NATIONAL QUALITY FORUM

Moderator: Measure Developer Maintenance
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OPERATOR: This is conference #: 8863376.

Operator: Welcome, everyone. The webcast is about to begin. Please note, today's call is being recorded. Please stand by.

Suzanne Theberge: Good afternoon, everyone, and welcome to the Person-and-Family-Centered Care Committee Off-cycle webinar. Thank you so much for joining us this afternoon.

Just a quick reminder before we get started for the committee members to dial in to the phone line as well as joining us via webinar, and for those of you on the webinar and the phone, please do remember to turn your computer speakers off.

So, next slide, please. I'd like to just run through the agenda very quickly before we go ahead and get started. We're going to do a quick roll call just to see which committee members are on the phone with us today and then have the team introduce themselves and then we're going to talk very briefly about NQF off-cycle work and what that is before we dive into a presentation about what we actually like you to discuss today.

We'll go over an overview of the brief presentation and go over the discussion questions and then we will open it up for committee discussion which will be facilitated by our co-chairs, Lee Partridge and Chris Stille. And then finally, we'll close out the call with holding a comment period and next steps.

So, next slide, and next slide. I'm just going to do a very quick roll call. So, if you are on the phone, please just say "here" when I call your name. Lee?

Lee Partridge: Hi, everybody.

Suzanne Theberge: Chris?

Chris Stille: Good afternoon.

Suzanne Theberge: Beth Averbeck? Sam Bierner? Adrienne Boissy? Rebecca Bradley? Jennifer Bright? David Cella? Sharon Cross? Dawn Dowding?

Dawn Dowding: Here.

Suzanne Theberge: Thank you. Nicole Friedman? Stephen Hoy?

Stephen Hoy: Yes, hello, I'm here.

Suzanne Theberge: Hi. Sherrie Kaplan?

Sherrie Kaplan: Here.

Suzanne Theberge: Thank you. Brian Lindberg?

Brian Lindberg: Here.

Suzanne Theberge: Hi. Linda Melillo? Ann Monroe? Lisa Morrise?

Lisa Morrise: Lisa Morrise, here.

Suzanne Theberge: Lisa Morrise, thanks, sorry about that, thank you. Elizabeth Mort? Lenard Parisi?

Lenard Parisi: I'm here.

Suzanne Theberge: Thank you. Deb Saliba? Lisa Suter?

Lisa Suter: Here.

Suzanne Theberge: Thank you. And Peter Thomas? All right. Is there anybody that didn't get a chance to introduce themselves on the phone? And I do see some other folks on the webinar, so hopefully, they can join us via phone shortly. All right. So, thanks, everybody.

So, next slide, please. This is Suzanne Theberge speaking. I'm the Senior Project Manager on the PFCC team. I have worked with you, all, for a couple of phases of work now and glad to be back here.

And I'd like to just quickly turn it over to my colleagues to introduce themselves and let you know who they are. Kyle?

Kyle Cobb: Hi, this is Kyle Cobb and I am a Senior Director at NQF and I just recently joined NQF about a year ago, so that's a small tenure compared to most folks here, and have also inherited Sarah Sampsel's rule, we've worked on the PFCC committee. So, happy to meet everybody and happy to be working with you.

Karen Johnson: And I am Karen Johnson, I am another one of the senior directors here at NQF. I've been here about five years, a little over. And one of my responsibilities here at NQF is to be, I guess, one of the overseers, if you will, of our evaluation criteria for endorsement.

So, many other questions I think that are going to come up today we're asking you to discuss because there may be implications for some endorsement requirements. So, I'm really looking forward to hearing what you have to say about that. Thanks.

Suzanne Theberge: All right, thank you. And Madison?

Madison Jung: Hi, this is Madison Jung, I'm a Project Analyst, and just the sixth month mark here at NQF, happy to be helping you, guys, out today.

Suzanne Theberge: All right, thank you. So, next slide, I wanted to talk briefly about our off-cycle work because this is really the first formal off-cycle work that the PFCC committee has done so far.

And once NQF moves to the standing committee set up a few years ago, we realized that there are going to be years in which our committee might not have any measures to look at or there might not be a project in that area, but we wanted to keep you, all, engaged and keep talking.

So, we set up what we're calling off-cycle work which is going to be these quarterly webinars. Next slide, please. And there are a number of different things that we look at in these off-cycle webinars.

We may do an ad hoc or an off-cycle review of a measure. We might do a presentation on updates about what's happening at NQF. We might seek the committee's input for another committees or something like this where we're asking you to think about a bigger picture issue in measurements or we might ask you to do some follow-up work in the CDP.

So, with range of different topics but basically, we just bring you, all, together on the conference call and webinars, have you discuss something and then the staff write up a brief summary and that's it. So, it's a much shorter term project than our measure review project but it is a way to keep talking and keep working with you, all.

So, next slide, please. So, for today's call, we have asked you to join us today to talk about how NQF should be thinking about instrument-based measures and what we might want to be thinking about in terms of classification, in terms of how we frame these measures, but also in terms of our endorsement criteria and what may or may not need to change for those criteria.

This has come up in -- well, this is the committee -- the PFCC committee is the committee that has to review the most of these instrument-based measures and these patient-reported outcome measures. We do have other projects that are looking at this and it's come up on other projects, and so, we decided that it was finally time to start thinking about it.

So, next slide has a couple of those questions that we have put in the memo that we sent you a couple of weeks ago. And, you know, basically, we're interested in asking some questions around the instrument-based measures, are all instrument-based measures PRO-PMs, and if not, which ones are PRO-

PMs? Do we want to think differently about how we evaluate patient-reported outcomes measures? Do we want to describe these measures differently or more -- with more detail than we currently do?

So, next slide, I wanted to talk a little bit about the background of where we're at now and kind of why this is coming up now. So, our current criteria for PRO-PMs, which was established in 2012, and we have four key domains, health-related quality of life, symptoms and symptom burden, experience with care and health behaviors.

And before I go any further, I also wanted to just quickly run through the actual definition for the terms that we're talking about here. These were in the memo, so you may have had a chance to read them. But I know we've also got a lot of folks on the phone who are listening in just to kind of hear the conversation today.

So, NQF describes PRO or defines a patient-reported outcome, you know, a PRO, as any report of the status of a patient or a person's health condition, health behavior or experience with healthcare that comes differently from the patient without interpretation of the patient's response by a clinician or anyone else.

A PRO measure or a PROM is an instrument still or single item measure used to assess the PRO concept as perceived by the patient. And we do -- we do say patient-reported but it can also include in our -- kind of the term of ours and we can also include patient's family's caregivers in that as well.

And then we also have PRO-PMs, PRO-based performance measures, and that's the performance measure that's based on PROM data aggregated for an accountable healthcare entity, so something like percent of patients in an accountable care organization whose depression score as measured by the PHQ-9 improved.

So, we're starting to see more of these measures. The measure environment has changed. We have a lot more experience with these measures and we're seeing new questions and new concerns have come up.

So, right now, we do have criteria for our PRO-PMs that in some ways that there is a little bit we -- one particular piece of it is that we require evidence that the target population values are measured well and finds it meaningful, and we also require both item and score level testing for these measures.

So, what we're interested in looking at is whether we can make some changes and expand our thinking about this. So, next slide is one of the diagrams that we included in the memo. And this leads to currently how we classify these instrument-based measures, they're the patient-reported or the clinician-reported, and we have a few different buckets in each of these topics.

So, as we said, we're thinking about this and talking about it at NQF. We started thinking that maybe we need to have some more buckets in here, and maybe we just really need to reframe.

And so, on the next slide, we have this proposed classification which was also included in the memo, and I think it might be hard to see for folks on the Webinar depending on the size of your screen. So, over the next several slides, we've broken it out into pieces.

So, the next slide looks at the top two levels of that -- of that framework. So, what we're thinking here is that maybe we have instrument-based measures but they're not all outcomes, maybe we have instrument-based measures that are processes, maybe they're structure, maybe patient experience (needs to be) on bucket here.

And, you know, there's a bunch of different ways that we could classify this but we started thinking maybe you want to start with instrument-based measures being the top kind of overarching bucket and then you split it out by type of measure.

And then on the next slide, you'll see we go down a further level. And for these outcome, process and structure measures, maybe what have patient-reported, clinician-reported, observer-reported and then performance outcomes.

So, rather than having the patient-reported outcome, you could have an instrument-based measure data process that's reported by the patient or reported by the clinician or an observer, which might be something like a family member.

