we review the white paper, and of course we'll know more once we see the form and format and content of that, but as you see there are rich experiences from the task force itself and whether...how can that best be incorporated? Some are specific, some are aggregate from work we've done either in past patient-generated health data committee work and compiling examples or in our own sort of professional or organizational capacities.

But beyond reviewing the white paper, is there...what would you like...what would be most useful and efficient for you to be able to capture insights like we've just heard and can certainly be expanded upon by several members of the committee or the task force? How can they be best fed into this process? This is Donna speaking.

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Thank you, Donna, this is Margeaux and I also have in the room with me some of the people that are working directly on the PGHD Project. You know, and I think that's why we are turning to you guys just because we know that you have such a wealth of experience in PGHD, on the ground you know in various, whether it be personal, such as John's story or from like a patient perspective, also from your own work as well in the healthcare settings. So, I think we're really wanting to pool that information in a way that will help you to use that...use those experiences to inform your comments to the white paper.

So again, we're going to be providing very clear, sort of questions as we have before and you know would welcome you to use those experiences to kind of help to look at the information that's presented in the white paper, by saying does this match my actual...does this match the experiences that I've experienced? Does this...are there other things that you've experienced that might not be...that you feel have been important that might be highlighted in there? All of that will definitely be taken into account and to your point, I think that's why we're turning to all of you, just because of your real on the ground experiences on all of this day-to-day.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Excellent, thank you. And then one other point just a note perhaps to sort of tuck in the back of people's minds as we go through this, Emily, in your comments you made a differentiation between patient-generated health data and clinical data and as John's example just sort of gave light, a large subset, an increasing subset of patient-generated health data is clinical data. So perhaps as we think through the language that is being developed around this and is evolving around this, the distinction is instead

between patient-generated health data and health system-generated health data or some other construct, so as not to unfairly disparage or minimize patient-generated health data and a...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

I would like...this is Leslie...

Brian Ahier – Director of Standards and Government Affairs – Medcity

Yeah, this is Brian; I'd like to make a comment on that. So I think that's a really excellent point. You know the other thing to keep in mind in making that point and that valuable distinction is that, and this is oftentimes what I hear from clinicians when they talk about sort of their fear of being inundated with what they might consider useless patient-generated health data is that it's not clinically valid. And there's some good reasoning behind that in that the calibration of the instruments, for instance, you know in their office, whether it's taking blood pressure, weight, simple things like that or more advanced instrumentation, you know it has to be calibrated to a degree that they can feel secure and trust the information that's being produced.

And you don't have any such controls, you know whether it's in the patient's home or a wearable that they have, and you know we've seen reports on wearables and other devices that would produce these data where their accuracy may not be up to snuff, so to speak. So I think you know while we do definitely want to validate that patient-generated health data is certainly not all non-clinical, at the same time that's an area I think that really needs some investigation.

Emily Mitchell – Program, Project and Service Senior Manager - Accenture Federal Services

And this is Emily, thank you...

George Mathew, MD, MBA, FACP, CMQ – Chief Medical Officer, Clinical Analytics – Hewlett Packard Enterprise

Hi, this is George, just to add on to that very great comment. You know I am a provider, I do see patients on a regular basis and I can definitely say everything in terms of the calibration, the sensitivity of the device and I think the sensitivity is heightened now because with MACRA, as physicians are being judged on some of that data, and it does affect their reimbursement, they are more likely to defer to safety, which is why we need to be extremely clear as to what each definition means.

And by safety I don't mean safe the product or harm the patient, it's I know, I've calibrated the produ...the items in my office, I know that I can depend on them. If I'm getting a let's say a pejorative or negative response out of the device, is the device wrong for my patient or is my calibration wrong? There's going to be a little bit of fear unless it's clearly defined as to how this data is being used and could it judge them?

Kevin Fowler – Consultant – Kidney Health Initiative

And can I, you know the point...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie, I think that also...

