

**HIT Policy Committee  
Quality Measures Vendor Tiger Team  
Transcript  
January 30, 2014**

**Presentation**

**Operator**

All lines are bridged with the public.

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

Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Quality Measures Vendor Tiger Team. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Ginny Meadows?

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Here.

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

Jim Walker?

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

Here.

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

Mike Aswell? Chris Bontempi? Annette Edmonds?

**Annette Edmonds – Senior Product Manager – QuadraMed Corporation**

Here.

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

Joseph Geretz? David Lansky? Kip LeCrone? Maggie Lohnes?

**Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

Here.

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

Stirling Martin?

**Stirling Martin – Senior Vice President & Division Manager – EPIC Systems Corporation**

Here.

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

Jon Morrow? Karen Nielsen?

**Karen Nielsen – R&D, Analytics and Business Intelligence – Siemens Medical Solutions**

Here.

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

Lynn Scheps? Melissa Swanfeldt?

**Melissa Swanfeldt – Associate Vice President, Marketing – Meditech**

Melissa's here.

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

Hi Melissa. And are there any ONC staff members on the line?

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator for Health Information Technology**

This is Kevin Larsen.

**Kim Wilson – Health Communications Specialist – Center for Disease Control and Prevention**

Kim Wilson.

**Julia Skapik, MD, MPH – Office of the National Coordinator for Health Information Technology**

Julia Skapik.

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

Thank you. And I apologize to the public for starting late and we will now turn it over to Ginny Meadows.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Thanks Michelle. Hi everybody, happy to have everybody on the call today. I know most of you are probably safe in your offices or wherever, I'm in wonderful Atlanta, where we – I'm sure you've seen the news, so we're recovering from our snowpocalypse down here and luckily I think things will get back to normal today, I'm hoping. Anyway, so today we have a fairly short agenda. We're going to talk about the feedback that was given on the quality measures patient-reported outcome recommendations that were made to the Policy Committee on January 14, and along with that, we're also going to talk a little bit about the recommendations on patient-generated health data and our feedback on both of those activities. In addition, we just learned that at the end of the call we're going to have someone from CMS talk about QRDA Validator Project that they're working on, so we'll do a short discussion on that right at the end. So we'll preserve about 5 minutes before public comment to do that.

Okay, let's go to the next slide. We've already talked about that. The next slide. So the recommendations that were given at the Policy Committee are right here on the screen and those consist of basically saying that ONC and CMS should continue to include patient-reported outcomes as meaningful use objective measures. And the Quality Measurement Workgroup actually recommended that CMS included a collection of any patient-reported outcome measure as a meaningful use objective measure, which would support the development of a flexible ability of EHR technology to broadly incorporate patient-reported outcomes. It also would allow for the patient-reported outcomes that would address some of the specialties and conditions that are currently covered or essentially not even covered as well as they should be. So some of the examples they gave, and these were expanded upon in the Meaningful Use Workgroup, in fact, yesterday or the day before yesterday during their meeting, were things like functional status assessment or other questionnaires, health risk assessments, PROMIS 10, things like that that they would – the patients would respond to and that data would then be incorporated into the EHR. And their suggestion was that this objective measure could function similarly to the CDS objectives where they would actually allow attestation rather than specific reporting of the use of those – that patient-reported outcome data.

And can we go to the next slide before we discuss that? I think we can discuss this altogether. Can we go to the next slide? I think we skipped a slide, can you go back one? Ah, okay, thanks – sorry, probably my fault. So the other recommendation that the Quality Measurement Workgroup made to the Policy Committee was that as discussed by other working groups, which included the Consumer Technology Working Group, and the Consumer Empowerment Working Group, there's a need to develop HIT infrastructure and guidance for supporting this outcome data, patient-reported outcome data and the data generated by external providers. And some of the examples that they included were things like the shared care plan and how that could be incorporated, patient portals, and mobile devices and secure email.

And the Quality Measurement Workgroup supported recommendations on patient-generated health data that came from the Consumer Empowerment Working Group that the Policy Committee approved on December 4. They also supported the ongoing work of the Consumer Technology Workgroup of the Standards Committee for standards and endorsed the extension of standards into additional domains that included the non-traditional determinants of care – of health. So the things – I think the main points to bring out of that is that there were definitely recommendations that this would be supported, but there are also some discussion topics around what the standards would actually be.