So, next slide breaks this down even further, so looking at the patient-reported, so you could have an outcome, process or structure, and then you could have all these different domains under that patient-reported outcome, maybe patient experience would be under here instead of up above. Maybe if you're looking at functions, symptoms, behaviors, health-related quality of life, which is some of the ways that we think about patient-reported outcome measures now.

So, the next slide lists out a bunch of measures that are currently endorsed as process measures but we think could actually really be considered patient-reported process measures. So, these measures about parent's experience with care coordination or patient's experience receiving -- did they receive medical assistance with smoking and tobacco use of patient, management of urinary incontinence, things like that, that are process measures but maybe they are really more of these patient-reported measures.

And so, that leads us to the next slide which gets at one of the big questions that have come up from other projects which is currently all these kinds of measures are evaluated as process measures, did something happen or not.

But what you do when the data source is the report of the patient, sometimes these measures are classified as patient-reported outcome measures, these PRO-PMs, and the evidence criteria for PRO-PMs is the outcome evidence requirement, which is about, can you link -- is there a rationale for relationship between the outcome and the process rather than a full assessment of the quality/quantity inconsistency of the evidence for the measure focus.

So, that has come up in a number of -- a number of projects and has been kind of an ongoing discussion that we've had with other committees, and we're interested in getting your take in and thinking about, you know, do we need to

think about these measures differently, how do we -- how do we classify measures when the data source is the report of the patient?

So, on the next slide, we wanted to just show you what some of these clinician-reported measures might look like, so we could have functions, symptoms and behaviors under here, and the next slide has some examples.

Many of these will be familiar to all of you as they are the -- some of the functional change matters that we've looked at in this committee's work over the last couple of years or it could be something like a clinician-assessed behavior or symptom progression, things that are managed by or that are assessed by standard scales and that clinician -- and any tools and instruments that clinicians could be using.

The next slide, we were thinking observer-reported measures to be broken down to function, symptoms and behaviors. And the next slide, those -- we've had some examples and those might be things like the CAHPS measures.

And then our final -- our final bucket under the -- under here was the -- sorry, next slide, performance outcome function measures, next slide, and examples of that might be things like gait speed or memory recall on cognitive testing, the functional capacity in COPD patients, so, just things that are looking at functions that come out of these instruments or these tools.

So, the next slide kind of takes us back to where we started with the discussion questions. And we really are looking to just get some input and some thoughts from you, all, that we can write off and take forward as we think about refining our criteria.

And, you know, maybe you'll look at this and say, NQF has gone too far. You don't need to clarify -- or you don't need to break things out, you know, this far. But we are interested in hearing really about whether instrument-based measures need a little bit more refinement and what kind of implications it has for our criteria going forward.

So, I will pause here and see if either my colleagues, Karen or Kyle, wants to add anything before we turn it over to the committee to begin your discussion.

Karen Johnson: And this is Karen. I think the other thing just to kind of have -- floating around in your mind might be, you know, even if there is not a need necessarily to differentiate these things and label these things to this extent that we're (fitted for) as a straw man in terms of criteria, but would it help the field, you know, understand better, help clarify language, maybe even promote, you know, good practice and thinking in terms of measure development.

So, you know, if the answer is no then I don't think we need to go to this extent but that might be the other thing. Even if it doesn't impact our criteria, there might be other reasons potentially to be a little bit more descriptive. So, we wanted to make sure that that came up as well.

Peter Thomas: This is Peter Thomas. I joined the call. I just wanted to make sure you're aware of that.

Suzanne Theberge: Hi. Thank you for letting us know.

Peter Thomas: Could I also ask a question that I'm not sure whether this is I'm tracking fully? But in the -- in the slide deck in the presentation you just gave, you defined patient-reported outcome measures as being reported by patients, which makes perfect sense.

So, why are we even talking about measures? Why are measurement tools that are -- where the providers involved considered PROs?

Suzanne Theberge: That is a good question and I don't think that they always are sort of more getting at the instrument-based measures, you know, where -- what are -- how are we classifying these measures that are based on standardized tools and measure -- and instruments.

Again, I think some of the ones that you, folks, have looked at could -- you know, they are -- this clinician report of an outcome, you know, something like the Oxford knee scale measures that you, all, looked at, and I'm just

trying to -- average changes, functional status following total knee replacement surgery, things like that.

Maybe these are -- these need to be considered slightly differently than outcomes because there I -- you know, they're being reported by the clinician. And, you know, again, maybe this is taking it too far down and we don't actually need to go this far but, you know, maybe we want -- we were just kind of thinking this through and trying to clarify our thinking and how we're taking it to you.

Karen and Kyle, do you have anything to add to clarify that a little further?

Karen Johnson: Yes, I mean you did a good -- a great job. Basically, what happened is, you know, just in the chronology of how things work out, we have all this great foundation work back in 2011 and 2012, and that was all about PROs and PRO-PMs.

And then, you know, eventually, we set up, you know, the PFCC group and you, guys, started getting this kind of measures, and lo and behold, this other kind of measures that were based on instruments came in and you, guys, had to do something with that, then we realized, "Hey, we had only talked about PROs and PRO-PMs, but this -- here is this other class of measures that we really don't have a title for."

And as a matter of fact, it was your group that I believe really encouraged us to expand our testing requirements because, again, with the PRO-PM report, we had initially had said we want to see testing it both the item level and the score level for the PRO-PMs.

But then these clinician-reported instrument-based measures came in the door and we didn't have, you know, that criterion and we subsequently get to change that, so now, we do have that criterion, but that was really from your work and really from, you know, things coming in the door that we were reacting to, to be honest. So, we're trying to get a little bit ahead of this curve right now and not so much to be reactive. So, hopefully that helps a little bit too …

(Off-Mic)

Peter Thomas: It does. Thank you very much for the clarification.

Karen Johnson: Thanks.

Brian Lindberg: This is Brian Lindberg, if I could chime in. And I do think this is a really interesting and great thing to think through, but let me make a general comment and then ask a question, I guess.

My biggest worry would be that we would in some way, if you will, in merging, no, that may not be the right word, but merging these measures, we would somehow dilute the patient perception, information we're gathering, and it may be kind of simplistic but I've always thought of, you know, kind of three buckets of measures, you know, the process measures and the outcomes measures and then the patient perception measures.

And what I would want to feel good about was, you know, if you could make the case that, in fact, will understand better and know more about the patient's perceptions if we, you know, go down this avenue. I'm not sure if that makes sense but that was a question in there somewhere.

Lisa Suter: This is Lisa. Can I ask a clarifying question?

Suzanne Theberge: Yes.

Lee Partridge: Go ahead, Lisa, this is Lee.

Lisa Suter: So, I think I missed the conversation about the Oxford knee measure since I joined sort of mid-cycle. I read the materials and the thing that struck me was the provider-administered PROM if -- whether or not that can be a PRO-PM.

And I guess I just need -- I need a definition of what a provider-administered PROM is because my understanding of the Oxford Knee Score is it is a patient-reported survey instrument. If you hand that to a patient and that patient fills that out and then the physician collects it and evaluates it, that still seems to me to be provider -- patient-reported.

So, it's technically a patient -- a provider-administered but the provider is not answering the questions for the patient. Is that what we're talking about? Are we talking about a situation where the provider actually fills the survey out based on what they think the patient is experiencing, which I completely agree, doesn't belong in the conversation around patient-reported outcome measures? But I think I'm missing that sort of definition here.

Suzanne Theberge: Yes, I think that's a good question, and I'm reviewing these facts now. I think this -- you know, I think -- and I think there's a question I -- if I'm recalling correctly, you know, our definition say that, you know, it has to be the patients report without interpretation of the patient response by a clinician.

So, I guess my question would be, and perhaps that was not a great example of a measurement, if the clinician is, I guess, reading that measure or reading that performance to say, "OK, you answered this way to this many questions, et cetera." So, if they're interpreting it, would that then become -- you know, is that bringing a clinician voice or, you know, make it less of a patient-reported outcome?

But I think we do also do have some -- you could have measures where you would have a standardized tool that assesses the patient for something and, you know, the assessment id done by a clinician and scored by a clinician and, you know, that would really be the clinician-reported -- perhaps clinician-reported outcome.

And I think to the earlier question about diluting, I mean I think that's one reason why we hold off. And Madison, if you could jump to that slide that -- with the proposed diagram, it's -- let's see, Slide 13.

The instrument-based measure is we're thinking, you know, maybe we want to pull -- yes, this one, thank you. Maybe we want to pull that patient experience out and put it on the level with outcomes process and structure measures. You know, maybe we're thinking about this is something. So, are there other questions …

Brian Lindberg: So …

Suzanne Theberge: Go ahead.

