

NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
October 11, 2012
3:00 p.m. ET

(Karen Pae): Good afternoon, everyone. This is (Karen Pae) at NQF, and (Karen Adams), Gene Cunningham and Evan Williamson are here with me. We're still waiting for just a minute or two for some additional people to join the call, so but we've just decided to go ahead and transfer the public lines in, but if you'll just hold for a few minutes, we will proceed.

Female: Yes. OK.

(Karen Adams): And good afternoon. This is (Karen Adams), and thank you everyone for being on the call both our expert panel, as well as our public participants and I just wanted to do a quick roll call in case someone is on the line that we didn't catch. So, far I have Lori Frank, Dennis Kaldenberg, (Uma Kotagal), Charles, Moseley, Gene Nelson, Collette Pitzen and Linda Wilkinson.

Is there anyone on the line that I may have missed?

(Marcel Salive): My name is (Marcel Salive).

Karen Adam: Hi, Marcel. Good afternoon.

(Cindy Kelleher): (Cindy Kelleher) with RTI.

(Karen Adams): Great! and I had (Ann) as well. Thank you, Cindy.

(Uma Kotagal): (Now) and this is Uma, I may have to step up the call. I'm waiting for a call from a patient. In which case, I'll come back (on).

(Karen Adams): Certainly, Uma. Thank you.

(John Wasson): (John Wasson) at Dartmouth.

(Karen Adams): Hi, John. Thank you for joining us. We'll be starting in just a minute. We're finishing up the queue getting in.

(Audio gap)

(Karen Adams): I just wanted to make a quick announcement. We see from our virtual log on that Ethan and Jim have joined us. We know that you can web stream through your computer, but we encourage you if you can please (ring in) as well because certainly if you need to provide comment, we'd like to be able to hear from you, so if Ethan and Jim, if you could (ring in) to the call online as well that would be terrific, and we're going to get started.

Laurie Burke: This is Laurie Burke joining.

(Karen Adams): Great! Thank you.

(Audio gap)

(Karen Adams): OK, so good afternoon, and this (Karen Adams) and as (Karen Pae) said with our other teammates, Gene and Evan, and we're going to get started. First, Patti and Joyce are going to be (ringing in) but out of respect to your time, we'll get things rolling. Thank you all for taking time today.

(Ethan Basch): Oh, hi Karen. I'm sorry. It's Ethan. I would – I'd called in to the other number where I think you couldn't hear me. So, I just called back in. Sorry to interrupt.

(Karen Adams): Oh, great! Thanks, Ethan. We're glad you're here. I was just getting started.

So, I just wanted to take a moment to speak to the purpose of our call. You received a draft report that (Karen Pae) had sent to you and this was the (staff's) best attempt certainly with your guidance and input to try to capture all the rich discussions over our to workshop.

Today's we're going to review the report and take your high-level comments. We're doing this in preparation for our public comment period, and we always like to meet with the expert panel before this goes out to public comment. We will be, of course, circling back with you after public comment so that you know what was said, and certainly, to get your ongoing guidance on shaping the final polish of the report.

So, this is another step along the process where we value and need your input, but there will be another opportunity certainly as we move in to the public comment period. There may be some times during the public comment period particularly if it's a specific question where we know you have an area of expertise that we might reach out. But we'll keep you abreast of the progress during public comment, and we're actually very much looking forward to getting that feedback.

So, I just wanted to give you, you know, a bit of an overview of the purpose of the call, and what it's leading up to as we – as we work to our process. I think I'd like to also share an approach, and we hope that as expert panel member this approach is comfortable for you as we tackle the paper today.

So, first thing we'd like to do is have a high-level feedback from the group. I like to call this the pulse check. So, it's really helpful to know if you feel the report overall certainly, you know, there's going to be recommendations and further guidance from you. But it's good to get a big picture pulse check on how you feel about the report. So, we'll start with that.

And then we'll move into taking a deeper dive into each section and, you know, getting your input there. We feel on this call, and we found from prior experience that we certainly welcome your input, that it's best that if we kept our comments high level and (worthy matic), we certainly welcome any additional redline edits that you would like to provide and, of course, this paper will be going to professional copy editing. So, we didn't want to, you know, burden you with any of that. So, I think that if everyone agrees on the call that we'll work on more of the high-level conceptual type of comments, and then offline, we can do the actual words (missing) if you feel that's necessary recognizing that words are important.

As we go to this process, we will be collecting real time, some of your high-level theme so you can see that – it will be screen shared and report it back to us – report it back to you. So, you could tell us if we're capturing that right and in the spirit of what you wish to offer.

So, before we dive into more of this broader overview, I just want to make sure everyone is comfortable with the approach, and we can – we can certainly get started. So, I'll take a pause now.

Patricia Brennan: This is Patti. I just want to let you know I've joined the call.

(Karen Adams): Great!

Joyce Dubow: And it's Joyce also. I want to let you know I'm – and there's a mistake on the information we received.

Male: Yes.

Joyce Dubow: That's the problem

Stephan Fihn: Steve Fihn, I'm on as well.

(Karen Adams): Great! Thank you.

Greg Pawlson: Greg Pawlson is on.

(Karen Adams): I apologize. OK, so we have Steve and Greg and then, of course, Patti and Joyce. Terrific!

So, Patti and Joyce, I just gave a brief overview of the purpose of the call and our time line certainly in that there – this is in preparation for public comment, and we'll be moving on to meet again with the group after we get back public comment to get their ongoing guidance.

So, Joyce and Patti, I'm going to give a quick roll call so that you know everyone who's on the line with us. We appreciate the member – expert panel members who are able to join us today and then we'll get started.

And I did provide the overview of our approach providing high-level comments that we'll capture the themes real time, and certainly, we welcome any specific redline edit offline.

So, joining us, we have (Ethan Basch) is joining us. Patti, Joyce Dubow, Steven Fihn, Lori Frank, Dennis Kaldenberg, (Uma Kotagal), Charles Moseley, Gene Nelson, Greg Pawlson, Collette Pitzen, (Marcel Salive), (John Wasson) and Linda Wilkinson. And we also are fortunate to have our commission paper authors with us in (inaudible), Cindy and Laurie.

So, we're set to go. Joyce and Patti, I wanted to turn it over to you for some opening remarks and then we can turn it to you to the discussion on the high level kind of big picture feedback from the group before we dive into the report section. So, Joyce and Patti, I'll turn it to you.

Patricia Brennan: Thanks...