And at this point in time, the Standards Committee has not come back and given their feedback on this, but I think it's an important thing for us to discuss here about what – how we feel the standards actually support patient-generated health data today and being able to capture that data. And what our feedback on that specific topic is as well as you can see discussions around the PROMIS framework and whether that's something that could be incorporated. And whether patient-reported outcomes should be added in Stage 3 as a meaningful use objective requirement. So I'm going to open it up for discussion now and see what folks would like to start talking about related to this. Thoughts? Maybe start with the standards.

#### **Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

Hi, this is Maggie Lohnes; I'll start with a thought. I think I'd be – as a nation agree on what standards should be used in terms of even the language around patient-reported outcomes. I'm familiar with the project, as I'm sure many of you are that's been reported up through the National Quality Forum as well that there are patient-reported outcomes and patient-reported outcome measures and so the lexicon of PROS versus PROMS has not been socialized yet as clear definitions or standards for exactly what they mean. And then secondly would be the technical standards to support that. And just as one example, the question of a patient-reported outcome can be a patient-reported outcome to a provider, who then documents that outcome or a directly patient-entered outcome entered into the electronic health records. And so, of course, the standards would be different for the technical support of that. So I would recommend that further thought be placed on defining what is meant by a patient reported outcome so that the resulting technical standards can be built and eager to hear other thoughts about that.

#### **Melissa Swanfeldt – Associate Vice President, Marketing – Meditech**

This is Melissa, I would agree with that. I think we – the definition isn't clear and I think there's a lot of ambiguity right now around patient-reported outcomes. And again, whether it's something that a provider enters in for the patient or a patient directly enters into the EHR through a portal or some other mechanism, and I think that – having that area of gray makes it hard for the vendor community to program things.

#### **James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

This is Jim. I agree and I'd add that if we had standard categories say for patient goals and preferences and capabilities and outcomes and then standards about how – what are the – how do you express those? How do you – is locus of control one of the things that needs to be communicated among the care team and how do you express what a given patient's locus of control is? That would speed the day by a decade or so as to how fast we could build those things in and actually start communicating and making use of them.

#### **Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Good points. Anybody else have any other thoughts on the – specifically around the patient-reported outcome framework and how – our recommendations on how this should move forward or any –

**Karen Nielsen – R&D, Analytics and Business Intelligence – Siemens Medical Solutions**

Are we talking about the actual PROMIS framework from the NIH? Because that is a significant activity that's been going on for quite some time, that particular initiative has been funded by the NIH, I believe. And the important aspect about it is that it is putting forward tools that have been validated for reliability and validity and it is a place where I know most of it is in a PDF format, these tools, where you can then go ahead and utilize them within your practice. So ideally, I think, everybody would like this kind of information to be put into the EHR for strategic use. So the question is, from the PROMIS framework, I think it's a very important aspect of the entire patient-reported outcome framework. It is not an outcome measure in the way that we currently talk about outcome measures, it is an important gathering tool to ensure that the patient's view of their world is correctly captured and provided to the individuals responsible for their care. So, I think it's an excellent framework if we're asking about that.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Thanks Karen. Any other thoughts on the PROMIS framework?

**Stirling Martin – Senior Vice President & Division Manager – EPIC Systems Corporation**

This is Stirling. I guess going back to the question of the standards at play, because I think it'll play into the question about PROMIS, you can sort of think of there being questions, answers and then some overarching scoring that might get done. As the landscape of where are their standards, at which of those levels do people think that there are accepted standards today that would allow for exchange of this information. Certainly, at the answer level, you could start to envision how that might be mapped to things, but it's a very broad set of possible choices there and I worry that there probably aren't standards that would encompass all possible answers that someone might want to capture just on patient-reported outcome question.

**Karen Nielsen – R&D, Analytics and Business Intelligence – Siemens Medical Solutions**

This is Karen Nielsen again. I would ask for clarification of what the holistic goal of this data is, are you asking it for simply to have the data available for the provider to be able to utilize the data directly at the point of care? Or are you thinking about a much broader utilization of the data externally? So for instance, patient-reported outcomes are of great concern to the FDA in a lot of the activities that they have been putting forward around biopharmaceuticals, pharmaceuticals in general. So then the question then becomes, how is the broader framework being considered in this and therefore what are the standards that would support that broader framework, because that impacts our answer dramatically.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

That's a really good point Karen and when I think about it, especially in terms of what the Quality Measurement Workgroup has discussed, then we're really talking about having more of a capability to utilize the actual output of that patient-reported outcome to then use in specific types of quality measurement, when you're looking at things like functional status, etcetera. So the need to think about standards, I would say, is very critical, that there's no way we could truly utilize the data to do things like that unless it was standardized and codified in the way that we could kind of utilize it in that calculation.