Kevin Fowler – Consultant – Kidney Health Initiative

This is Kevin, I was just...I was just making the point that the two points that were made were very consistent with my experience and I would just add to the two is that there's also the concern many providers have is a legal one as well, too, that they think that sometimes...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Right.

Kevin Fowler – Consultant – Kidney Health Initiative

...that increased data puts them in increased legal risk and so I just, you know share, this is about you know 8-12 months experience in this...look at this market, is that I think that when you approach this you have to think about how this is going to help the outcomes that that physician has at this point in time, or maybe they need help and that's to provide greater incentive because all the things...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is...

Kevin Fowler – Consultant – Kidney Health Initiative

...all those things that are being brought up is what I've experienced as well, too.

Emily Mitchell – Program, Project and Service Senior Manager - Accenture Federal Services

Thank you so much...sorry...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie, I'd like to go back to just Donna's point real quick and that is, if we think about what goes into a record where we have an observation or a finding or a result, we...or a history, all of those things can be patient-generated so I do believe it's very important for us to think about the author might change, but I might have a finding that I'm presenting, an observation of myself, my daily living, my pain scale. I might have also results that are coming directly from devices that I might use with all the caveats we just heard from, so having a common language I think cannot be overemphasized.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Thank you so much Leslie and thank you also the previous speaker for raising those concerns. I think that those provider concerns about I heard legal risk, I heard calibration and validity and they were all captured, thankfully we have a transcript of this. I think raising those concerns is an appropriate role for this committee and will hopefully help the report be that much richer.

You know, I would just give as an example perhaps a response to some of that in line with John's comments, you know the way I take under the same circumstances, at 8 o'clock you know every morning, same time, same day daily is I feel a much more valid result than, you know my fancy scale, you know the...and graph and send into the Cloud, it...and be able to analyze three years of trend data, it's frankly higher quality data than the random standing on the old metal scale sometime after lunch or the last time I had an appointment, you know in the morning, I think we need to raise the issue of the quality of data and the provenance of data as we look through this.

But I think that the assumption that perhaps could have made in the past that patient-generated health data was of lower quality than that generated in a physician's office or a health system is now antiquated, or at least bears challenging. So, I would just sort of put that forward as we look forward to...I think this is a great opportunity of having the white paper and the pilot demonstrations.

John F. Derr, RPh – President & Chief Executive Officer – JD & Associates Enterprises, Inc.; Founder – LTPAC Health IT Collaborative

This is John Derr again, I'm a big advocate, as Leslie knows, on person-centric electronic longitudinal care and trending. One of the things I've found in this area that we're talking about is that we do things

on a static, episodic basis, one-time type shot and the key in all of this, to get rid of some of those anomalies and outliers is we've got to set the process up where there's trending information.

Trending and aggregation are the key so we can see what somebody's real normal is and that is I also take my blood sugar numerous times during the day because I don't like to take meds and I'm a Type 2 diabetic and the reason, everything is influenced by my diet and if you don't take the diet, you get all these outliers and...so, I want to emphasize so much of our life is built on episodic, one-time things and then say, okay, this is something, if it's a one-time measurement and that is not going to do it because it's got to be trending so we can get normalized data and get trending lines because one time might be abnormal or normal and the rest of the time not.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Yeah, thanks John. Hey, this is Patty...

M

This is...

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

...and I'm just thinking that you know we've had previous conversations that have talked about the, you know the tsunami of data that's out there and can potentially come to any provider and so what do you look at? So I'm anxious to read the white paper and see if it addresses you know, the how and the when that providers could and should interact with their patients to, you know begin the process of you know collecting patient-generated health data, that there's some kind of a conversation between care providers, whether it's a physician or a nurse practitioner; you know I had to say that being a nurse.