Joyce Dubow: This is Joyce. I just want to thank everybody for joining us today. It's already 10 (into) 3, and I want to make the most of their time. So, thanks for joining us and let's get down to business.

Patti?

Patricia Brennan: You come before me (inaudible) Joyce. You want to start?

Joyce Dubow: I think that Karen gave an introduction before on I (don't hear) what everybody else has to say.

Patricia Brennan: Fine. I think that she is asking first for our high-level comments. So, I'll begin with you Joyce.

Joyce Dubow: Oh, I'm sorry.

Patricia Brennan: This is Patti Brennan, and I'm from University of Wisconsin -Madison, and I've been co-chairing this activity. First, I want to commend the office for taking with very large amount of information and trying to place it into a coherent context.

The theme that I got as I finished the draft report was that we are talking about improved accountability and performance improvement through better patient reported outcomes, but the challenge of doing that is the problem of measurement that the measurement challenge exist on two levels, first, on capturing the phenomenon and then on converting that capture into some type of a metric that allows one to make a quality appraisal and to then convince both the method development audience, as well as the clinical audience of the importance of doing this work.

So, I want to make sure Karen and Karen that that's what the message that you had hoped I would (get) from it because that's the message I got.

(Karen Adams): Patti, I think that's very consistent, and I (inaudible) stated, and if only I could have captured that better in the intro or the executive summary. So, thank you for that high-level synopsis, and I welcome feedback from the rest of the members of the groups.

Patricia Brennan: I just – I just have two points I want to add to...

(Karen Adams): Sure, certainly.

Patricia Brennan: ... but hitting it right, and I think the words accountability and performance improvement should be in the first paragraph.

Kathleen Lohr: This is (Kathy) Lohr, and I absolutely agree with that. It's too varied the overall arching – overarching purposes.

Patricia Brennan: So, if you bring that forward, I think it would be a lot clearer, and the second point is that the report itself addresses the problems of capturing the phenomenon other than the problems of creating the accountability metric. So, if you will, the PROMs are better addressed than the PRO-PM.

Joyce Dubow: This is Joyce. I guess I've been playing baseball inside too long because it's always a task in understanding. I think when the steering committee or when the CSAC reads these reports that purpose of an NQF measure is quality improvement unaccountability. So, I took it on safe value that that's what it

was, but I think that these reactions are important because maybe we just need to reinforce that all the time.

My general reaction is that this document should be pretty useful in guiding the thinking of both measure developers and those committees that are going to be considering the measures that have come across the (trend) some – when they see these Patient-Reported Outcome Measures. I think some of the comments have been very useful though, and I'm eager to have that conversation with the committee because I think that's where the report can be strengthened to address some of the – some of the issues that were presented.

I particularly saw (Charles') recommendations on how to strength this would respect to thinking about populations and measures to include people with disabilities were very important and very useful in my view.

(Ethan Basch): Hi, it's Ethan. I was going to make a couple of global comments or would you prefer to stay with that train?

(Karen Adams): Ethan we're accepting global comments now?

(Ethan Basch): Yes. So, I really enjoyed it. I thought that it was, again, I would echo the comment that this synthesized a large amount of discussion and really brought that together. I think it would be reasonable to bring up accountability and actionability (shore). I – to me the, you know, this is really a blueprint and, you know, I think we spend a fair amount of time talking about the purpose of doing this and giving background and then we provide the figure, and I think it might be useful to actually spend some of the body of the document annotating that figure.

You know, I think that some of the boxes are little bit abbreviated and to kind of draw them out a little bit more, and I apologize as I missed that in the document itself. So, that sort of one high-level comment, you know, because I think this is, you know, there – as was pointed out in the meeting here, there kind of two disparate groups. There are people who develop (pure) measures and there are people who do performance evaluation and the two haven't really connected that much in the past and actually the point that could be made upfront that.

You know, one of the purposes of this document is to kind of bridge those two, would also provide methods that both, you know, both can use but I do think this is a blueprint for both of those stakeholder groups in order to tell them how to actually do it, and as such, some of these boxes will make sense to one group, some of these boxes will make sense to the other group but, you know, there a number of these boxes that people might scratch their heads at.

I had a couple of other very global comments. You know, there is a fair amount about shared decision making and improvement of clinical care. I think it's important to note that into this aggregate shared decision making and improvement of clinical care from performance evaluation, you know, there are cases where we might, you know, might send out surveys to people and, you know, that's not used for shared decision making. It's not used for, you know real-time clinical practice improvement, and in fact, it may not be desirable. You know, there are some settings where you actually want to collect the information but not feed it back in real time to improve, you know, communication or patient centeredness or symptom management because of Hawthorne affect. They may actually change the results that you're trying to measure.

So, you know, I think that that actually is worthy of mention. I also thought it would be useful to draw out the distinction between PROs as a process measures versus an outcome measure. You actually get into this, but there's not really like a little introduction there that says, "You know, there are two different ways to think about this or they're multiple but, you know, two main ways. You think that this is the process or an outcome. What are the cases where we think about doing it, you know, as a process, and what are cases where we would think about using as an outcome," and I think that the downstream discussion is actually very strong where you kind of get into the detail of, you know, why, you know, when it might be more desirable to use one versus another, but it's kind of missing that introduction.

You know, so people might not actually understand the context of that which is that, "You know, hey this is actually can be a process measure not just an outcome measure." You know, we're getting to that point in our beliefs about

the important of patient centeredness and there are emerging data about the value of PROs that might justify that.

And then final thing is that you might want to draw out the discussion about risk adjustment, a little bit more as it pertains specifically to PROs or the patient-reported information. There might be some special cases that we discussed when we're all together.

(Karen Adams): Ethan, thank you. (Inaudible) back into those who are following along on the web, we're doing some real live capturing of these themes. We've gotten some – just to do a quick and certainly we welcome a few more broad-level thoughts, but the notion of bringing accountability and performance measurement. They may enforce in bringing up much further. I think, you know, we're hearing that as a repeated theme certainly and Charles, I'm going to welcome your input on this particularly as we move forward, but Joyce mentioned and, as well as Ethan that as we would think about end users and measure developers and then those who will looking at the endorsement process in evaluating in that bridging, and how this can be of utility to them.

But as far as in the document, how do we make sure explicit the diagrammatic flow and kind of annotate that in such way because some of these as we – as Karen and I are looking at each other. There are two Karens. It's so intuitive to us. So, we will give that another (go to). I certainly welcome feedback. You've mentioned some things around the group with very passionate in regard to undertaking the process of shared decision making and that this (aggregation) comment there.