**Karen Nielsen – R&D, Analytics and Business Intelligence – Siemens Medical Solutions**

So to go on that theme a little bit more, the idea would be okay, if we were just thinking about quality measures, right now we have the HQMF standard. So that is there to support qua – electronic quality measures, but what else will this data be utilized for and are there other standards that also have to be considered as a result of that?

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

That's a really good point and I think that actually pulls us into more of the discussion around patient-generated data, which is kind of the second part, I think, of what I thought we really needed to discuss. So hold that thought and let me see if anybody else has anything specifically to – related to the patient-reported outcomes, the specific charge of how this would be utilized in the quality measurement, the PROMIS framework and then we'll go to the patient-generated health data kind of issue around it being a meaningful use objective.

**Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

Hi, this is Maggie, and just on that score, I just have a couple of comments. One is, and to refresh my memory, I'm on the PROMIS website making sure I'm accurate in this; PROMIS uses the term patient-reported outcomes to mean the instruments that are used to collect data elements from patients to come up with a conclusion about their level of pain, fatigue or physical function. So they're specifically using that term, patient-reported outcome to mean the instrument and so therefore we would be talking about what kind of technical standards are there to build those instruments into EHRs. So then if we would encourage the use of the term patient-reported outcome measure to be a quality measure associated with those patient-reported outcomes, so is there something like, a 100% of children will be screened for physical function or some quality standard – quality measure around that. And then of course the associated quality measure specifications that Karen just pointed out.

One other just comment I want to make, which in recalling from earlier discussion, is the necessity to consider the patient an authorized contributor to the EMR. If we're going to be using patient data to be calculating quality measures based on their direct entry, we would need to clarify the role of the patient as an authorized contributor to the EMR.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Thanks Maggie, good points there and I think you raised a really excellent point about the fact that we're really thinking about two or maybe even three different aspects of this. One is the actual instrument that's used and potentially we should consider the fact that a lot of these types of assessments and questionnaires are licensed and they're not in the public domain, so that may be one topic we would want to discuss a little bit. The second thing is that then definitely we've got the quality measurement aspect. And then thirdly we've got the overall patient-generated health data and how do we deal with that technically, and what standards are there to support it. So, any comments around the actual instrument itself and the licensing kind of considerations that we would need to think about.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

This is Jim, just to that prior comment. I think we ought to state that the patient absolutely is an authorized contributor to their electronic health record, whether it's to existing EHR products or not is a slightly different question. The only issue is being able to verify that it's the patient and I think we ought to take that stand strongly. I mean, if they don't – we obviously need validated instruments, we need to know what the sensitivity and specificity and what the operating characteristics of the answers they provide are, particularly if they're going to be directly computable. But that's sort of like, does the patient have a right to read the doctor's note that ought to be – the only question should be executing on how the patient becomes in fact the core member of the care team.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Good point. Any other thoughts before we kind of go on and look at the rest of the presentation?

**Kevin Larsen, MD – Medical Director for Meaningful Use – Office of the National Coordinator for Health Information Technology**

Maggie, this is Kevin Larsen, just a kind of clarification of what the proposal was from the Quality Measures Workgroup. It's really to focus on the instrument collection and allowing providers much in the way that they currently could attest to using CDS in a fairly broadly open way that they use CDS would be to allow providers to attest to the use of patient-reported outcome instruments. And so that's really the proposal, not to require them all to do an NQF endorsed patient-reported outcome measure.

**Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

That's helpful to understand that.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Yeah, thanks Kevin. All right, let's just look at the rest of the presentation; I think it might trigger some other discussion. So can we go to the next slide? Specifically along that line, the Meaningful Use Workgroup is looking at their Stage 3 recommendations and they, at this point, have this specific recommendation around patient-generated health data. And it is that the eligible professional or hospital would actually attest to the use of those types of patient-generated data that would come from questionnaires, assessments, medication adherence surveys, they give a number of different examples here; or even possibly secure messaging. And they're proposing that this would be a menu option. And let's go to the next slide.