Whether there's a discussion about the purpose; so when I have a conversation with a patient, that patient and myself will say, hey, let's start collecting your data. I'm going to be looking for it so if you could send it to me, otherwise you know I'm...the reason I say this is because I think of my dad who back when he was alive and was watching his blood pressure, would just arbitrarily put in Excel spreadsheets or Microsoft Word tables a whole list of his blood pressure results, because he would take it at home and he'd just send them in, just you know and I don't think the docs were expecting it or you know, so I'm just, I'm just curious as to how the white paper will address sort of that collaboration and communication between the care providers and the patients for this whole thing.

M

That's a great point.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Excellent point, Patty.

M

Yeah, definitely.

Kevin Fowler – Consultant – Kidney Health Initiative

Could I add one point, just through and through experience; this about, you know again I'd say probably close to a year is that especially when it comes to kidney disease so much what the doctors are looking at is they're looking at clinical you know endpoints and clinical measurements and frankly they're not as in tune to, you know some of the softer things; the, you know the parts reflect mood and so forth and so

I think if you're looking at you know, these physicians and get them to begin to understand the link that if someone reports to you they're not feeling, you know they're not feeling good or they're not feeling well or feeling depressed, you know that behavioral component is going to have an impact on those clinical outcomes because I just think it's, you know especially in that area in transplant, dialysis, they've been conditioned to look at certain areas of measurement.

But if they begin to see in the current system that that understanding can improve their current outcomes, I think you'll get a positive response. And that's...it's...because you're talking about making a change right now that as patients I think we all understand, but for the provider, you've got to start speaking also in their language and say how this is going to help them, in terms of outcomes.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

I think...

George Mathew, MD, MBA, FACP, CMQ – Chief Medical Officer, Clinical Analytics – Hewlett Packard Enterprise

Hey this is George. I actually wanted to respond to that if that's okay. Just so you know, there are actually several startups that are trying to put behavioral monitoring components along with you know physical vitals or other checking out there. There is an...for doctors to understand how patients understanding wellbeing and even emotional states can affect care, so they're looking into it. I haven't seen a lot of papers come out yet, but I know they're definitely in the process. Thank you.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

So this is Donna, I just wanted to amplify those points. I'm certainly in agreement with them and I think that you know building on the point of dialogue and collaborative sharing I think that part of this evolution is the identification, by patients within specific and, let me start back; by patients about additional factors that may be relevant to care. And we acknowledge that that will need to be tailored and curated a bit to be specific to a condition.

Kevin Fowler – Consultant – Kidney Health Initiative

And Donna, you know and I'd like to illustrate for the audience so they understand what that, you know, I'm sorry, go ahead, just...because I just feel so strongly. Go ahead, I'm sorry.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

No, no, no, no, I think that's a gre...I was just going to continue and I think that perhaps this may be where you're going. I have a transplant as well, so...as well as four other active conditions and so a lot of the array of specialists and array of blood work and array of data that flows through, there's really just a small subset of critical success factors. Some of them are, you know specific blood measures but some of them are fatigue, or other things that were not initially on my doctor's radar screens and so we've created a different sort of tracking sheet and list of critical measurement that's relevant to me.

And now working with a mobile App and a coach, and I recognize that in the 33 years since my initial diagnosis, as a patient that two weeks ago when the App pulled everything together, with the coach was the first day that I actually had a plan, a total plan for my life that included medications, but also nutrition, sleep, how my energy and mood were during the day, how productive I was as well as being able to put in, you know key lab values and things that are normally tracked. So, I just think that expanding the definition with patient input, in terms of the type of data that are deemed clinically meaningful, would, I would think be a very important outcome of the paper and the pilots. And Kevin, if you wanted to add to that, please do.

Kevin Fowler – Consultant – Kidney Health Initiative

Yeah, no and I think Donna you and I are speaking a common language right, from a common experience and I think just trying to illustrate the point is that you know like my first year when I would see my doctor after the transplant I was doing well with all the clinical measurements looking at kidney function and so forth, but there was a psychological part that I was having a hard time with the medications. And so when I went to those doctors to ask them questions about it, I didn't get any help at all and that was a real struggle during the process. And so you know that struggle then it could have immediate impact on outcomes, but it has a larger impact on outcomes.