I know Gene Nelson and others on the call who have been very (immersed) from this work can offer us additional thoughts or guidance there. So, this is and, of course, you had talked about the risk adjustment, so these themes that Karen has just captured here very, very helpful. I'm a little bit of the time master here, but I do want to allow if there's anyone else who has some global comments because certainly we want to move into the individual sections, but I think this more overarching comments are very helpful in framing the work.

So, I'll pause now and see if anyone else wants to add.

Charles Moseley: Yes, this is Charles Moseley. I do have some global comments. I enjoyed reading the document, and when I went through it, I tried to kind of put on my long-term support spectacles and read it with those kinds of outcome measures and performance indicators in mind, and I was struck by – with the exception of the kind of detailed description around the psychometric properties that needed to be there. The document really focuses on a (tutor) or relatively time limited medical care and does not really address the kind of broader – the nature of the performance measures outcome indicators, the use of the data, the purpose of the data that is really evident...

Female: Did we lose him?

Male: I think so.

Female: Sounds that way.

(Karen Adams): Charles, I think he may have...

Charles Moseley: How about now? Do you have me back?

(Karen Adams): Yes, we do.

Female: Yes.

(Karen Adams): Thank you, Charles.

Charles Moseley: We had Comcast come in and put in all of our phones yesterday, and we're finding that we're dropping things out of calls. So, sorry about that, I'll try again and let me know if I drop off again.

Anyway, what I was getting to, I'm too sure when I stated out, but I would think the introduction that would be important to mention that what you're really talking about here is relatively short-term medical care that is asking...

Female: Oh, dear.

Female: Oh, dear. Yes.

(Karen Adams): Let's just pursue I guess...

Female: Yes.

(Karen Adams): ... for a minute. Is that the intent?

Female: No, the intent was to be more...

Female: Intensive?

Female: Yes, exactly.

Female: Yes.

Female: So, I think...

Charles Moseley: Was to be more comprehensive did you say?

Female: We want to be more inclusive not...

Charles Moseley: Oh, mm-hmm.

Female: ... (inaudible) to acute care.

Charles Moseley: Well, I think there needs to be several changes then – revisions to the document to really fully explore the differences in long-term care and validate the kind of indicators that those groups that will be submitting them for review will be submitting.

Female: So...

Charles Moseley: It really – it really goes from the various, and I provided just some of my feedback various focus on committee participation and employment on the one hand to looking at the use of proxies on the other. We found, for example, with – people with– doing outcome measurements among for services for people with (intellectual) disabilities is we have a sizeable number – 35 to – excuse me – 25 to around 39 percent who are able to provide an answer but can only do so through a proxy. And so there needs to be...

Female: So...

Charles Moseley: ... some mechanism to include that data not necessarily to mix it with the self-report data but at least to include it and record it.

(Karen Pae): Charles this is (Karen Pae). We can work with you offline a little bit more on that and one thing you might be thinking about is some specific example measure that we...

Charles Moseley: Sure.

(Karen Pae): ... could maybe even do in the appendix to show how it applies...

Charles Moseley: OK.

(Karen Pae): ... or where it might be different. So – you know, our intent is first to be inclusive, and I would assume that the categories we talked about from the very beginning of PROs being functional status, are health-related quality of life, experience with care, symptom and symptom burden and health behaviors. Those apply to long-term support service recipients, right?

Charles Moseley: I think generally, functional status is more of a background descriptor so that you can cut the data by people with different kinds of personal or environmental characteristics. Do people have a change in functional status as a result of the services that they're (doing)? We hope that they do, but there – those can be very long.

(Karen Pae): Right. So, we can work more with you offline, but I think that's exactly what the report is trying to get at that if you're measuring PROMs and developing a PRO-PM for that target population then the tool and the measure that's constructed need to be relevant. So...

Charles Moseley: Mm-hmm.

(Karen Pae): ... constructing a measure of improvement may not be relevant to that population. So, I – we can certainly draw that out more, and we'll work with you about that.

Charles Moseley: Great!

Kathleen Lohr: Yes. Could – this is (Kathy). I wonder if I could just add that the criteria from Dave Cella at (old) paper that talks about modern methods kind of thing may have some sort of amplifications there that will address a bit of what Charles is talking about.

So, it might pay to think about some of these within the context of those – of that whole first paper and tables and the appendix.

Charles Moseley: Sounds good.

Female: That's really helpful. So, I think we...

Charles Moseley: (Inaudible).

Female: ... we would have time for an additional overarching comment, and Charles I really appreciate you willing to give us a little bit more time offline so that we can be much more crisp in adjusting this because as Joyce shared our intent was to be inclusive.

So, I want to open for anymore overarching global comments as we move to the – before we move into the paper section.

Stephan Fihn: No. This is Steve Fihn, and I'll just enumerate three that maybe you can tell me if they are specific for the sections or, you know, but I'll just be very brief. So, one the – and maybe (Gene) can depart this one is I got a little hard for and over the alternative – the way the alternative pathway was presented, and I don't think that in my – maybe I was hearing at very different view, but that it seems to me given, you know, it's not really presented in the paper as a lesser pathway just a different one, and I didn't hear in the meeting, and I don't agree with that but now that – leave that one.

Number two, you know, there was a lot I thought that went in the discussion about sort of generic approaches, you know, but particularly looking at the overseas and other examples at other places that really I thought provided some thematic sort of guidance about what's being done and what seems at

least an early returns to be working in terms of the very types of PROMs that are being employed and really this sort of opens it up to the universe of PROMs, you know, sort of from the get-go and I wonder if it really what needs to be laid out as more of a pathway of what early efforts might look like versus, you know, what this might look like a decade or two decades from now when we have more experience under our belts, and specifically that again gets back to the issue where, you know, are we going to take some starters with some more (nearly) focused ones, where there is a lot of data and so on and so forth and move to sort of the harder ones.

And three, you know, I think, you know, I – let me say, I think this is a great paper, and I really like it, and I thought you guys did a heroic job. I just wonder, again, thinking about users and readers. It does operate more in a conceptual and theoretic framework – theoretical framework, and I know that anytime you pull out examples and that sort of seems to me, you know, would perhaps convey that you're endorsing, you know, a specific measure or something. I know that's very hard. But, you know, I was kind of left with the sense if this is going to be read by people developing that, you know, how are they going to know, you know, specifically with their specific measure, you know, how well it fits in and, you know, I don't know if you want an appendix or some way to give some more sort of concrete examples or something that would, you know, I think add out sort of a dose of reality to this.