So, the Consumer Technology and Clinical Operations Workgroup also had a number of different recommendations that they supported. They were concerned if this was only a certification only item, which was the initial proposal because they felt that systems could be engineered to incorporate standards and processes which may not yet be mature and applications could be constrained – should be constrained to where they're needed and useful. So let's go to the next slide and talk about their overall recommendations.

So the Consumer Technology Workgroup felt that if there's a need for patient data sharing that the Consolidated CDA was a suitable standard and that it could be used for a container for certain types of templates that are pretty well understood already, like problems, meds and allergies. They felt that it was a reasonable way to get data in and out of EHRs, PHRs and patient-facing applications. And that they should not be required as the architecture that organizations such as ACOs would have to use, because the outcome goal would be for the entire care team. In that situation, to be able to contribute to an integrated medical record, so more of a longitudinal kind of workflow versus having to move documents around is the vision I think they had there. And then if they were unable to integrate, they could have the functionality to receive the Consolidated CDA with the specific templates that were related to what they were trying to accomplish. Finally, they were concerned that there was a need to allow innovation and flexibility in this space, to not unduly constrain options for consumers and patients to connect with their care teams in ways they would prefer in the future. So even though the Consolidated CDA templates are mature, they're not – they didn't want to over-specify how that should all happen.

And then let's go to the last slide. So finally thinking about the need for innovation, they were talking about the Continua standards. And I'm not sure how familiar everybody on here is with the Continua standards, but they're really more around – built around how specific device and telehealth type of instruments would connect and the standards around that. But there was concern that they would need to align with FDA guidance and other regulatory or sub-regulatory policy without constraining the marketplace. So there – obviously, there was a need to align with other types of guidance, but there's still that concern around innovation and being too prescriptive. And finally, due to the immaturity of the market, they need to allow for the flexible adoption of device data and other remote data sources.

So that was something that actually was specifically discussed on Tuesday's Meaningful Use Workgroup and Dr. Halamka came to speak with them from the Standards Committee to talk about the standards and the level of maturity of the standards for some of this patient-generated health data. So there was definitely a concern from his perspective, even though the Standards Committee hasn't specifically done their formal addressing of these recommendations, that there was still evolving standards at this point. So, comments on the whole topic of patient-generated health data and the standards potentially that would be used to support it and how mature they are.

**Annette Edmonds – Senior Product Manager – QuadraMed Corporation**

Well I'll jump in; this is Annette Edmonds from QuadraMed. I would agree that the standards are not in place yet to address the data from devices, but it is the direction that a lot of – if you look at a lot of the clinicians that are becoming more savvy with technology, are recommending to their patients. Which means that that would be – which is a better way to track things, because when you're tracking things from patients that they're entering, you don't always – it's a little bit subjective and so this would be more realistic data, but I do believe that the standards are not there.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Other thoughts from others?

**Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

This is Maggie. I – the thought that there's a difference between data generated by medical – by devices that a patient is wearing and patient-entered data. If – I'm thinking from the patient perspective, they may not feel that they're an intermediary between a heart monitor say that is – that they're wearing and the fact that it is entered directly into an EHR through some electronic interface versus some patient-generated data. So I wonder if there's a need for further definition and splitting of the recommendations, one being from devices, which a patient's not an intermediary, but just happens to be wearing versus something like a patient completing one of those screening instruments.

**Annette Edmonds – Senior Product Manager – QuadraMed Corporation**

This is Annette; I was going to say, I would agree with you on that. I think that that's – because that's kind of where I was going is that there needs to be a – there needs to be standards around it because you need to be able to determine where the data is actually coming from and the reliability of that data. Because again, there's...when a patients entering information, they are – it's – like I said, it's subjective more to what they feel at that moment in time whereas a device may be more precise and technical in the information that it's providing. And there are – I mean, there are devices other than heart monitors, I mean there are things that are coming out on the market, if you look at some of these devices for activity and measuring your activity and then that translates into really what you're doing. So in other words, if you were using a FitBit, let's use that as an example, and you could upload that information, that information could be interpreted into whether or not you're active or you're not active as opposed to the patient saying, I'm really active and they're really not, because it's not demonstrated. So I see them separated, but I could see them in some ways complimenting each other because one is more real data as opposed to the other one, which is, again subjective based upon the patient.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

This is Jim. I'd like to take friendly exception to that. You think about that heart monitor, you're going to want to know often what was the patient feeling when that funny rhythm was going on. And it turns out that in medical decision-making, the patient's symptoms and history, but symptoms, are often the most useful and the most powerful information in making a diagnosis. So, I think we don't need to say we trust the machine, we don't trust the human, what I think we should say is, that there are two information streams. The – nothing is more valuable than the patient's information if we collect it appropriately, we'll often need to compare or to synergize or whatever you say, the machine information with the patient information and so that's the real issue is, when was each one done, what was happening.