Brian Lindberg: This is Brian. Let me just follow up then on a kind of a specific example then. Let's say we're talking about a process measure that you're going to get the patient's perception on and you also have information from the healthcare provider, did the physician or the hospital give you, you know, a certain medication an hour before your surgery, you know, an antibiotic?

And how -- you know, are you going to be asking the patient questions like that with their perception of the care they're got, some similar to that, and also be getting -- gathering information from the facility itself?

It's just an example of how this -- in my mind, I just want to make sure these aren't, you know, kind of conflicting pieces of information or if they are, how is it used. And really, some of those process measures, are they really -- is the patient really the best person to be in a way validating what the health provider did?

Suzanne Theberge: Well, I can't say the …

(Crosstalk)

Stephen Hoy: This is Stephen.

Suzanne Theberge: Go ahead.

Stephen Hoy: No, please, you go ahead.

Suzanne Theberge: Oh, yes. I mean I can't say we've seen a measure precisely like that but we did see in the few projects, we have a number of measures for the pediatric project. We did have a number of measures come in that were parent's assessments of whether this thing happened. You know, did your provider talk to you about -- your health provider talked to you about various safety issues, for example, or various screening issues?

And, you know, so those are measures of, you know, a patient, and they came in as PRO-PMs and that committee was very uncomfortable with that saying,

"Well, this is a process. You're asking -- and, you know, process measure, you're asking the parent, "Did this thing happen?"

And, you know, you could -- I ask them to go back and, you know, with some work cross-check, OK, were the providers said they talked about these things, you know, on 10 out of every 12 visits. And the parents are always saying it's six out of every 12 visits.

So, I mean that -- you're -- that would actually be very interesting, you'd be getting at parental perception of whether something happens which might actually be more interesting or more, you know, kind of a picture of the quality of care that you're receiving because if you're providing this counseling and it's not -- parents aren't remembering it then maybe they didn't do a very good job. So, that's, you know …

(Crosstalk)

Suzanne Theberge: But that's the kind of question and problem that we're running into quite frequent -- or not quite frequently but, you know, with some frequency on other projects.

Brian Lindberg: Yes, thank you.

Lee Partridge: Suzanne, this is Lee. I -- Brian, I think you've hit on the thing that I've been struggling with because in preparation for this meeting and reading our memo, I went back and actually read the pediatrics reports and listened to the transcript of the discussions which the issue came up.

And I keep thinking of it, trying to think of an analogous situation here in the State of New York, and I think one way that I've been thinking about it is you can have a checklist measure which is what we actually use here in New York right now to assess whether or not the well child adolescent -- well adolescent visit, the provider addressed issues of sexuality, substance abuse or et cetera. And that's reported to the state and it's publicly reported as well.

You could just as easily turn that measure around and ask -- and use a patient survey asking the teenager whether or not the -- his doctor asked those same

questions. I would say both of those are process measures and should be evaluated according to our process criteria.

Chris Stille: Yes. And …

Lee Partridge: But I totally agree.

Chris Stille: And this is Chris, if I could chime in as well, I agree. And so, the dilemma that comes up are, you know, when we look at how actionable patient experience measures are, patient experience measures that report process or clinician behavior or outcome are the things that are really actionable by healthcare teams.

And so, if there's anything left, if we take those out, are there any patient experience -- patient experience measures that are relevant or are they all really measures of structure, process and outcome? So, I sort of wonder about that.

Stephen Hoy: This is Stephen. I'm going to piggyback on that at least with my opinion …

Chris Stille: Yes.

Stephen Hoy: … that the -- there -- I fully believe there are process measures that, you know, the person of reporting could be not on patients and put on the system, you know, "Yes, we checked the blood pressure. Yes, we discussed these alternative, you know, treatment options, blah-blah-blah."

But I think there is still a space where the patient's interpretation of their care can only be measured by the expertise of the patient.

Chris Stille: Right.

Stephen Hoy: And as an example, like our -- is -- you know, I think where we cross that line is where you start thinking about, is your care, you know, aligned with your preferences, priorities and goals, so that really -- you know, that really like the gray area of the patient experience that can't be yes or no questions but really diving in.

And those are the things that start the discussions between providers and patients. So, when -- even if a provider, I would have no problem with the provider eliciting those surveys or those tools because that is -- it almost becomes a communication tool between providers and patients, right, or caregivers or whoever it is.

So, the -- just totally lost where I was going with that but, you know, just because the providers eliciting the -- eliciting or using the tool, I think it could still be considered a patient-reported outcome if the patient's expertise or opinions of care are what are actually being measured, right, or the perceptions, not, "Yes, we measured blood, yes, we've talked about this, no, we did not talk about this."

You know, those things are pretty cut and dry in my mind, what isn't cut and dry and where the patient experience comes in is if your care is aligned with your preferences, priorities and goals for you own healthcare, right?

Chris Stille: That's a nice …

(Off-Mic)

Stephen Hoy: But it's just kind of my two cents.

(Crosstalk)

Lisa Morrise: This is Lisa Morrise. I really like what Stephen just said. And as he was talking, I was thinking about we have kind of two buckets of outcome measures. Some are objective, they're very cut and dry. Basically you can measure them easily, you either did it or you didn't do it. The others are more subjective and get to how the patient felt.

So, indeed, for example, HCAHPS, there's a question about listening and if the patient don't listen to. Well, the physician or provider may have listened to the patient but the patient may not have felt listened to. So, it's a subjective response versus being able to say, "I told them X, Y and Z," right?

Sherrie Kaplan: This is Sherrie Kaplan. I think a long time ago when we, Paul Cleary and John Ware and those of us at RAND were struggling between reports and ratings, were headed back in that direction because the report tells you it happened sort of in a dichotomous way, yes or no, and a rating is evaluated.

So, you go to the patient while it may have happened but it was terrible. You know, yes, the doctor explained the side effects of medications but they did such a rotten job I couldn't understand it. So, I think this distinction is framing back a long time ago that the old distinction between reports and ratings.

And I had a kind of further question which is I got a little confused in the last discussion about process versus outcome. So, various depression scales are administered either the patient self administers or they're administered by a provider.

And so, if the -- if the goal is to get a depression measure, which is the source as it is, it isn't necessarily a provider measure, it's a provider-reported measure but it's still about depression is an outcome. So, I'm getting a little bit muddled about this distinction that we're talking about right now.

Karen Johnson: And Sherrie, this is Karen, when you say, this distinction, are you talking about this distinction between outcome and patient experience or distinction between outcome and process?

Sherrie Kaplan: Well, both. I got a little confused about process versus outcome measures and then who reports it. So, I think we've got sort of a two by two table going around. Is it a process or an outcome, and who's the best source of the information?

Karen Johnson: OK.

Sherrie Kaplan: It's an outcome, you know, and you've got various different Hamilton and you've got CES-D and you've got various depression measures, where do you put those in that two by two dichotomy? Does it really matter who is the source of the information? And then it does, what are you going to call it?

Karen Johnson: And I think you're exactly right. I -- you know, the depression went here at NQF, we would just automatically call it an outcome and, you know, if it's based on an instrument then that has implications in terms of what we're looking for for testing.

It may not actually matter at all who is -- you know, if it's patient-reported versus clinician, you know, and that takes us back to our question more along the lines of clarity, would it help this field to label these things?

Even if it didn't matter, even if it made no difference, whatsoever, in terms of how you, guys, would evaluate a measure for endorsement or not, you know, with having that label help anything or is it just, you know, adding words with …

Kyle Cobb: With noise.

Karen Johnson: … noise, yes.

Stephen Hoy: This is Stephen Hoy. I have another comment on your notes in the memo regarding the international term of ours, the word patient being inclusive of persons, including patient's families, caregivers and consumers more broadly for -- you know, for the definition of patient -- of a patient-reported outcome.

And that why would we then have -- I guess I'm just having a hard time deciphering why we'd have then the observer-reported because to me, a patient-reported outcome can come from, you know, any member of the care teams on the consumer side. Does that make sense?

You know, so that definition almost opens up what a patient, you know, is considered and almost the observers fall into that. So, it's almost to me like there could be one patient-reported, you know, and that has to do with the consumer's interpretation of care and then the clinician's interpretation of care and then the performance outcome.

I'm sorry, I'm looking at the new diagram that you have on the slide, right? It almost get rid of that observer and put that with patient reported in my mind when I'm referring that definition. Did I word that well?

Suzanne Theberge: Yes, I think that makes a lot of sense. I mean I think we were -- we were kind of talking out a bunch of ideas to things that we saw and questions that we had. And, you know, as I said, this is intended to be the final be-all and end-all.