So, those would be my three comments.

(Karen Adams): Steve, thank you very much and certainly as we get into the discussion of the flow, we welcome, you know, your additional thoughts here particularly around how the alternate pathways are described. I think certainly as Ethan spoke to the annotation (that would) be helpful there. We did have discussion around generic and where to get started and whether we should, you know, I know there were some things offered around perhaps (tip) or the advantages of those – of these disease specific and generic approaches, and I think here too, because this is conceptual and we want to bring it down from these guys so to speak, I do think some of kind of case study (Karen Pae) and I were discussing about mean or maybe I know David Cella had played out

something in his paper, but we had talked about maybe the depression being further played out because that is (inaudible) PRO-PM.

So, we really appreciate this feedback here, and we can certainly pick another layer at it as we move through.

Joyce and Patti, only because of the time, and I want to make sure everybody o that line are we comfortable with some of the broader themes that we've captured. It is being real-time captured on your screen to make sure we're getting it right, but we can open up for another one or does the group feel comfortable to move to the sections?

Patricia Brennan: I'm prepared to move at the sections. I want to thank everybody for the very careful read and comments in the last few minutes have really very clear why committees are more important than singular reviewers.

Joyce Dubow: Amen.

(Karen Adams): Great! Any objections to the group for moving forward?

Female: No. May I ask if we have questions or considerations, might we forward those to you offline, and you can decide to include it or no in future discussion in order not to derail the discussion moving forward?

(Karen Adams): Certainly, and certainly...

Female: OK.

(Karen Adams): ... to our (WeBWorK), you just want to shoot a quick e-mail, we'd be happy to do that...

Female: OK.

(Karen Adams): ... and to thank you. And one thing I wanted to mention that we – as with all NQF processes, we do have our call open to our interested public comments. We were very pleased at our workshop to have such a robust and expert public following. So, we will make attempts throughout our comment that if there

are people joining us on the line, you know, to particularly invite them as well.

OK, I'm going to move us to the introduction and just to offer a little rational, I think consistent with the overarching theme of our work and of person centeredness et cetera, we did want to introduce some linkages around patient and family engagement, improved outcome, how this is nested within a patient-centered environment or patient-centered care, and we did bring out the national quality strategy because certainly from a broader policy perspective, this is – this is there.

You know, we – one thing that was brought out not only in the papers but in our discussions is that by engaging patients and using PROs and PROMs that, you know, this could be a step around along that pathway. So, just a little bit of rational based on the guidance we received from you earlier and then naturally we just set up the purpose of the paper.

We try to keep that the same. I have to admit, I did a lot of cutting back on my end here. So, welcome any additional guidance. We did hear, of course, with the earlier comments in regard to bringing up the accountability and performance improvement, but I will pause now for any overarching guidance and specific guidance, of course, on the introductions.

Lori Frank: This is Lori Frank from PCORI. I think you did a great job narrowing in on the specific project goals on page two with those three bullet points. I would just suggest that the introduction should move there more quickly as it is, the role of patient report in performance measurement is a point that's not made until close to the end of the introduction, and I think making that point early as well as a point that the focus is on what is and is not unique about PROMs in performance measurement should be made as soon as possible. The other points about engagement as a process versus as a potential outcome, I think might confuse the opening part of the introduction for some readers.

(Karen Adams): Thank you, Lori.

Patricia Brennan: This is Patti. I found myself really very confused about the second paragraph one, page two with – before the case is made that PROMs are important.

We're running into challenges about the PROMs. And so, I think that could just be reworded into a more positive way that the goal is to accelerate their use, and we are going to address measurement to do that.

And I agree with the plan earlier to try to make an example. The one that's provided here to me didn't quite clearly – I give the example and it introduced already idea of process performance instead of outcome performance and I think that's a new one, second come much later.

(Karen Adams): Example might be yes. OK. Great! Thank you, Patti. Any other comments in regard to the introduction? I'm hearing some certainly excellent (building) or framing the argument, comments and just framing it. You're speaking to Patti that we jump to the problem without speaking to why this is a good solution (inaudible) with you.

Kathleen Lohr: (This is Kathy) Lohr. I would say in restructuring the introduction, it might help if you had about three subsections with some headings. One, about the overall purpose which we talked about already and bring the accountability and performance improvement up as, you know, the shining goal for NQF. And then something about patient-reported outcomes and information we have there. And then something about what the project was actually intended to do. Right now, it seems disjointed in some fashion or it doesn't flow that way.

And you might also, even though this is a short document, consider whether to say that the remaining parts of the document cover guiding principles and this and that and whatever, just so people have a roadmap at the end of the introduction as to what's coming next.

(Karen Adams): Very helpful structuring, Kathy. Thank you.

Linda Wilkinson: Linda Wilkinson here. I don't know if this is too low level a concern but in the definitions of patient-reported outcomes as – I'll give you the shorthand version – "information we get directly from the patient without intervention by clinicians and others." If we're going to re-include the population that, in fact, requires just by definition, assistance by others in making the report, you may, at a later date, want to look at ways to clarify that they are, in fact, included nonetheless. That's just a consideration for later.

Female: (inaudible) just made that point, too.

Female: Yes.

Linda Wilkinson: Oh, pardon me.

Female: (inaudible).

Female: (inaudible).

Female: (He did) in his comments.

Linda Wilkinson: OK.

(Karen Adams): This actually reinforces...

Female: Yes. That's good.

(Karen Adams): ...this point.

Female: Yes.

(Karen Adams): Yes. I think that we wrote – the original definition wanted to emphasize, of course, they're much...

Linda Wilkinson: Sure, you know, that's understood how we got there. Just thought I'd sort of add that thought. OK.

Laurie Burke: Well, this is Laurie Burke and on that very same point, I think it's important not to expand the definition of PROs but, yes. Then you may want to include other types of report beside patient-reported outcomes. Nothing can be patient-reported unless the patient reports it.

Female: Well, not necessarily...

Laurie Burke: When they want to include – oh no, that's clearly a very critical foundational definition. If the patient doesn't report it then it's not patient-reported. If it is going to be report – recorded as an interview where the patient still reports

back and still be patient-reported. But an infant cannot produce a patient-reported outcome, nor can someone who is cognitively impaired.