So, it's the...when you're looking at any type of healthcare area, so much of what those reimbursement incentives are going to drive, you know the things that are measured. But I think as we go through this period of transformation, I go back to making the connection between the two groups and to get people to begin to understand why it's important, so.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

This is Leslie and just to add to that, there's all kinds of way to incent things and the...there was a study done by Johns Hopkins using the Military Acuity Model and they took all tangible and non-tangible paths, they moved them to appropriate caregivers and patients and determined that a pre-visit preparation for the patient was one of the most important and meaningful things they could do to improve care. It's not only care, but efficiencies in the organization.

So incentives can be both what I'm paid and what I create in terms of an efficient environment and in this particular case they were looking at pancreatic cancer patients and although they didn't specify PGHD, they specified pre-visit importance and the physicians reported that they went home on time more often, that they were happier in their jobs as well as the patients reporting a much higher degree of satisfaction in very complex cases. So I think incentives are both what we make and what we improve, both operationally as well as...care and I don't think we should lose sight of that.

Kevin Fowler – Consultant – Kidney Health Initiative

Yeah, I agree Leslie, but I think we also have to look at reality from of how powerful those incentives can be. And so I just always like to offer a countervailing perspective, and this is just based on what I've seen firsthand, so, and that's, you know 12 years' experience looking at this area, so, for what it's worth.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

I think that you know what I've seen though is in terms of incentives and maybe again expanding that term, recognizing physician's time pressures. Because my information is so organized ahead of time and...

Kevin Fowler – Consultant – Kidney Health Initiative

Right.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

...so I know the questions that they're going to ask, so for an experienced patient, it's like you know, it's not a pop quiz like it is for most patients, it's a take-home test. But because the information is...I know what they're going to ask ahead of time and I'm prepared for it and the data is organized in a way that they can receive it very easily, the visits are much more efficient.

And so I think that's an incentive, I think we've heard discussions of, you know people being able to go...and this...you know...better if you're at a systems administration level, patient throughput is better, but conversations are also richer. But I think that in terms of incentives of having...I'm constantly

amazed that really already so much of clinical care whether it's in gastroenterology or a host of different things really is reliant already on patient-generated health data, it's just verbally given and unorganized. And the fact that practitioners haven't given patients for the most part in most settings, tools to organize that data ahead of time is a constant source of consternation for me.

So for those of us who have the you know wherewithal to organize it ahead of time, increasingly enabled by technology, I think that the incentive to both patients and provider is a richer, more seamless, more constructive visit. So that's...

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

So Donna, this is Leslie and I wanted to add some, I don't know if we're going on to the next section or we're just going to continue to discuss, but I did have...

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

Yeah Leslie, I was just about to do that.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay.

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

Is that okay? You're going to...well you'll get a chance to talk anyway, so. So yeah, I can tell this is going to be an exciting, engaged topic for everyone so we appreciate all the engagement. We did ask two of our task force members to share some of their experience with us and they both were actually also interviewed by Accenture. So we've asked Carolyn and Leslie to provide some of their experience. So Leslie, since you interjected, I'll let you go first and let you share some of your experience.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise

Okay, thanks. Well first of all, I really want to thank Accenture and ONC for asking me to participate in the interview; I think it's really showing the commitment that ONC and HHS at large has for patient engagement and having patients participate in their care with patient-generated health data and seeing it reflected in so much of the Strategic Plan, the ISA, the MACRA; we see continuity of momentum that's quite impressive, and I also believe this is exactly government's role.

We...some have struggled with how infrastructure changes like Meaningful Use has had some dramatic impacts, but then difficult for many. But as a government, we look to how do we empower our citizens and our population, and I think this is a great example of how government can help to promote new activities to help its citizenry; so thank you for that.