But I think that there is one of the questions that we were interested in, you know, is the report side of patient, you know, is that -- is that still the same kind of thing and, you know, is a report by a parent, for example.

Stephen Hoy: I would -- I would

(Off-Mic)

Stephen Hoy: … you know to offer my two cents of that exact question is I would say yes. A lot of caregivers would consider them, you know, an ad hoc patient, right, and there is, you know, a lot of work going around about taking care of caregivers.

So, you know, I would argue, yes, that the -- you know, it's almost the consumer-reported outcome as a whole to me and that I think a lot of patients and family members would consider those things that you are considering observer-reported outcomes as, you know, still classified as a patient-reported outcome although the terminology may be confusing, but I can almost combine those two fields, that's my two cents.

Adrienne Boissy: Hi. It's Adrienne Boissy from the Cleveland Clinic. So, a fascinating conversation. I think part of where the struggle is coming in, I go back to sort of this perception of process versus perception of how I feel or how the organization made me feel.

What's interesting is that I think the perception -- again, just to take it to a conceptual place for a second, what's interesting is that perception is not a reality and, in fact, if you had -- I think that comparison, you know, based on lots of studies about the patient perception of this, if the physician greeted them versus the clinician's perception and the clinicians always say they do those things, and the patients says they never do that.

So, there is a high discordance between sort of the perception of the same process or experience. And I don't know how you capture that because I think it is beyond process and outcome into something much more subjective.

So, I personally resonate with sort of thinking about experience a little bit different. It's not -- there is no black and white, it's not black and white that the process occurred or didn't because one is measuring my perception of the, if it occurred, which is influenced by how you made me feel not just whether or not it occurred or not.

And that's really important to remember because we know that, you know, comorbidities, length of stay, all these other things impact the perception that make it so hard sometimes to move the needle.

The second thing I was thinking about with this doc-reported or patient or family, I would advocate that there are different perceptions. You know, my father just died -- my stepfather just died within a healthcare system and his perception of his care is totally different than my perception of his care.

I think those perceptions are quite different. And I also think that it's, again, a conceptual question that we know patients don't tell their doctors things that they'll go home and tell their friends, meaning because they're afraid it's going to impact our care.

So, a clinician-collected patient-reported outcome could reveal very different information than the patient would share directly themselves. Now, that's -- I'm not aware that that's been sort of comprehensively studied. But I think it begs the different category in my mind because I'm not sure they say the same thing when they're so worried about how it's going to impact the care if the clinician collects it.

So, again, those can answer your concrete language about -- your concrete questions about language but I think part of the challenge which is exciting to talk about is, it is not concrete. And whatever category you choose will have lots of fuzz around it because these issues are much more subjective and important to think through. So, I'll stop there.

Lee Partridge: This is Lee. I would echo Adrienne's feeling about the -- I wouldn't lump the observer and the patient together. And there actually has been some research in adolescent medicine because if you ask the parent about the child's experience of care and you ask the child, you will -- I should say, it's not just adolescents that goes down to -- I think the research actually goes down to nine-year-olds. That will be quite different.

And I'm not sure that -- do we have to sort into so many different buckets, Suzanne and Karen? I mean in the long run, wouldn't we get into some of these issues when we look at the measure itself and look at the questions that are being asked and that (inaudible) they target and whom you're asking?

Sherrie Kaplan: This is Sherrie. I totally agree with Lee because I think the data source …

Chris Stille: Yes.

Sherrie Kaplan: Because things like pain, who actually is going to get it and who's the best source of information about pain? You know, what are you going to do? Even if the clinician administers the pain scale, it's still the pain scale, and the patient is the only source of that data.

So, I wouldn't get hung up on who's the data source. That can be, you know, already discussed. I think what you're getting at, Lee, is that would come from the validity and reliability discussions about individual measures, who's the best source of this information?

Lee Partridge: Right, right.

Sherrie Kaplan: And if an individual who is so compromised that can't give you the information, and by the way, in geriatrics, it's the same deal, Lee, that you ask grandma how she's doing in the nursing home.

Chris Stille: Yes.

Sherrie Kaplan: And she says one thing and then the child, the reporter, says, "No, grandma was a train wreck," and so, they're very different impressions about, you

know, how well an individual is doing when you ask different data sources. I wouldn't get hung up on who's the best data source right now.

Chris Stille: Yes, yes. This is Chris.

(Crosstalk)

Chris Stille: I agree that, you know, I think expanding some buckets makes sense and expanding other buckets probably doesn't make quite as much sense. It might be useful to maybe have a poll about what buckets people were going to choose that they think need expanding.

Karen Johnson: So, this is Karen. And if we didn't expand at all, that would be fine, and if we expand it to this, you know, kind of ridiculous-looking fact that we think is quite pretty, that would be fine as well.

And, you know, again, we just think -- the question really was more along the lines, if we had more labels, would that help clarify anything for the field? And quite frankly, if it wouldn't, I don't think we need any labels -- any new labels.

We certainly aren't going to the extent of trying to say, you know, one person versus another the best data source. So, we're leaving that alone. That would definitely come up in the -- in the evaluation regardless of what label or no label we'd put on there.

Kyle Cobb: And I would just even think about backing up and taking the path of the first level in this tree before we even get into who's doing the reporting.

Karen Johnson: Yes.

Kyle Cobb: And think about the outcome, process, structure potentially patient experience.

Karen Johnson: Yes. So, if we -- if we went to the next slide, Madison, that is I think the next -- the next one. And I think I'm hearing -- I'm hearing that there is some appetite for going ahead and saying, "Hey, there really are and we've seen some process measures that are based on instruments regardless of who is doing the reporting at this point and probably also some structure measures."

So, it sounds like adding that process box and structure box makes sense to you.

I'm a little bit unsure where the folks are leaning in terms of should patient experience kind of be brought out a little differently than outcome. Right now, patient experience is what we would call a sub-domain of the outcomes. So, you know, all this CAHPS measures we just consider outcomes.

Chris Stille: Yes.

Karen Johnson: All those kinds of things. And that's fine if we leave it as it is or …

Chris Stille: Yes.

Karen Johnson: … you know, would it -- you know, would it not dilute or would it make things clearer to bring it outside? I think that's our question for you.

Chris Stille: So -- and this is Chris, and I'm not speaking as chair but just as me too, I think patient-reported measures have matured to the point where they can't all be lumped together just in terms of experience.

There's valuable experience in subjective things as Stephen really nicely pointed out, but there is also, you know, pretty good process measures that may even be more valid as patient-reported stuff. So, I would -- I would argue strongly to broaden them beyond just, you know, putting them all in outcome buckets.

Sherrie Kaplan: Yes, this is Sherrie. The one other thing I was going to add was that the value in parallel in the national clearinghouse's definition for the quality measures, they include access and that's not here. Did you mean to leave that out or is that part of the patient experience or where was access?

Chris Stille: Patient experience.

Karen Johnson: You know, Sherrie, that is a great question. In my own mind, I think of access measures as kind -- in my mind, we have quality measures, we have cost and resources measures and we have access measures. And for access measures, you can have outcomes, you know, what -- you know, is the access actually

happening, or you can have process measures that might help facilitate access or even structural measures.

So, in my mind, an access measure is kind of at the same level as the quality measure. And we didn't add, you know, quality versus cost versus those things on this. But I hardly know a lot of people think of it that way or not but that's how I class -- you know, that's my hierarchy in my head.

Lee Partridge: I would think of access measures as -- also as a potential under patient experience.

Adrienne Boissy: It's Adrienne. I would absolutely agree. I mean …

Chris Stille: Yes.

Adrienne Boissy: The way we've thought about access here is also something to consider, and I'm sure many of you hopefully feels the same, is that, you know, access to the four walls of your organization is one thing, but access to education, access to information, access to your care team, those are all experience measures in our mind.

Chris Stille: Yes. You only have to ask, you know, a couple of patients, "You know, could you get in," and then say, "Well, no, I really couldn't," and then the hospital says, "Well, you know, the third next available appointment is the week from Tuesday but it turns out that that's not really what they need." So, anyway.

Karen Johnson: So, and that sounds like it's kind of another potential argument for actually pulling out that patient experience and talking about that a little so differently.

Chris Stille: Yes.

Karen Johnson: Maybe -- does anybody had any burning -- what would be the way to say it? You don't want to have patient experience pulled out. You think it works fine. So, kind of like the contrary, would anybody like to make that case that just call them outcomes and be done with it?

Kyle Cobb: I could try but it wouldn't go well.

Chris Stille: Yes, I'm not going to try.

Kyle Cobb: That was a challenge.