Male: Oh, well, certainly, the personal cognitive impairments, intellectual disabilities can certainly report. The challenge...

Laurie Burke: OK, they can report. I'm not saying they can't but they cannot...

Male: No, let me finish. I think the challenge comes when you have someone who might need some careful explanation by a family member or a friend or another person as to what, in fact, questions (that's been) asked and what are the alternatives to chose from in terms of the answer and then what – how to deliver an answer that reflect their own perspective.

So, it can get really muddy in the process. I don't disagree with you, however, it's important to identify...

Laurie Burke: Right. And that's the reason we have to keep our definitions...

Male: ...the separateness between those answers that come from the individual themselves and those answers that come with assistance from another person. I think those should be kept separate.

You may or may not, as I mentioned before, decide to analyze them together in the date depending on what your goals are in terms of the measurement system. But I do think it's important to crack those two because the responses are, as you mentioned, different.

Laurie Burke: Right. And that's exactly my point. I just don't want to mix up patient-reported outcomes from – that are not reported by the patient. Now, that's why we have added a term to our discussions here called observer-reported outcomes.

That's where patient's family members need to help interpret or assist or add some (learnt) information to what the patient reports directly. But that needs to be clarified and not represented as something that the patient, themselves, is reporting. For example...

Albert Wu: It's Albert. I think that – this is Albert. I think it is important not to at least conflict with the existing definition – NQF is coming a little bit late to the game. It'll be better not to invent any new classification that conflict directly with existing classification.

And I think that the, you know, the patient perspective versus the clinical perspective is easy. I think that, you know, sort of, when you talk about child measures or proxy measures for people who can intermittently respond for themselves, you know, I think that you can speak for people who are reporting for the patient but some way or other, you need to clarify that that is not the individual themselves who are reporting.

Female: Correct.

Laurie Burke: That was my point, originally, (inaudible).

(Karen Adams): So, without tampering with the definition, can we somehow, include those proxies by simply recommending that they be stratified – that the responses be stratified?

Albert Wu: Well, you know, I mean, another way to do it is to say that, you know, to think about things in – and I think that some figure which describes what you're doing is – could be important but there are certain things that are essentially from the patient's perspective and there are things from the – or patient/client perspective – slash /person perspective – and there are things that are form the clinical perspective. And...

Female: So, I was exactly...

Albert Wu: You know, and that's – and that's how you could – you could do sort of a little bit of a lump there.

Female: Well, I was thinking about the proxy, but the non-clinical proxies.

Albert Wu: Yes, yes. And as long as we – so we're talking about (inaudible) family members and...

Female: Right.

Albert Wu: You know, and so forth.

Male: Yes, I think making sure that they are identified separately and that the rationale for including them together – for merging them, aggregating the data – is found and reflects the purposes that they're trying – that the administrators of the survey are trying to do.

I still think that you can have a PRO, you know, performance measure that includes, you know, a provision for including a proxy for some of the time or even all the time for child health. You know, I don't think we have to call them – call those an (inaudible) performance measure. You know, so you could lump them all under PRO performance measures but just somewhere I think you need to, at least, have your definition of what a – strictly speaking what a PRO would be just that.

Male: I think, typically, I mean, what you do a lot of times – and we certainly do this with co-indicators data – is we look for self reports on more subjective areas where the person is clearly the one who knows best. The proxy responders are – is a different segment of the survey that tries to – or that focuses on more objective measures that another person might be able to make an appropriate determination about but are not necessarily the same.

(Karen Adams): So this is – I'm Karen. And certainly, this is a very important conversation. And I think that (anyway) because of valuing everyone's time and progressing too, I think that we have been – the issue has been raised about the definition and certainly, we have quite a bit of discussion around the proxy not only in the methodological section but certainly, as we present the definition, we will capture these important considerations.

And I believe it was you that said, you know, at this point, NQF isn't going to advance different classification schemas. I know that would be outside our scope. But I do think importantly to capture this, that important nuances of this conversation, the staff will reach out as we put forth that definition and make sure that we get this included.

I think that – I did want to—just out of making sure we can get as much guidance from you as possible for the whole paper, if I may impose to say that, unless (we feel) we've not thoroughly addressed the introduction, I would like for us to be the guiding principles. I do think some of the scenes that are emerging and being captured real time, our study is built (to there as well).

Would everyone be agreeable to that?

Female: Yes.

Male: Yes.

Male: Yes, and I just wanted to add one comment, actually longitudinal to that, which is that, you know, it has to do with the definition of "patient-reported outcomes." And, you know, I think that this guidance applies to measures of say, symptoms and maybe global health status and functional status, or mental health functioning, but it may not really apply to measures of satisfaction with care or other sort of care process types of stuff that we may care about in quality assessment or performance assessment but that may not really need to go through this kind of rigorous assessment.

For example, you know, were you satisfied with the discussion of prognosis? Now, you know, you could argue that maybe something like that should go through this but maybe not. But a lot of this stuff that's in, like CAPs or (Picker) measures. You know, although they are patient-reported and, I guess, technically could be considered patient-reported outcomes, I don't know that this whole paradigm applies to that. And you might want to qualify that.

I might even go a step further to say that maybe some behavioral stuff may or may not, you know, be appropriate here, like around smoking or nutrition. But again, a lot of that stuff is patient reported. I don't want to get you off track but I think it's an important point.

Female: Right. And just to kind of go back to what we purposely, at the beginning of this project, purposely included, experience with care and health-related behaviors as in this general category of patient-reported outcomes because of

the way that – first of all, they're patient-reported and also, for example, even health-related behaviors can be influenced by intervention.

So – but you're right. Not all things might apply equally and we can (inaudible) where we need to make some distinctions.

Jennifer Eames-Huff: This is Jennifer Eames-Huff, PBGH. I also have a comment that I'd like to make on the introduction that I haven't heard anybody say yet that (inaudible).

(Karen Adams): Hey, thank you, Jennifer.

Jennifer Eames-Huff: So, like everyone else, I think you guys did a great job in putting all this information together and doing this. I think – the one thing that I saw about the introduction that really stepped out to me is it really was good at focusing on the problems and the challenges without the balance of what we already do have and what we can build upon.

So, it gives the impression that – it does highlight some of the activities or things that have already been occurring in the field that we do have. For example, I think there are a lot of PROM measures out there. But when you read that it's saying it's not been widely adopted in clinical use, it sort of – people could drive to the conclusion that we don't have a lot of measures but that's not necessarily the case.