I have a couple of examples, one is from Healthwise and another is just something I read last week. Kaiser presented that by using technology and online communication, they have now reached the point of their 110 million interactions last year, 52% of those were done through a smartphone or video conferencing kiosks and other technology. This is dramatic and goes to cost-savings and efficiency and opportunity for communication that is unheard of and I'd love that to be highlighted in the paper, an interview with Kaiser.

One example in Healthwise that we've been working with is based upon some work with the Informed Medical Decisions Foundation, which is also part of our organization and we have been using decision aides for about 20 years, but most recently done this in a way that includes patient-specific education

materials and also Round-trip, which is patient-generated health data back into the record. And these are the kinds of things that are asked of the patient.

So the patient would be, for instance maybe they have lower back pain and they're trying to decide whether to have surgery for a herniated disc and they're taken through education about what are the options, how effective each of these options are and then ask the patient certain questions that determine things like the decision they're making which says things like, I'm ready to take action and which way are you leaning with regarding surgery and no surgery and the answer is a graphic that says I am leaning toward surgery or not toward surgery.

It asks the patient what's your level of confidence about this decision, anything from not sure at all to somewhat sure to very sure. Then it reiterates how much the patient understood of the education; so for instance, I have...if I have pain because of herniated disc, I probably need surgery your answer was false. You're right, most people don't need surgery. Or a question like surgery might help me because I have really bad pain and sciatica; the answer is true, yes, that's correct. Another comment or question, years from now I'll probably feel just as good without surgery as if I would have surgery; the patient answers true.

So the knowledge of the facts demonstrated by the patient are reported back to the provider and then the patient is asked other questions about getting ready to act. Do you understand the options available to you? Are you clear about which benefits and side effects matter most to you? Do you have enough support and advice from others to make a choice? And then the provider is given back a...along with the specific answers to these questions, they're given back three grid areas which are I'm leaning towards surgery, I don't like surgery at all or I do, I think that exercise has been improving me so I'm not eager to have surgery and so forth.

So we're really trying to take that step where the patient is presented with the education materials for exactly as it's indicated in Meaningful Use, so it's patient-specific education materials provided to a patient with shared decision-making tools, as mentioned in MACRA and then answers back in a format that's integrated back into the EHR using standards and indicating all of the patient's response to those questions. So this is a project we're working on, I can't say the name of the actual providers involved, but we've been working with EPIC on this Round-trip to get patient-generated health data back into the record and that's going quite well.

So when we started to look at patient-generated data, we looked at some of the testimony that we received early on at ONC. And we had a day-long listening session and I was struck in particular by one physician who provided testimony, and she was from Geisinger, and we asked her, "So how did you feel about accepting patient-generated health data?" And she said, "I hated it, I didn't want to do it, I thought it was a waste of time." She said, "But I'm now a better doctor."

And when asked why, she explained specifically just one item alone, medication reconciliation was so much better. She felt that she was providing much more safe environment because she knew what the patient was actually taking, not just what she ordered; and that also included things like over-the-counter drugs and the provider had much richer information. She also said, and I'd have to go look at the testimony, but I think it was as high as 30% of the medication information they had in the chart was incorrect. So they felt this was absolutely an important step to just providing the basic information they count on every day in care and that patient-generated health data had dramatically changed her opinion of the accuracy of the record and her opinion of positively engaging patients in care.

So those were just some examples that I can cite although I do believe that just secure messaging alone has dramatically changed how we think about patients and their data. And I mentioned earlier I was on a path in Idaho, on a trail and I came across an internal medicine physician who I knew and asked him about patient-generated health data. And he said he was so eager, they were about to start a pilot that he felt that his work and his life would be better; he would be more prepared and he'd have a better and more complete picture of the patient. This is a provider who's an internal medicine doctor who he has patients that are not as young as many and he still felt very eager to participate and he did say, my quality of care and quality of life would be improved.