Karen Johnson: I mean right now, from where I'm sitting, I don't think -- we would actually have to think about the evidence criteria in a little bit. I think we're fine in terms of testing. We still want item testing and we still want score level testing.

So, no matter -- you know, if it's based on some kind of instrument or tool or survey or anything like that, I think we're always going to look for that kind of testing. The question might be what do we do for evidence.

And to be honest with you, for the patient experience things that kind of show up in some the CAHPS measures, you know, timeliness, respect, dignity, those kinds of things, in my mind, they're more like outcome measures than they are like process measures. So, I wouldn't expect, you know, a systematic literature review and quantity/quality consistency as the evidence for those kinds of things.

Kyle Cobb: And they're already seen as subjective outcomes.

Karen Johnson: They are really subjective anyway, yes. Does that ring through that, you know, the evaluation of these measures would probably be the same?

Kyle Cobb: Yes.

Karen Johnson: So, in other words, the CAHPS measures, we wouldn't treat them any differently than we've been treating them all the way along even if, you know, we -- I'll start being more specific with the label that we apply. Does that make sense to you, guys?

Lee Partridge: Karen, this is Lee. I think so. I think I would probably want to go back and look again at some of the questions, which some of the measures might look a little bit more like what I consider to be just the standard process measure.

Karen Johnson: Yes.

Lee Partridge: But I think for 90 percent of them, the measures that we've approved based on answers to CAHPS surveys, they're fine.

Karen Johnson: Yes, and you're exactly right, in one instrument, somebody may come up with 10 or 12 or 15 different performance measures and some of those may be outcomes and may be experience and may be process, it could be a mixture of any kind, there's no -- they will now have to be one thing or the other. So, that would complicate things a little bit if both were in there. But you know, a combination were in there.

Lee Partridge: I don't want to dance away from this topic, but I would be curious to know if some of my fellow committee members were interested or got struck as I was by way up the beginning of the slides we talk about the extent to which the -- whatever we're measuring is relevant for the patient.

It seems to me over the two years that we've been -- or three years we've been evaluating some of these measures, a lot of our questions revolved around the instrument itself and our discomfort with it. And as I -- and (Karen) who's not on the call today would frequently ask the -- about the extent to which a patient or a group of patients were involved in the development of the survey or the instrument.

And I wonder we should be trying to help developers understand a little better why that was relevant and what we were looking for.

Stephen Hoy: I love that, Lee.

Lee Partridge: If silence is …

Lisa Morrise: Silence is a sense for me, so I totally agree, Lee. This is Lisa.

Jennifer Bright: Lee, this is Jennifer Bright. I agree with you very much. And I also think there's a number of emerging best practices or structures for developers to be using as resources, so certainly pointing them in the right direction of what kinds of expectations the patient community looks for when it talks about patient experience would be helpful to them, to be proactive.

Stephen Hoy: Yes, I could very easily argue. I think that the instruments themselves should be co-designed with patients and family members included. And that's everything …

Lisa Morrise: Absolutely.

Stephen Hoy: Otherwise, we'll probably -- you know, it may come out a different -- make it, you know, denied in a different way, but, you know, the instruments themselves absolutely need to be co-designed with patients and families, and that's kind of the piece of healthcare that's been missing for so long. So we -- I think we could all very easily argued that with you, Lee.

Sherrie Kaplan: This is Sherrie. I'm a little bit lost about the definition of an instrument because you've -- if a survey, for example, include multiple different measures that are multi-item measures from different sources, you can put the SF-36 together with the CAHPS measures together with the depression scale, together with all kinds of other information. And the whole thing is a single survey, but it's got these multiple different measurements on it.

Can you help me understand what you guys mean by instrument?

Karen Johnson: So, Sherrie, another great question, and instrument might be the wrong word. We are basically thinking of any -- Kyle, if you come up with something, it could be a survey.

Sherrie Kaplan: Yes.

Karen Johnson: It could be -- like you said like the CAHPS. Those are surveys.

Sherrie Kaplan: Those are surveys, but it could also include item response theory. It could be -- there could be -- - it could be based on something like with the item banks promise where you had a series of questions that where there's inference and you get to some sort of a goal around health-related quality of life, for example.

Karen Johnson: Yeah. I guess, I'm …

(Crosstalk)

Stephen Hoy: And this committee -- oh …

Karen Johnson: Oh, go ahead.

Stephen Hoy: I was going to say this committee also have the functional status …

Sherrie Kaplan: Yes.

Stephen Hoy: … tool.

Karen Johnson: Right.

Sherrie Kaplan: Yes.

Karen Johnson: Right.

Stephen Hoy: And that would be considered an instrument, right?

Karen Johnson: Exactly, yes. I'm kind of using the word "instrument" as a very broad thing. It can be -- you know, these kind of tools. It could be surveys. And it could also be, you know, a one item thing, you know, what is your pain today, you know, or, you know, which, you know, that one question really isn't an instrument but I could -- you know, I don't know another word. So maybe …

Stephen Hoy: I guess, to me to help clarify in my mind, I think of an instrument as something that ensures that the measurement is taken the same way across the facilities, right, so the one details -- the one to 10 scale, the one to 10 pain scale, you know, that can, to me, be considered an instrument because it's, you know, kind of ensuring consistency across the organization.

Sherrie Kaplan: So there's some fidelity and have their -- and we talk about validated instruments so that they are the same across measurements.

Karen Johnson: Yes.

Lisa Morrise: And I think -- I mean, that's where -- this is Lisa. I think that's where the NQF criteria for data element reliability and validity. If you're -- you -- if you're creating a PRO-PM, the data element reliability and validity are the

reliability and validity of whatever instrument is contributing to that measure. And then the measure result reliability and validity -- I would caution against, you know, at least initially requiring patient input all the way from instrument development all the way to measure development because let's face it, there aren't many co-developed instruments out there as patients. There's a lot of work in that area now, but they're -- you know, there -- I think we might slow the movement towards PRO-PMs if we made that a requirement.

And I think making sure that patients are engaged in the measure development and are helping select the appropriate instruments even if the instruments weren't used -- weren't developed with patient like I think there's a way to bring the patient voice and to ensure that the patient's voice is informing what is being measured and making sure it's meaningful in the PRO-PM, but it may not be that we have to require in the same way that you need measure result validity. And part of measure result validity for a PRO-PM is the patient's voice in the development of that measure.

You may or may not have data element validity, but if you have measure result validity, do you need data element validity? So I -- I think maybe that's where I'm sure of leaning on the way NQF criteria have been applied in my understanding.

Sherrie Kaplan: Yes, I don't think -- no, I think -- I mean, we're more confused because I think what's (plating) is -- which has made a collection mechanism with measures, and measures are -- can be multi-item or single item. But remember the validity of any measure is always a score. You're validating the score not a measure, so those scores require replication and all that stuff so you wouldn't go, you know, revalidating necessarily the SF-36 and the population of healthy patients because that's been done a gazillion times.

But again, you're only validating scores. So I think we have to be a little bit careful, and I would look to NQF for better definitions of what you mean by instruments, by data element. And I don't know what that is either and by measures.

And if there are multi-item measures as many patient-reported outcome measures are, because they represented abstract concept like satisfaction with care or whatever, and you have to think back to math. If this is -- if this is math and you got algebra and trigonometry and all these things that themselves require multi-item measures, then I think that would -- that would help me a lot put out those definitions and be very clear about what you mean by them because I think that would help this discussion along. At least it would help me.

Karen Johnson: Thanks, Sherrie. We'll try to come out with something I know in the 2012 PRO-PM report. They didn't use the word "instrument" by itself. They always said "instrument surveys tools" or "instrument tools and scales" or something like that. So I think even at the time, it was a little hard to come up with the definition that everybody was happy with, but the way that you characterized what is needed in terms of the performance measure and how that's different than what we'd be looking for in terms of reliability and validity of the instrument scale or tool or whatever.

The way that you portrayed it is exactly how I'm thinking about it as well.

Sherrie Kaplan: Thanks. Maybe data collection method something like that would help for -- you know, because the same measures as people from the deck collected from two different data sources, one maybe from the medical record and one from the patient may give you very different answers and we may require very different sort of reliability and validity evidence for using that measure in the context that's being used.

So we'd really -- again I think it would help -- at least it would help me clarify some of your thinking on who's correcting the data, where is it coming from versus what -- how are you measuring this, and is it multi-item or single item.

Karen Johnson: So, Sherrie, one more quick question kind of in the weeds, the multi-item versus single item, in my understanding, that comes really into play in how you would show reliability and validity of the items. You would probably use a different methodology. But once you build a performance measure, it would

matter if it's based on a single versus a multi-item in my -- do you agree with that statement?