And when I've been involved in some of my work with the AMA-PCPI or other organizations, when they've started to delve into developing PROM performance measures, the challenge that they've had is that there are so many – like (inaudible) are using a wide variety of measures out there that there's no agreement on one. So, it gives the indication that there is, I think, a lot more activity beyond the use in clinical trials in terms of provider (inaudible).

Female: This is...

Female: (inaudible). Go ahead.

Jennifer Eames-Huff: It doesn't point to, at least, on the performance measurement piece of what has been done internationally. And that there are other places that it has been done and is being used. And that's another place that we can build on. So I think there's a foundation of work that would be important to elucidate instead of just (planning out just the challenges).

Lori Frank: This is Lori Frank. I think we can use this as a segue to guiding principles because my suggestion here was to add a brief section between introduction and guiding principle to reference past experience with patient report as quality indicators.

(Karen Adams): OK. So, I think, a theme that we're hearing from the introduction with (inaudible) overarching is that we know there are challenges but we should shine a light on some of the bright spots and things that we can build upon. And then Lori here suggested, perhaps this could warrant a (small) section. And as Steve indicated earlier, that (pulled) from some of the key lessons learned from our international as well as our national examples that were featured (inaudible) had upon. And so, I think that this is advice well-taken and we appreciate that.

So, Lori, since you've allowed us to segue into this guiding principles gorgeously, thank you, I'm going to ask the group now is we can – we've gotten some really good (shoring) up of this intro and context is critical. And so, I'm going to now ask the group if we could turn our attention to our guiding principles.

If you recall, what we tried to do in this section, you had provided input after our first meeting to a SurveyMonkey. We hope and we did our best but, of course, with your feedback and guidance, we tried to distill not only what came from the feedback there but also, if I may say, I think we had a terrific panel with – on this and particularly, Ethan and Patty and Eleanor and really, I think, I think crystallized some things with us.

We coined the (DCs), Patty and, of course, I think Elizabeth Mort really helped us with kind of thinking around the various levels. Steve, I think, that

might also speak to the – where do we get started that you were addressing so smartly in your overarching premise.

So, just these are relative (inaudible) process and rationale. So, through that (distillation) of feedback from the SurveyMonkey as well as some of that rich panel discussion, we felt that this was overarching and guiding our work and so we positioned it here. So now, I would like to be able to open that up to the group and get your comments.

Lori Frank: This is Lori. I'd like to press my advantage then on the guiding principles. And my question is, are these principles or are these criteria for evaluation? And I think it's very important to make the point that these are the same principle against which – or criteria against which any quality measure should be evaluated.

(Karen Adams): OK. And I believe Eleanor is trying to get in from online.

So, Eleanor, can I open this up for you and then I want to answer this question with Lori. I saw something from the website.

Male: Operator, you may have to open Eleanor Perfetto's line or bring her in to this speaker's line if she got on it?

Operator: OK.

(Karen Adams): Thank you. So, well pardon us for that interruption but as we're bringing in our panel representative.

So Lori, you're posing a question – guiding principles versus criteria. One thing that we have heard, not only from this group but also from others is that there's a lot of criteria in this phase and so what we are trying to do is we have the NQF endorsement criteria and as this is the guiding principle were used...

Female: Excuse me.

(Karen Adams): ...because our (operational) discussion was around how do we start to locate PROMs that might have a state of readiness to (go down) that.

Female: Could I...

Lori Frank: The (inaudible) has consequences for how you use evidence then.

Female: Right.

(Karen Pae): This is (Karen Pae). And that's a good question. When we get to the section on, you know, implications and recommendations related to the criteria, you'll see that some of these principles really show up there. So, for example, the recommendation that there should be evidence of actionability or the principles of (person-centeredness) shows up and we would want to see evidence that people providing this information were actually involved in identifying outcomes of importance.

So, I think they're related but we put them here as guiding principles and certainly, we can get your feedback about whether those things that need to be translated into criteria have been or if you have suggestions of doing this another way.

Female: Could we call them attributes?

Kathleen Lohr: Well, this is Kathy Lohr and I thought the guiding principle's idea was fine and sort of, you know, foretell something that might show up later with respect to actual criteria for evaluating for endorsement.

My problem, in a way, is that I would have thought the fourth leg of the chair for guiding principles is the whole set of psychometric attributes that must attend to any either PROs or the PROMS, you know, the tools that are used to measure them and they got really (short thrift) compared to the three things here that are far more abstract and sort of intangible.

So, I would certainly try to add a section that is very much oriented toward the measurement properties and attributes of PROMS before you go off into the other stuff like, you know, that has 12 syllables in it.

Male: Yes. And (inaudible) also. I think (inaudible) of the first paragraph, you can say, you know, in addition to the required measurement properties and, you know, these guiding principles.

Male: Yes, I kind of think that being psychometrically sound or whatever words you want to use really should be right up there along with the other principles as one of the key...

Kathleen Lohr: Yes. That's what I'm saying. Thank you.

(Karen Adams): So, we need to make the intro that we have now where we basically say, "the workshop participants agreed the psychometric processes were, you know, kind of the baseline." We need to further amplify that and so – because we – that introduction because as I'm hearing from Kathy and others, you know, that certainly – we spent a lot of time on those and that perhaps pulling out some of those key areas – so it's just...

Kathleen Lohr: We can – we can bring that forth. Thank you.

(Karen Adams): Right. (I got it.)

Male: The one thought that I did want to express and I referenced in think in some of my comments were under meaningfulness, the third bullet of consequential. I think – and maybe I don't think this is necessarily exclusive to long-term support but I think it's important that information that is gathered through this be used by policy makers and system administrators to improve service delivery over the broad spectrum to prove not only public policy and private policy, if you are an MCO, but also program operations and outcomes that are achieved by broader systems activities.

(Karen Adams): OK, thank you. So, I wanted to – so, in addition to this guidance and further amplification of the psychometric key, I want to make sure (into which) you have put forth attributes – I want to make sure where the group is on guiding principles.

(Karen Pae) (inaudible) help these were mapped to the criteria but Lori, I think you made a very important point that losing that would be not to our

detriment. So I want to make sure that, you know, these were kind of the overarching framing.

So, if we're not comfortable with guiding principles – I used that terminology because it's something that we've used before in this case. So, but, you know, certainly it's up to this group if you prefer attributes or if you prefer some other – we were just trying to discern between the NQF-endorsement criteria and these were overarching things that we wanted to permeate our work.