So those are some of my examples and thanks for giving me an opportunity.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Thank you. So Michelle, how are we doing on time on your agenda and where would you like us to proceed next? We usually have a public comment period as well and I want to make sure that we have time for that.

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

Yup, we still have a little more time. We've actually asked Carolyn to share her expertise as well...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Carolyn, we'd love to hear from you.

Carolyn Kerrigan, MSc, MD – Professor of Surgery – Dartmouth-Hitchcock Medical Center

Great. Thanks. So for those who don't know me, I'm a practicing surgeon at Dartmouth and our...we sort of have two streams of experience. Our longest experience is with patient-reported outcomes as a sort of sub-category of patient-generated health data and we now have that very broadly thread throughout the organization for many different health conditions. And as I think it was Elise Anthony who described in her introduction, you know we use it to obtain health history from the patient's perspective in advance of the meeting; information about health habits. We certainly use it for just quality of decision-making and patient preferences.

And the, you know at first, starting in the late '90s, early 2000 our biggest struggle was just trying to come over the technology and get the technology to be able to do what we wanted to do. And, you know we've been through a couple of different IT platforms and they're certainly working a lot better than they did 15 years ago, but they still have a long way to go, particularly with the user interface. You know, what is designed, built into the current electronic medical records looks very like clinical data, and when you're actually wanting to share this information with patients, you probably need a different suite of graphic capabilities, which haven't been fully developed yet.

But you know once we began to overcome some of the barriers, the technology barriers, we recognized that there were huge issues around like just basic clinic operations. And I think Jennifer who recently joined us, was you know alluding to that; where do you put this information not only into the care teams' workflow, but into a patients' workflow? And even if you can redesign workflows to make it possible and more efficient, then you're dealing with the culture. So like do I want to do this? Why do I want to do this? Make a lot of the care teams' initial reaction; is this going to be more work for me? And so you have to convince them that in fact it could be a lot less work for you and it could be more accurate gathering of information and less rework, less scrambling to try to find the information.

And so wrestling sort of with the workflows and with the sort of the cultural stuff on both sides, the care team and the patient. I mean it's amazing how obviously the people who are on this call representing the patient's perspective, I guess all of us are, but who have lived with disease and chronic disease are highly activated. I think if the whole population was that ready to jump on and measure themselves and you know, join in this journey, it would be terrific but I don't think our culture is quite there yet. And it might be, but you certainly don't have a core healthcare system that's encouraging that type of behavior.

I think the other, some of the you know the realizations that have struck us around creating this you know, like what's in it for me dialogue recognizing that every member of the care team from the person who takes the phone call to schedule an appointment to the health coach, to the registration person; everybody sort of needs to be as fluid with understanding the value of patient-generated health data. The way they understand that if a blood test is needed, I mean it just kind of happens or an image is needed, it just happens and it should be just as easy to collect patient-generated health data.

I guess one of our greatest success story is certainly the Dartmouth Spine Center, but an area of care really is mental health. I think mental health providers have been struggling with years with kind of shooting in the dark; they've had no way to measure the outcomes of the care that they provide, not quantifiable ways. They don't have a blood pressure, they don't have a hemoglobin A1c and so to be able to introduce patient-generated health data from the patient, patient reported outcomes as a measurable component of the success of mental health interventions is hugely valuable.

And so we've at many other places have been successful in building out collection of patient reported outcomes around mental health and to the point of looking at sort of bigger data sets, like a population of patients who are being managed for mental health and tracking over time and being able to tell, well so and so was here three months ago and their scores were really bad and yikes, we haven't seen them, we have no follow-up information on them.

We can now manage that process better and reach out to them and get them either back into clinic or do it through telehealth, do some repeat measures if they are doing well. But I think mental health is one of the easiest areas to, you know begin adopting robust use of patient-generated health data, certainly from the questionnaire patient reported outcomes perspective.