We've got to remember that the machine information, humans are all the time correcting for machine goof-ups and so that'll be part of this; did it fall off the patient? Did it run out of electricity? Was it shorted by a power surge? And so I think the issue is just to have – to understand the value of each for different settings, be able to merge the two or link the two – link the two when that's needed. And that would be a fairly complex set of tasks to perform, but it isn't sort of one or the other or which is better.

**Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

And this is Maggie, just to build on that. I was going to say that, excuse me, you mentioned the value of each data element and I heard a presentation by the American Health Information Management Association the day before yesterday talking about the need to identify the value of data elements. Because the question is not really is it more or less accurate, its clinicians, speaking as a nurse, are taught that data can be subjective or objective. So something coming from a machine might be objective, but for instance, the hardest thing to measure is pain and there is today no objective way to measure pain that I'm familiar with, and the patient would be the most reliable source of information about their pain level. So if you have a machine that could measure it, that would be an objective source, if the patient reported it, it would be subjective.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

This is Jim, thank you. That's a perfect example about how our objective is bias is one of the causes we don't manage pain well. And there are other cases like that where we get into an odd and embarrassing when you think about it, situation where we're sort of saying, we don't trust the patient, we trust machines, and then we get into all kinds of funny things like doing a horrible job of managing pain.

**Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

Um hmm – of that –

**Annette Edmonds – Senior Product Manager – QuadraMed Corporation**

This is Annette again. I think I might have not –

**Margaret Lohnes – Quality Measures Manager – McKesson Provider Technologies**

– and behavioral health as well, that's very subjective. That patient reported data would be very subjective in a behavioral health environment.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

It's subjective everywhere, but it's also often incredibly valuable and the most useful information that exists. That's the thing, objective doesn't mean good, subjective doesn't mean bad. Objective doesn't mean reliable, subjective doesn't mean unreliable. They're just different.

**Karen Nielsen – R&D, Analytics and Business Intelligence – Siemens Medical Solutions**

So if we think about taking this to the level of really what are we trying to accomplish with the data and the use of the data, it sounds from the direction that Kevin was giving, it was really ensuring that the tools would be there for the providers to use, if indeed they felt it was appropriate. And I think there's been plenty of research that shows patients are much more honest when they're typing something into a computer or on a web instead of face-to-face verbal communication with the physician. So, lots of research came out, especially in HIV patients, where utilizing a tool that allowed the patient to capture in writing how they felt was very important.

Now, so the question then becomes the proper use of the tool, the proper use of the data. I think right now the tools themselves in the PROMIS, as far as the PROMIS website, I think there are some with – you could do Boolean logic with some, but then there are also some that are going to require free text, I believe – I could be incorrect on that. So, we need to structure then the idea of what is the – what's the right thing to do from a technology standpoint, and that would be allow for the interoperability of the data to be able to share – share – be sh – I can't talk, sorry, with the larger care team that was described earlier.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

That's a really good point Karen.

**Annette Edmonds – Senior Product Manager – QuadraMed Corporation**

This is –

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Go ahead.

**Annette Edmonds – Senior Product Manager – QuadraMed Corporation**

I'm sorry this is Annette again. I was just – I purposely stayed away from devices that had feelings with – that there would be some type of interaction from the patient as to their feeling at that moment in time, that's why I went to something like a FitBit that is just data relative to their activity. So if I was looking at activity and I wanted to be able to take that information in, yes, you might ask – there might be some questions. But there might be a goal, an objective based upon the – what the clinician actually put in place for the patient to say they need to do certain things, that they would not necessarily have to type the data in, that that data would come from that device rather than them saying, I walked 200 steps today. So I was just – I was trying to go to – I was sitting on the innovation side of where – that there are less complicated items that might be part of the innovation that we need to think about and how does that play into the – because we always go to the more complex items, but we don't – but there are so many other devices out there now that a lot of care providers are using.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