Male: Well, you know, down below, you have in the NQF endorsement section, you actually have endorsement criteria and then up here the guiding principles. And I think maybe it's not entirely clear, you know, what's enforceable and what's not and what's kind of, you know, -- you know, touchy-feely or, you know, sort of what should be, you know, how we're feeling about this as opposed to what we actually have to do.

And, you know, you may want to think about capturing of what's up here and put it down below. For example, you know, it should be demonstrated through prior work that a measure yields information that, you know, that is meaningful in a particular population in a particular context of use. And that's actually discreet and could be considered a criterion.

But, you know, I think currently, that kind of lose up above in the guiding principles. I actually sort of like the idea of guiding principles only because it's sort of an introduction to the reader what we're thinking about and what our orientations is, where we're coming from. And so I like it, you know, as long as things that appear up in the guiding principles aren't necessarily mutually exclusive with what's down below in the NQF criteria.

And, you know, to be very specific within meaningfulness, I would add in something about, you know, within the context of use, which is something that I think was discussed a fair amount at the meeting particularly by Eleanor and Laurie Burke.

(Karen Adams): Great.

Kathleen Lohr: This is Kathy. I'm just going to weigh in saying that I believe this section with the title of Guiding Principles is perfectly fine. It comes up front and you can weave an (arc) of a story about going from principles to criteria or measurement – you know, properties of measurement tools or something like that. I think the language is fine.

I wanted to draw your attention, though, to the last paragraph in patient-centered – or person centeredness. And actually note that we've shifted from patient-reported outcomes to person-centeredness which is probably fine. I think that's what we intended. But in that third paragraph, it starts out importantly, you've hit on important point whether it belongs under person-centeredness or meaningfulness or something – I'm not sure. But this idea that people get their – the information back in some fashion or other, whether it has to do with shared decision making or not, is kind of buried there but I think it's an important point.

What I wouldn't do is bring up this idea that somehow, doing the patient-reported outcomes responding to questionnaires or whatever is such a burden. It may be that it's good to say getting information back offsets some burden. But this came through as more negative with respect to how much trouble it is to fill out these forms or whatever.

And if you're moving down the road to things that are (IRT) and CAP – computer adapted testing – the burden can be really pretty low and so, I wouldn't throw that up here as a – quite such a potential negative about this. Getting information is important in its own right and it's not simply to offset some problem about what a pain in the neck it is to fill out these questionnaires.

(Karen Adams): OK. Thank you. Go ahead.

Joyce Dubow: Karen, it's Joyce. I just want to come back to the point that I think Lori made when she was first talking about the guiding principles. And that is that these really apply to all measures, not just PRO-PMs. And, you know, we'd hoped that all measures would be meaningful to the audience who are using them, et cetera. I mean, you could go down the list.

And I don't want us to convey the idea that these things are such oddities that they are, you know, so vastly different from the kinds of principles we might apply to other kinds of measures as well. And I think we should make that point someplace.

(Karen Adams): Thank you, Joyce. You know, it was interesting, actually when I was drafting this section, I was thinking the same thing. It's like, didn't we went there? You know, or I was just looking with another group where we were looking at measure gaps and they brought out either disparities or (inaudible). So I will incorporate that in. I think now, to keep us a bit on time, I want to do a quick recap so that we feel comfortable moving to the next section.

It seems as if guiding principles – the heading and the segue, there's a relative level of comfort certainly in that we make sure that it is not very deliberately to the criteria and Karen and I would do that. We want to ensure that the psychometric properties at our favorite Table 4, as we've been affectionately calling it, gets further amplification.

We also want to make sure – I think Kathy, as you were saying, that the important thing is that – and Patty, of course, you say this much more eloquently – but the patient needs to derive value and benefit from this because if they're only just continually giving you information but they're not getting it back and being able to use it and quite frankly apply (as we see), you know, we're not getting there. So, we will look to further sharpen that.

So, I think with those comments that everyone is comfortable – and Joyce, as you had said that, you know, in our preamble to this, you know, these certainly aren't unique to PROMs and perhaps PROMs offers an opportunity to refocus on how these things really are important.

So, I think that we have gotten – and I would like to thank the group because certainly, this write up reflects a distillation of our workshop and your feedback on the survey and additional comments. So, I think that, you know, it really reflects you weighing in on several times.

So, as long as everyone's comfortable, I'm going to turn in over to (Karen Pae). And we're going to move to the pathway. So, (inaudible) back here?

Albert Wu: By the way, it's Albert. I'm (inaudible) in an airport. I'm going to have to sign off in a minute.

Female: OK.

Female: OK.

Albert Wu: And could I just read my two comments? One is that you could turn this sort of a negative – this is not so (good news) unless you think into a positive and to say that, you know, in fact, these require, you know, an equivalent or less burden that getting most clinical test.

Which is true. And, you know, less pain, less burden. And you know, even though they're – you know, the means of obtaining that data are different that getting those conventional measures.

And the thing that I want to end with this is that this section on page 7 which says, it is process measure a mark for patient engagement. A current – the way it's currently written, I had to read it sort of a few times to understand really what the point was. So I think that that just needs to be (recasted) a little bit.

And I think the answer is – and I think the answer is no. But in any event, I'll leave you to figure that out.

Female: Thank you, Albert.

Albert Wu: Thank you very much.

Female: Thank you.

Albert Wu: See you. Thanks, bye. Bye guys.

(Karen Pae): So, this is (Karen Pae) now and we're going to move in to the section on the pathways from the PRO to the NQF endorsed PRO-PM. And I know that we've already talked about that suggestion that we have more text explaining these steps. I think maybe it would be best if we looked at the steps and then,

you know, we can certainly enrich the narrative explanation that I think, maybe in the interest of time, we should identify if there are issues with the pathway as it's currently configured and what those might be.

Kathleen Lohr: Well thought – this is Kathy. I thought it was much clearer than the one we were – you know, the draft that we were working with at the last workshop. And although I might have some quibbles with language and whatever. What I really want to do is say could you please make the – all these colors, which are useful, less vivid.

(Karen Pae): OK.

Kathleen Lohr: And pull them down into very pale pastels. They can still be different colors. And then turn all the text in to black because I couldn't read. With the colored one or the one in black and white. You have to remember most of this is going to end up being...

(Karen Pae): No, that's very good. Thank you very much. That's – we'll definitely do that.

Kathleen Lohr: OK. Good.

Stephan Fihn: So, this is Steve and I mean, I don't know if you want to get back to the comment I had about the alternate pathways.