Sherrie Kaplan: Well, no, because it depends. Again, the attribution comes up then how are you using it. And what's bothered me a little bit in our prior discussions is that when you go to multi-item measure that's developed -- that's been tested and evaluated for reliability and validity at the patient level and now it's being used to discriminate institutions one from another or providers one from another so it's a different purpose. And the validation and reliability exercise is different.

And so it -- that's bothered me before and it's going to come up again when you talk about attribution. Are you -- how are you scoring this and how are you using it? If you're trying to discriminate institutions one from another, then you would use a different intraclassical relation coefficients, for example, and you'd want to make sure that in that case between variance versus within variance, which is there at the institutional level is being evaluated. So yes, not quite.

The individual item, single item measures, you almost always have to use intraclassical relation coefficients. These multi-item measures, it depends on how you're using them.

Karen Johnson: But at the end of the day, we at least agree that we want to see reliability and validity at both of those levels at the patient level and at the aggregated level.

Sherrie Kaplan: Yes, depending on again how they're being used. If they're being used to compare institutions then you have to look at how much between versus within institution variation areas and how much error there is in measurement at the institution level, yes.

Karen Johnson: Absolutely.

Sherrie Kaplan: OK.

Karen Johnson: Sorry to get into the weeds of testing. That's where my brain is a lot of times, trying to get everything straight.

But to go back, let me make sure I understood where you guys were going in terms of meaningfulness. Right now, we do as part of actually our evidence criterion for PRO-PM, we say that we want to see some demonstration that the outcome itself is meaningful or important to patients. So it's not going so nearly so far as to look for a co-design of the instrument although that could be part of it.

But I think we also need -- there's no reason to limit that to outcome measures we -- you know, if we're going to say that there's process measures, and structure measures and experience measures that we're asking patients to spend their time answering questions and telling us about then we would -- I assume I want to make sure that that is meaningful to them and it's not a -- they feel like it's a waste of their time.

Does that at least makes sense to the group?

Sherrie Kaplan: It makes sense, and I will tell you that it's not an easy question to answer because I have three colleagues down the hall who are being financed right now by the National -- the New York Academy of Medicine to try to determine really what patients -- what information patients care about, but yes.

Karen Johnson: Well, and that may -- it may not be a question so much for today but maybe something we can explore with you guys a little bit later because I know somebody talked about that a little earlier, and I apologize for not knowing your name. But I think what we're seeing most of the time that's come through is some focus groups where folks have asked, but maybe there are other things that you may want to provide us in a direction to developers.

Female: Yes.

Karen Johnson: So …

Sherrie Kaplan: It comes up -- the research that the hospital fund is doing is in the context of choice of health plans, but it is an issue that comes up, I think, often when

there are situations in which there is patient choice and return to CAHPS data, for example, as guidance.

Suzanne and Karen, I want to be sure that we get out whatever answers you need from us before we lose everybody this afternoon. And are there issues that you would like our views on?

Karen Johnson: Let's go to the slide, Madison, that is -- I think it was actually -- it's the one right after the one we were on. Sorry, this is a little clunky having to do it this way. Yes, that one, so go back one. Yes, there we go.

So we've talked about this quite a bit. And I think I've heard that having clinician-reported does make some sense -- kind of spelling that out because that's a different animal than coming from the patient or the parent or caregiver or whatever and maybe a little bit of disagreement among the group about, you know, is it useful to split out patient versus observer. In a way it is because we understand that sometimes the perceptions may be different. But we also realize that our current definition patient-reported outcome encompasses that observer-reported, so I don't know that there were strong feelings of the group either way.

And that performance outcome piece, I don't know that we might have a couple of measures like that. But to be honest with you, that classification really that these four groups here come from the FDA. That's where we got that. That's how they defined the outcomes or their reported outcomes. So if this is helpful or, you know, you have strong feelings one way or the other, I think that's probably the next thing we just want to make sure from you guys.

Sherrie Kaplan: To recap, we would be looking at just two under this on the slide …

Karen Johnson: Yes.

Sherrie Kaplan: … patient and clinician-reported …

Karen Johnson: Yes.

Sherrie Kaplan: … differentiating those.

Karen Johnson: Differentiating those probably. Unless there's a strong feeling that, hey, we should go ahead and keep performance outcome even though we may not have actually seen any of that.

Any thoughts from the group?

Sherrie Kaplan: Karen, I'm trying to think of an example. What would one of these measures be?

Karen Johnson: Was it the observer-reported is probably the easiest one because that would be any of those kind of measures where they -- it's the parent who's the informant or, you know, the bereaved person after the hospice patient dies.

So in terms of our criteria, it wouldn't make any difference at all so this is really just a question of, you know, with splitting this out and making it very clear that you could actually be, you know, asking other observers and the patient, you know, would that be helpful at all? And maybe not so much, you know.

Kyle Cobb: There are -- and this is Kyle. There are -- we do have example slides, but there are some measures, functional status measures where they're both clinician and patient-reported so …

Karen Johnson: Yes, yes.

Kyle Cobb: … just to put a wrinkle into that slide one.

Karen Johnson: And it really is tricky, and I'm going back to what somebody said early in the call. And again apologies for not knowing your voices and remembering who said it, but the idea of provider-administered versus provider-reported, we need to make sure we get that straight because again our definition of patient-reported outcome is the idea that there is no interpretation by the clinician. So if there's some kind of an interpretation by the clinician, that wouldn't come under -- I mean, that would be a -- it really is a …

(Crosstalk)

Kyle Cobb: It's a clinician report.

Karen Johnson: It's a clinician report, which is why we were suggesting that we pull that out so. And I think these -- I'm not as familiar with the portfolio so the functional status measures. I honestly don't know which those were if they were straight clinician-reported just based on their observation or if it was …

Lee Partridge: We had some of each.

Karen Johnson: OK.

Female: Yes.

Karen Johnson: OK.

Lee Partridge: No, if we sort it out into these three or four buckets when we actually evaluate a measure, how much will their rules for evaluating the measure change depending upon the sort.

Karen Johnson: Well, right now, and you guys certainly let me know if you disagree, I would say it wouldn't change at all because you -- we would still be looking for the two-level testing that Sherrie described, you know, of the instrument or tool or whatever that was used as well as the performance measure.

And in terms of evidence, functional status, generally we would see as an outcome measure so we wouldn't be looking for, you know, extensive, you know, literature to back that up.

Male: Yes.

Karen Johnson: So I don't know that there would be any difference in criteria unless you guys think of something that you think we need to think about if that makes any sense.

Lee Partridge: I'm not hearing any comments. So did you have the -- are you satisfied that you have plumbed our reactions?

Karen Johnson: I feel like you're a little ambivalent in terms of this. I think it might be useful to go ahead and keep it split out because we do have some measures that are like that and …

Female: Or both.

Karen Johnson: … or both. But yes, if you don't have ideas and we haven't come up with anything about how it would affect the evaluation criteria, it's really just one matter that's being clear in our -- in our written material because again several of our things that we say are based -- you know, it's worded around PRO-PM, but again, you know …

Female: They're process measures.

Karen Johnson: … they are process measures. They are clinician-reported measures that are still based on an instrument, so we just want to make sure that, you know, everybody is clear about what we're asking for for these (critical) measures.

Peter Thomas: Well, this is Peter Thomas. It's a little bit -- I've been monitoring this conversation and trying to get my arms around it. It's a little bit of a nomenclature issue that strikes me. It may not be as accurate to lump them all together under the one title. But I guess, what I'm trying to figure out is -- you know, is the -- is dividing it into subgroups, if you will, you know, is the juice worth the squeeze? Does it -- will it really make things just more complicated or will it really be instructive and clarify exactly what NQF is looking for.

And I guess, my question that -- the bottom line question goes to will this have an impact on -- what will the impact be if we keep them together versus splitting them a part? Will there be any incentive to -- I don't know. I mean, what's the impact? Is the -- is the bottom line just a question of labeling or is it -- and clarity or is it pushing measure development or incentivizing measure development in a certain direction if we decide one way or the other?

Karen Johnson: Well, you know, I think that is what we were hoping to glean from you guys. Do you think that it would help the field at all to split them out or is it -- you know, I mean, there are -- I'm sure there are uses and reasons that we would

want each of these kinds of things, you know, different scenarios that we would want all of these, but developers may be kind of developing the right things and using the right language without us.