This is Jim. But just, granting that, just we need to remember that FitBit version 2 or 3 may enable the patient to say, right now I'm having or not having my heart pain; right now my knee pain is a 7 out of 10. And the FitBit will be even more powerful when we can correlate things like that together and say, oh, okay, as long as they only walk 3 miles an hour, as long as their heart rate is only this, as long as whatever it is, so that you could actually have better care planning. So we just need to remember that FitBit is going to be radically different in 5 years, probably be obsolete, but anyway, and the correlation of those two data streams is going to be incredibly valuable.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

So, along that line, I'm just kind of thinking about the technical implications of what we're talking about here and a couple of thoughts come to mind. I mean, first of all we've talked a little bit about it already, but the question of what standards exist today to make sure that we can incorporate this data. And then I think the other thing that I'm thinking about is, what would we need to do, within our products, to ensure that once the data's collected, it's actually somehow pulled into the patient record in the correct way and what kind of auditing capabilities or even permissions would be needed. Oversight of that data, review of that data, kind of comes to mind as far as thinking about eventually all this data that's going to be coming in for the physician to look at. How do we – what would be our kind of thoughts on what should happen in order to ensure that happens in a predictable, accurate manner? Thoughts?

**Stirling Martin – Senior Vice President & Division Manager – EPIC Systems Corporation**

This is Stirling. I think the question of standards is still one that I think requires a lot more investigation. I think looking at specific use cases and understanding which standards either are or aren't available against a backdrop of those specific use cases would be helpful because the patient-generated health data is such a broad universe of potential things, all of which haven't even been dreamed up today. That making sure that there are appropriate standards in place, especially if something is going to be an objective measure that applies to a large class of providers that they have to then make sure is appropriate for their specialty or for their practice.

**Melissa Swanfeldt – Associate Vice President, Marketing – Meditech**

This is Melissa. I'll add, when you think from a certification standpoint, it's very important that we have standards to go by, so that we know what we're – as a vendor community, what we're going to have to certify on. If it's too broad, then it sort of leaves too much interpretation in the certification process, which I think is important so we know what to sort of work towards from a programming standpoint.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

You know, to – this is Jim – to both of those points, one concept that might be useful here is the value set that came up in other standards work and NLM ended up being tasked with creating value sets. So, to Stirling's point, you say okay if we're going to try to manage osteoarthritis, what would be the objective measures, what would be the patient-reported measures, what would be the team-reported measures that would be needed. And then what would the standards be for all of those so that we could start with maybe the most common and the most expensive things, we start with angina, or whatever. But I think that would get us a lot farther down the road faster, give HHS a focus. They could say, look, we've already said cardiovascular is sort of the key thing in our quality blueprint or whatever it's called, so let's figure out what would the standards be that you'd need to have machine information and patient information that you'd use in managing the various forms of cardiovascular disease.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

This is Ginny, Jim, that's a really good point. I think what you're saying is we really should think about how to prioritize first of all what we'd want to be able to capture and then what standards are behind them so that we can incrementally think about how to build upon these capabilities.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

Right and just so it's clear, I think from HHS's standpoint, if they just said, these are the ones that we think are most important; they wouldn't have to build it into reg to powerfully influence the order in which we incorporate things.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Great point. And this is Ginny again, too. So are there other thoughts around the reconciliation of this data? I know we've been doing some reconciliation of outside data obviously with medications and problems and allergies. We start thinking about other data like this, anything come to mind around what would be needed to ensure that reconciliation?

**Melissa Swanfeldt – Associate Vice President, Marketing – Meditech**

This is Melissa. I'd say I think it would be very important for a clinician reviewing the chart to understand what is self-reported by the patient, especially that subjective data versus what may have been entered by a caregiver. So I do think it's important to have – be able to differentiate between caregiver-entered data or professionally entered data by a clinician versus what a layperson patient or patient family member enters.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

So a source, I mean, I think what I'm hearing is a source would be very critical to capture and display.

**Melissa Swanfeldt – Associate Vice President, Marketing – Meditech**

Yeah, so –

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

And there will be interesting questions about the source, I mean if I have to meet an exercise level to get a co-pay reduction for my insurance, do I just give the FitBit to my niece who is on the track team?

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Good point. Julia or Michelle, do we need to stop in a minute to have someone talk to us about the validator, is that happening?

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

Yeah, I believe Doug is on the phone from Booz, Allen, to speak to that.