I think certainly our...those who are speaking from a personal patient perspective today have really captured the essence of why it's important and helpful for patients. You know, clearly patients are sitting on a ton of incredibly valuable information about their day-to-day life that no physician can capture into one encounter of 10 minutes or half an hour or even an hour. And so activating patients to be truly, you know participate in tracking their symptoms is going to make a huge difference, I think particularly for chronic disease management.

I think I'll just stop there and open it for discussion or however...what you want to go from there. It's, you know, it's definitely something that we want to continue to encourage and will continue to do at Dartmouth and it's wonderful to see more and more discussion of it on a national stage. So thank you again for inviting me to share a little bit about Dartmouth's work. I should...let me...sorry, before I give up the...

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Okay...give up the mic.

Carolyn Kerrigan, MSc, MD – Professor of Surgery – Dartmouth-Hitchcock Medical Center

We did have...we do have another initiative called ImagineCare at Dartmouth which...and the primary focus there has been around patient collection of biometric data.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Um-hmm.

Carolyn Kerrigan, MSc, MD – Professor of Surgery – Dartmouth-Hitchcock Medical Center

It was rolled out initially to our employees and the biggest, I think one of the biggest learning there is that there...the technology has to be overcome, but to just provide the technology you're not going to get what you're expecting. There has to be this big sort of service component making sure that patients know how to use the technology, that there's a backup support team of coaches for abnormal results, you know it's...there's a huge infrastructure that goes well beyond just the technology solution.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

And I think we've seen that on the physician provider side as well. I can tell the difference between health systems that have invested in supporting their physicians in how to use their EHRs for six weeks and the hospital down the road that I know supported their physician staff and clinical staff in use of the EHR for six months, so...

Carolyn Kerrigan, MSc, MD – Professor of Surgery – Dartmouth-Hitchcock Medical Center

Yeah.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

...your point is well taken and I appreciate making that point about patients being supported to use the new tools as well as encourage to bringing them into the conversation; I think that that's an important aspect. So thank you both to Leslie and to Carolyn for adding your additional wisdom and examples. Lana and others, I think spoke up on Kaiser Permanente and other examples so this should be a very rich piece of work coming out of Accenture. I'm excited for you to be able to spend your time on this project.

So we have questions, formal questions I think that we have, not being shy, as Patty had promised and predicted in the future that we have pretty much addressed these. We've asked questions about the framework project; are there any specific quest...more questions about the timing or the timeline or what we'll get next? What we'll get next is the draft of the white paper to review; are there any other questions specifically around time or timeline or anything like that?

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

This is Mark with a question.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Sure.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

In looking the slides over before we had this meeting I...when I looked at the topics and importance, one of the things that occurred to me is PGHD is critical for shared care planning and those themes have been woven in on this conversation, the ability to contribute the patients and individuals own goals, concerns, data. In some ways this allow...in some ways this is the corollary to the patients access to data, PGHD provides the clinician with access to critical data that the clinician needs.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Um-hmm.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

And so I'm wondering if the white paper will, I see the research topics, I didn't see shared care planning lifted up specifically. It does seem to be at the intersection of several topics; I wondered if that's going to be addressed because I think it, as a topic, it weaves into what Elise was saying about delivery system reform. It's sort of the use case for some of these other functionality topics and it's a way of crystalizing things. So question is, will the white paper be talking about shared care planning?

Emily Mitchell – Program, Project and Service Senior Manager - Accenture Federal Services

This is Emily from the Accenture team. We don't specifically use the term shared care planning, but we do talk a lot about how PGHD can help increase the collaboration between providers and their patients and, you know so I agree with you that's a very important component of how it can be used and you know, kind of moving towards patient-centered care.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

So Mark...