Sherrie Kaplan: This is Sherrie. I think I get the prize for being most confused today, and that it might – not good news. So I would -- I lost the plot. What are you trying to do with this reclassification of instrument of measures, whatever. And how is this -- how is this serving NQF? How is this reclassification serving some purpose? Maybe I'm not seeing the context in which this is all happening so there would be a -- you know, this reshuffling would help you put things into buckets that had some property that you're looking for that distinguishes one from another.

Kyle Cobb: This is Kyle. I'll take a stab at that. I think, you know, from our perspective there's been some confusion and understanding through QPS what PRO-PMs are and how we interpret them whether they're a -- the outcome of a PROM or whether they're the use of a PROM. And so there's the difference between a process measure that may just, you know, checkbox of functional status versus what happens like the depression measures and, you know, was remission received or was it stable over six months to 12 months.

And people seem to think and that's very general, and I think give you much data. But there's some -- there have been some questions around is it important to identify the -- the measures that may not be full-blown outcome measures but are sort of leading towards an outcome. And in some cases, we've seen that understanding what an outcome of interest is or determining the outcome of interest for a patient-reported outcome measure may require some intermediate data gathering. And I think that was discussed definitely in the 2013 or '12 report, that there are instances where you will have to go forth and gather to understand what that outcome of interest is. So there may be some utility and understanding what the measures are that are trying to determine that or that are on that pathway, if you will, to becoming a PRO-PM.

Karen Johnson: And for those of you who may not know when Kyle asked that QPS, QPS is an outward facing search engine that you could go in and look for measure so

you can slice and dice, you can look for outcome measures, you can look for, you know, measures that are, you know, looking at clinicians. You know, all these different kind of ways that we label are ways that you can look for measures to kind of see what's out there so …

Kyle Cobb: And similar to our clearinghouse. We would go and look to assess, you know, what measures your -- you know, system may use. And so it's important that we have that information in a way that, you know, it's consumable.

Karen Johnson: Right. So it takes us back to the question. In terms of patient-reported going back, Madison, to the -- I think at slide 14, patient-reported, clinician-reported, observer-reported and performance outcome, in terms of criteria right now I don't see that there would be any difference. So now the question is would this -- do you think that, you know, being a little bit more specific in terms of the labeling would help the field in any way whatsoever. And my gut is that you guys don't think so, but tell me if I misunderstood.

Sherrie Kaplan: So this is Sherrie. I don't want to interject too much here, but I just -- to me all that bottom row does for you is who's the source of the data. And the data source may or may not influence whether or not you think that's the best source of the information you're looking for to evaluate the -- whatever you're trying to compare.

So is -- and I kind of don't get an example of the end one, but who's the source of the data is that bottom row, right?

Female: Yes.

Karen Johnson: Yes, that's basically it, yes.

Male: Yes.

Sherrie Kaplan: So then are you looking to figure out is the measure is from -- is from the field standpoint? Are you looking to sort of sort things into who's the best source of that information? I'm still kind of puzzling about what you're trying to do …

Female: Yes.

Sherrie Kaplan: … with the structure.

Karen Johnson: No, we're not trying to go really that far.

Sherrie Kaplan: No.

Karen Johnson: It would just be a way of slicing and dicing if we went that far. Yes, so if an observer-reported measure came in, you know, you guys as the PFCC Committee evaluating that measure would still have to decide, you know, is there -- you know, is that person the right person to be asking these questions? Whether we labeled it observer-reported or whether we didn't, I mean, that would still kind of come under your purview of consideration of the measure. So the labeling would say nothing about who's the best source.

Sherrie Kaplan: Let me just …

Karen Johnson: So I would say that there are various sources.

Sherrie Kaplan: Yes, let me follow it up with an example of what I was thinking and this is an extreme example, so apologies. And even though it may be -- for example, mortality as a -- as in the hospice situation, so mortality can't be patient-reported. It can't be -- you know, it could be observer-reported. Is that -- so would you be looking for -- if mortality came in as one of the measures that you were looking for to evaluate hospice performance or hospital performance or some kind of performance that does turn out to be patient and family-centered because they're concerned about it, would that -- how would that bottom row play into that kind of outcome?

Karen Johnson: You know, for mortality I don't -- I don't think it would because I don't know that we had ever ask, you know, the caregiver if the person died or not. You know, we go to claims or other clinical …

Female: Correct.

Karen Johnson: … data so it would -- it would never be any of these, I don't think, for mortality.

Sherrie Kaplan: So then …

Stephen Hoy: It wouldn't be instrument-based.

Karen Johnson: Probably not even instrument-based. I doubt it.

Sherrie Kaplan: Yes, right. So I'm pushing this example for a reason, but if -- so now I'm looking for quality of the death at the hospice center.

Karen Johnson: Yes. So there …

Sherrie Kaplan: So now you …

Karen Johnson: Yes, now it will become observer …

Sherrie Kaplan: Patient, right.

Karen Johnson: Yes, and potentially patient-reported if they're still alive, yes.

Sherrie Kaplan: Does it? Well, the -- all right, so yes. So if you're changing the parameters here, now it's not any longer something that the best data source is not one you've got up here. Now does it fall to the patient and family? I'm trying to get the sort of screening how this -- how this is going to work to drop things into buckets for you.

Karen Johnson: I guess, thinking about a quality of the death, you know, I actually think, you know, if it was instrument-based at some point, you could actually ask the clinicians or the process providers themselves so I can imagine that you could ask the observer or clinician, either one, knowing that they may not agree. You know, that's a whole another research kind of endeavor.

Stephen Hoy: Yes, and that …

Sherrie Kaplan: In the case of …

(Crosstalk)

Stephen Hoy: … it lends itself …

Sherrie Kaplan: Go ahead, Stephen.

Stephen Hoy: That almost -- that example almost lends itself to having that patient experience, Sherrie came out of the high level, does it not? Because, you know, was -- you're more so getting at a point of, you know, is the way -- is the treatment going forward to death aligned with, again, those preferences, priorities and goals of the patient.

So it's not necessarily something a provider can report on so it, to me, can almost fall -- you know, as evidence to why you would have that patient experience piece broken out. And, you know, that would obviously have to be in my mind an observer-reported outcome under the patient experience bucket.

Sherrie Kaplan: I'd agree.

Karen Johnson: Yes, that makes sense.

Sherrie, does that help you? I mean, I think the bottom line for us is it may not help anything and we're not wedded to splitting it out. These are just again, you know, this is how the FDA splits those out and we wanted to see if there are -- if you guys thought that that would be helpful or not from the field.

Sherrie Kaplan: Yes, I was more trying to get from your -- from the NQF perspective how the -- how the algorithm works to drop things into this committee and then drop things into various different buckets and how this additional stratification was going to help you kind of sort of measures into what end. And that's why I was trying to puzzle through an example in my own mind that would really spur back further up, drop things through this, you know, branching algorithm and land things ultimately in the following -- in the bucket you've described, but I'm still sort of thinking about that. It may -- I'll just kind of leave it there.

Karen Johnson: Yes, I think it wouldn't help us drop anything in any buckets at all. The most it might do is, you know, maybe let us write some guidance for committees to

think about, you know, if it's a clinician-reported, you know, think about XYZ, but you guys are already thinking about these things anyway and we tended -- we've tended not to like that level of guidance so …

Sherrie Kaplan: I think we've pressure-tested the criteria.

Karen Johnson: Yes.

Sherrie Kaplan: And that -- and it works. I mean …

Karen Johnson: Yes.

Sherrie Kaplan: … that was a question that we had had coming into the conversation.

Karen Johnson: Yes.

Sherrie Kaplan: The nomenclature could be tweaked, changed maybe some more definitions or not depending on who -- whether it's the committee or whether it's a user or index of measures.

Female: Correct.

Karen Johnson: So I would dare say that, you know, there's not a whole lot of appetite to go down to this second/third level going on to those other levels really wouldn't be helpful at all. I don't think they're already included in -- as part of the domains of PRO-PMs although the other levels we're saying is that, you know, depending on who the data sources, some of those domain would fit under a certain data sources but not others.

Lee Partridge: And, Karen, and Kyle and Suzanne, have we also helped you on some -- of the issue that came up at the very beginning the sense of equity of application of the criteria when the -- even though the source of the information is the patient, what we're really talking about is whether or not something happened. In other words, it wouldn't land in our committee presumably as a patient because it was patient-reported simply because it was patient-reported. It would -- it would be evaluated as a -- as a standard process measure.

Karen Johnson: Well, it depends, Lee. When we set-up the PFCC Committee, basically one of the reasons that we guys -- we set you guys up was so that you could evaluate measures that came through that looks like the CAHPS or that look like, you know, from different instruments or surveys. So that was, you know, the original thinking because they're a little harder and you have to think about things a little differently so we ended up bucketing …

Lee Partridge: Yes.