**Stirling Martin – Senior Vice President & Division Manager – EPIC Systems Corporation**

Michelle, before we do that, can I make a quick point –

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Yeah, I was going to ask if anybody had any final thoughts before we move over to that discussion. Go ahead.

**Stirling Martin – Senior Vice President & Division Manager – EPIC Systems Corporation**

Yeah, this is Stirling. I think as we look at the landscape here, especially as it relates to objective measures, I think exploring the path around something being a menu choice is prudent. I think that the universe of possible patient-reported questionnaires will vary based on specialty and there may be some specialties where there aren't meaningful patient-reported outcome measures that could be tracked or there aren't standards to support them. And so making sure that there's flexibility for provider organizations to use this where appropriate but not force it upon everyone inappropriately. And secondly, the licensing considerations of some of the patient-reported outcome assessment tools themselves and allow organizations flexibility in which and where they use different ones.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Any other final thoughts before we move over?

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

You know, this is Jim. It might be useful to suggest to them a working principle that proprietary standards with unpredictable and uncontrollable costs never be made standards.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Right.

**James M. Walker, MD, FACP – Principal Health Informatician – Siemens Medical Solutions**

And I would say that's an HHS principle actually. They bought SNOMED before they made it a standard terminology.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Great example Jim, thank you.

**W**

That's a perfect example.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

So let's move over – thanks everybody for the great discussion. We're going to have someone talk a little about the data validator tool now, so, Michelle?

**Doug Young – Senior Association – Booz Allen Hamilton**

Sure, this is Doug Young and I'm with Booz Allen Hamilton. For the past several months, we've been performing on a job for Margaret Pejeski with CMS CCSQ in the hospital reporting team. And basically we've been producing a pre-validation tool, proof of concept for the purpose of improving – reducing costs, improving the effort required to submit quality – report quality to CMS and the hospital system. Margaret's not available to be with us today, so I'll just give you a brief review.

Basically, for the past year, I guess, we've been helping CMS in interviewing folks about what is the enterprise solution across the agency that might help improve quality reporting. And uniformly lead by CCSQ, the answer is can you improve what comes in the front end and make it easier for both the reporting side as well as CMS in terms of validating and try to limit the cycle that goes back and forth between CMS and the folks that are doing the reporting. So with that idea, we came up with this thought of taking the validation process that happens at CMS today and moving it forward into the vendor and/or care delivery organization environment, in this case hospitals. So that QRDA, which we have been testing with, QRDA level 1, might be validated per the schematron set of rules that coincides such that all the QRDA that is produced in the hospital environment could be validated against the exact set of rules that CMS will use. And then submit through a gateway, as opposed to through the portal and have your QRDA be accurate the first time.

So I'll stop there, I know several of you on the call we have been working with to test this concept. In general, I think the reaction has been reasonably good in terms of the possibility of saving time and money. We're continuing right now on the project to do some detailed testing with several of the members on this call.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Thank you Jim. Does anybody have any questions for Jim before we move to public comments?

**Doug Young – Senior Association – Booz Allen Hamilton**

Yeah, sorry, that's Doug Young with Booz, Allen, Hamilton.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Oh, Doug. Sorry Doug. And Doug, do – would you want people to get in touch with you, should we send out your contact information after this?

**Doug Young – Senior Association – Booz Allen Hamilton**

Yeah, thanks, that's a good point. We can send out a deck that describes this process I just talked about and including our contact information if you'd like to learn more.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

That sounds great, and I'm sure Michelle or Kim, you guys can distribute that.

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

Yup. Thank you Doug.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Okay, so should we go to public comments?

### **Public Comment**

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

Sure. Operator, can you please open the lines?

**Caitlin Collins – Project Coordinator, Altarum Institute**

If you are on the phone and would like to make a public comment please press \*1 at this time. If you are listening via your computer speakers you may dial 1-877-705-2976 and press \*1 to be placed in the comment queue. We do not have any comment at this time.

**Ginny Meadows, RN – Executive Director, Program Office – McKesson Provider Technologies**

Okay everybody, thanks so much for joining today and we will talk to you in about a month. Thanks so much.

### **Public Comment Received**

1. How about patient survey responses, such as for PQRS measure 304, "Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey." as an input for patient-reported outcomes.
2. If a patient is made an 'authorized contributor' to the EHR, should this data be included in all interaction checking, CDS alerting, etc.?