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

So I'll just throw that there's a leadership opportunity here if you want to get at that.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Exactly, so I would absolutely endorse that and even in advance of getting the white paper, make that recommendation that shared care planning perhaps is the precursor to then care coordination that was mentioned. Does that language...we'll make that recommendation in advance; leave it at that.

Emily Mitchell – Program, Project and Service Senior Manager - Accenture Federal Services

Yeah, thank you and we also, I mean we do talk about shared decision-making as well, so you know that, I think that it's just a difference of terminology, I believe, but certainly look forward to your comments when you look at it and see if there are areas you think we should expand on, but we will certainly keep that in mind as we go through our final revision.

Mark Savage, JD – Director of Health IT Policy & Programs – National Partnership for Women & Families

Thank you.

Emily Mitchell – Program, Project and Service Senior Manager - Accenture Federal Services

Thank you.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Other comments or questions? Okay, we've certainly given some observations and experiences that we've had in patient-generated healthcare data. Okay, the last question, what areas of patient-generated health data use and sharing do members want to know more about and to discuss in more depth in the coming weeks? I think I would like to make that more...give that last question a little more duality and mutuality.

So because of the richness of experience of the members, so I'll ask both what do members want to know more about to discuss, but again ask my question, you know as to how we can contribu...how members of the task force can contribute all that we know to ONC and to Accenture to advance and enrich your process?

And it seems to me that the answer before was, in our comments to the...in addition to the comments that we've made today on this call and recommendations that we've had both from the patient and provider side, in terms of language and areas of consideration, that feedback to the first draft of the white paper will be how we contribute. But I will ask just the task force, are there things that we specifically want to...examples that we want to see included or things that we would want to know more or have emphasized based on the seven areas or the information that we've been presented with so far today?

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

Hey it's Patty. I think I've, you know in some ways we've kind of addressed this question but I think part of our challenge is that we haven't seen the white paper to know what's included, because maybe what we would add at this point is already there. So maybe our next step is to read it and then come back with our thoughts and ideas and input.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

Yeah.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

And I'm looking at the time for Michelle because I know you're probably sweating there saying, "Oh my God, we've got two minutes for public comment." Should we go there now?

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

Yeah, thank you Patty and then we can go back to the work plan and talk through the next few meetings while we wait and see if there's public comment. So operator, can you please open the lines?

Public Comment:

Lonnie Moore – Virtual Meetings Specialist – Altarum Institute

If you're listening via your computer speakers, you may dial 1-877-705-2976 and press *1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press *1 at this time.

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

Thanks, Lonnie. So Donna do you want to make another comment before we close up? I thought I heard your voice.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

No, all you. I think we've...

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

Oh, okay.

Donna R. Cryer, JD – Founder and President – Global Liver Institute

...just thanking everybody for such a rich discussion and we look forward to seeing the white paper.

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

And Margeaux any final comments before we wrap up?

Margeaux Akazawa, MPH – Presidential Management Fellow, Office of eConsumer Health, Office of Programs & Engagement – Office of the National Coordinator for Health Information Technology

Not from me, I think this was a really great discussion, so I'm looking forward to all the discussions that we'll have as we go forward with the PGHD Project. Thanks everyone.

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

Okay. Well, we have no public comment so thank you everyone, we really appreciate all of the feedback that we received today and we look forward to talking to you at our next meeting. I can't find the date because I was looking for it, if anybody has it and can should it out...next meeting, November 9th.

Patricia P. Sengstack, DNP, RN-BC, CPHIMS – Chief Nursing Informatics Officer – Bon Secours Health System

November 9th.

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

At 1 o'clock. Thank you and have a great rest of your day everyone.

Several speakers

Thank you. Bye.

Public Comments received during the meeting:

1. **Tom Agresta:** I would agree with the trending of data from patients entirely - I have been able to stop antihypertensives on patients who monitored their BP on a patient portal over time. I have also been able to convince patients they actually had HTN or to increase diabetes medications based on patients looking at their own data over time. Tom Agresta MD