Karen Johnson: … all those measures to you guys for that reason.

Lee Partridge: Yes.

Karen Johnson: You know, we don't do that every time. So, for example, the hospice CAHPS measure even though it's a CAHPS measure that you guys could have handled, you know, I wanted my palliative and end of life care group to handle that one and, you know, fill that expertise.

Lee Partridge: I'm sorry, I confuse you by talking about where -- which committee things land in.

Karen Johnson: Oh.

Lee Partridge: The issue I was addressing was whether or not if a measure came in and the source was -- the data source was patient-reported …

Karen Johnson: Yes.

Lee Partridge: … you consider that a PRO-PM or would you consider that a process measure. And that was -- as I understand it, that was the equity issue that's been raised in other …

Karen Johnson: Yes.

Lee Partridge: … committees, i.e., if it was considered a PRO-PM the evidence standard was different.

Karen Johnson: Yes, yes. So if it came through like an example that Suzanne described early on where it's a process measure came through a patient or parent in that particular case, but it was based on a tool or instrument, we would probably start calling it an instrument-based process measure. So …

Lee Partridge: OK.

Karen Johnson: … we would apply the evidence criteria that we would apply to process measures, but we would apply the testing criteria that we apply to PRO-PMs and other instrument-based measures.

Lee Partridge: And I wondered is the -- do most of my colleagues think that's the right outcome?

Female: This is -- everybody on?

Sherrie Kaplan: Maybe they're all on mute.

Stephen Hoy: Oops. I agree. I can -- I cannot see a reason in there.

Sherrie Kaplan: OK. Time has passed. It's almost 3:40.

And, Suzanne, and Kyle and Karen, should we open up for public comment or is there further discussion you want to have with our committee?

Madison Jung: So this is Madison. We had one question written in via the chat function and it is just, how is financial burden incorporated into patient experience?

Female: Can you say that again, I'm sorry?

Madison Jung: Sure. The question is, how is financial burden incorporated into patient experience?

Female: Oh, I like that question.

Stephen Hoy: Yes, that's a tough one.

Female: I like it. I don't know that it is. I could tell you that it's one of the greatest patient dissatisfiers for many organizations and it's not -- it's not exclusively or specifically explored on traditional surveys.

Stephen Hoy: Yes, I guess in my mind -- this is Stephen Hoy. I guess in my mind, you -- the financial burden's impact on patient experience is relative to how the financial, you know, how the different financial burdens for different treatment options were, you know, expressed and considered in, you know, the shared decision-making of treatment processes.

And I can't -- you know, I can't really see -- I mean, it's very easy to draw a line between the patient's experience but -- and the financial burdens. But, in my mind, the patient experience is again your perception of the care you received. And to me that lends itself only to be was the finances of your care considered as you were, you know, going through your treatment.

Does that make sense? It doesn't really make sense to me. That's a tough question.

(Crosstalk)

Lisa Morrise: I think that's an excellent question. It's not one I have seen addressed on any measures. I think it would be helpful to assess from a patient-reported standpoint the impact of the financial burden. And Sherrie may have some input around how that could be correlated to their payment options. So, for example, our financial burden with my daughter's extraordinary medical needs was limited when she qualified for a Medicaid waiver program. And while she was privately insured through her father's work or my work, the Medicaid picked up the balance of copays and deductibles and that kind of thing as well as covering things that insurance would not cover like private duty nursing for a child with a tracheotomy.

However now that she's 24, our burden for her healthcare is between insurance on the individual market and the very high out-of-pocket expenses. Our burden is significant and it impacts decisions regarding accessing treatment. By significant, I mean, our medical expenses range between $20,000 and $30,000 out-of-pocket first dollar earned every year. So it does

impact healthcare, and it probably should be considered in measuring and could be used than to factor into decision-making in terms of how financing healthcare is achieved. So I think it's an excellent question and one that we could definitely explore. Thanks.

Sherrie Kaplan: Yes, that's a really good point. That's why I raised the issue of access early on because access is where usually those financial burden questions get asked. And they are not as specific as you just described but -- and very often the clinicians don't even know, and sometimes the patients. And very often the patients don't even know until they have experienced the healthcare burden, you know, and then they can't follow through on treatment recommendations because of the financial burden and so on.

But that usually falls under the -- those kinds of questions usually fall under or traditionally fall under the access construct. So it kind of depends on how finely details you want to get them, but access involve -- financial access especially involves insurance, involves the socioeconomic status, initial socioeconomic status of the patient and it involves the billing of the healthcare system so it's very complicated issue. But generally, those questions fall under access.

Female: And I don't remember seeing questions specifically related to the financial burden asked in different measures that our committee has looked at.

Sherrie Kaplan: I count them in there -- the CAHPS -- original CAHPS wave a long ago had a number of questions on access in there, and they distinguish it from availability like wait times and call centers and all that stuff, and they had financial burden, transportation burden, geographic access and so on initially. And I think those have gotten dumped in favor of a much more brief measure, but they're certainly important. And I think that's why, you know, adding that access parameter, the access sort of high order construct in there would be important for at least NQF to consider measures around.

Female: OK. Suzanne?

(Crosstalk)

Suzanne Theberge: Thank you. Yes. Let's see. I think we'll go to open public comment now. That comment do come in via chat, but let's open the line, operator, and see if we have any further public comments from anyone on the phone.

Operator: OK. At this time, if you would like to make a public comment, please press star then the number 1.

I think you have a public comment from (Deana Hayes).

Suzanne Theberge: OK. (Deana), go ahead.

(Deana Hayes): Hello, this is (Deana Hayes). Just focused on therapeutic outcomes, thanks for the call this afternoon. I've learned so much. I'm just really heartened by the great conversation and the insights.

I have a couple of comments or questions. First of all, I wondered if the issue or the category of performance measures should be a part of that discussion whether performance measures should be elevated as a category. If I understand correctly, at the moment, the only performance measure category is PRO-PM. So by definition it can only be a patient-reported outcome measure. But I hear questions about well should process measures be considered or be allowed to become performance measures and should clinician-reported measures be allowed to become performance measures. And I think they -- some of them have actually going to evaluate it as such. So I'm just wondering if that term PRO-PM should be reevaluated.

A second comment is related to the observer weighted issue. And I agreed with Stephen's comment about the patient family focus where it is our intention to be patient family focused. And I just felt like the -- maybe not intentionally, but if it's an appropriate parent, family, caregiver proxy such as for pediatrics, geriatrics or other reasons for cognitive impairment, it seems like those should be -- may be elevated if -- you know, it -- to being maybe secondary to the patient report.

If you can't get the patient report and if we're going to put someone in the position of evaluating the providers the performance, maybe it should be the close caregiver or family member before we're putting a provider in the

position of evaluating themselves. So those are my thoughts and questions. Thank you.

Suzanne Theberge: Thank you. And this is Suzanne from NQF. I'll just clarify. We do have a lot of process performance measures and outcome performance measures but as data source wouldn't be from a patient or clinician, they might be more clinical data, you know, something that you might call from the health record or something like that, so my apologies. We just totally skipped over that whole part of the performance measure around -- in our -- in our presentation earlier as we -- my eagerness to drill down here to the patient-reported measures.

Do we have any other public comments or any last comments from the committee?

Operator: And at this time there are no public comments.

Suzanne Theberge: All right. Any last comments and thoughts from the committee? OK. Hearing none, next slide is just our next steps. And they're brief for this. We will be working on a summary of today's call and we'll share that with you next week and try to get your input. We'll be probably asking some further questions or just asking you to weigh in on what we've written up, and then we'll be sharing that summary. Once it's finalized and completed, we'll be sharing it with NQF leadership and thinking about changes that might be made going forward.

So that's -- and that would be it for this particular piece of work, but we will be meeting again in just a couple of months on August 2nd, which sounds very far away now. But as we are discussing earlier before the call started, June crept up on us pretty quickly, so it's actually coming up quite soon. We'll be talking about shared decision-making. We'll be having a presentation from some of the other teams at NQF. We're doing some work on shared decision-making and they'll be seeking your input for some other committees.

So I wanted to say thank you so much for your time today and for the thoughtful conversation. We really appreciate your input and just thank you

so much, and we look forward to hearing your thoughts on the summary that we'll be sending out next week.

Female: OK.

Stephen Hoy: Awesome. Thank you, guys.

Female: Thank you.

Lisa Morrise: Thank you.

Female: Thank you.

Stephen Hoy: Have a good rest of your day.

Suzanne Theberge: Thanks.

END