(Karen Pae): Yes. Yes, please.

Female: Sure.

Stephan Fihn: So, you know, -- let me expose my bias. I think the alternate pathway is an inferior pathway. There may be reasons why you would pursue that and I think you do address that in some way. But the language of the text and the figure are rather neutral. And it almost sounds like, well if you really don't want to go through all the trouble of validating your measure and doing all the thing that we just so nicely laid out in those principles, what you can do instead is, you know, just kind of, you know, wing it. And, you know, say that this is a really important area. You don't really give those criteria for

what, you know, what makes it not suitable – or what makes it, you know, important, you know, for those things.

And I could see, you know, lots and lots of folks with – you know, perfectly, I mean, I think defensible in that – you know, I'm probably being a little bit, you know, overly dramatic here but, you know – you know, maybe places with, you know, good causes per measurement but we're actually – the homework hasn't been done yet and needs to be done.

And yet, you know, a point in case is made for why we need to measure here and hold everyone accountable. I mean, I would disagree with Albert that almost all the measures that are using medical tests are (inaudible) phenomenal. They're using data that have been collected for another reason or because, you know, in the best of circumstances, those are clinically warranted tests and experts have agreed that, you know, that test ought to be done in that patient.

In this case, we really are asking patients to take some time and energy, you know, for a good cause but, you know, with their expectations that, you know, their care would be improved as part of that. And they're already getting bombarded with all other sorts of questionnaires as well.

And so, I think, my own view is that, you know, you will have to make a very strong case to use the alternative pathway – the alternate pathway.

(Karen Pae): Steve, could I make a suggestion?

Stephan Fihn: Yes.

(Karen Pae): I had the same concern that you did and I tried to play with words. And I would suggest, just for the discussion, to see whether you think "a preliminary step along the pathway" would suffice as a substitute for alternative.

Female: Could somebody clarify in looking at Figure 1 what you mean – meaning by the alternative? Is it the stuff in purple? Or something else? Or I missed something entirely.

- Male: Excuse me everyone, I'm going to have to step off the call. The telephone guys are here to fix our line. So, I will communicate though over e-mail. So, bye-bye, everyone. Nice job. It's great working with you all. Bye-bye.
- Female: Thank you.
- (Karen Pae): So, Steve, I'm assuming you're talking about 6.1.
- Female: That's what I'm wondering because you have text that's called "diversions" which isn't quite the same thing as an alternative.
- Female: Right. I did not interpret 3.1, 5.1 and 6.1 in the purple as necessarily alternatives.
- Female: But I thought we had discussed that...
- Male: It says that in the text. There's a whole section, two pages, of the alternate pathway.
- Female: Right.
- (Karen Pae): And wasn't that because we thought that in some cases we weren't going to be able to come to an outcome measure so fast and we wanted to be able to acknowledge that the process measure might move us along. Isn't that the origin of the alternative?
- Female: OK. Is that what's on pages 6 through 8-ish that says "diversions from the pathway"?
- (Karen Pae): Yes.
- Female: OK, all right. Well, yes – I wasn't – and I think I'm going to be in agreement with a couple of the people that I thought there was way too much about going off under these process things and what-have-you and not nearly enough with respect to test about walking people through what you actually want them to do.
- (Karen Pae): OK. No, that's good. That's a good point.

Female: And like I said, I'm looking for – you're going to talk about a pathway and then an alternative, somewhere maybe it needs to be tied back – if you're only going to have a single figure – tied back to the part that sort of illustrate whatever these diversions are.

But they're getting an awful lot of play for the process that you could almost think of talking about, not as a diversion from the main pathway which is the crucial goal. It's the boulevard you want to drive down.

(Karen Pae): Right.

Female: And the process elements to it might be sort of an adjunct to really focusing on outcome measurement because there are some purposes that might be served by using PROs but not to drive all the way to accountability and performance measurement. I mean, maybe that it's the alternative-slash-diversion that's not the way to conceptualize it.

(Karen Pae): OK. So, Karen and I were – of course, you don't get to see us on this side – but if we may, because Steve and Kathy, you're raising a very – I think this is pretty critical and I think that from an emphasis point, certainly, we want to describe the pathway the way we want it ideally to go.

Of course, Joyce, as we had discussion during the workshop that there may be times where we can't do the ideal, it shouldn't be the diversion. But that, you know, if we have to, the process pathway might help us.

I also think that visually, what we might want to do – and I say this after the group, is that we first show the pathway the way we want it to be so it's a clear path and then we can show the alternate or something like that.

Female: Yes.

(Karen Pae): But we'll play with that more with you here. But I'm hearing that the emphasis of going to the way we want it and then presenting an alternate as you were saying, Steve, you know, not the superior but the you know, the inferior (set) of data.

Female: (inaudible).

(Karen Pae): OK, great. This is really helpful. It's such an important point on this (call).

(Uma Kotagal): (inaudible) this is Uma. And I agree with that discussion. I think that process portion of it takes away from our really important issue about the primary (driver) being the patient-reported information.

(Karen Pae): Right.

Dennis Kaldenberg: This is Dennis Kaldenberg. When I read this section, I didn't think about this as being a permanent diversion but instead maybe a necessary first step in the implementation process. So...

(Karen Pae): Who is this?

Dennis Kaldenberg: This is Dennis Kaldenberg.

(Karen Pae): OK, hi, Dennis.

Well, you know, that's I think what the issue is that why is that a necessary first step? I think that it's not necessarily – a necessary first step. And that's what's trying to be conveyed here that we don't want to have everything go on the pathway that you first have to have a process measure of whether you're administering a PRIM before you can actually get to what the goal is...

Dennis Kaldenberg: There's some precedent for doing that. If we look at, say the CAPs measure in particular, the initial steps were simply to collect the information and there was less emphasis in terms of how would an individual or an organization would be held accountable for it.

(Karen Pae): Well...

Dennis Kaldenberg: (It was) deemed as a step in the direction of moving the organization toward the use of the measure.

(Karen Pae): Right. And that's the whole purpose of box number 6 is to use the PROM in the real world. The question that we're – I think we're debating here is

whether you need an NQF endorsed performance measure about using the PROM before you move to using that experience and moving directly to then, an NQF –endorsed outcome measure.

Female: Karen, I think that...

Female: Karen...

Female: ...the concern is that if there is an area of patient-reported outcomes where we don't have a good outcome measure and we want to move things along, that a process measure might suffice in the interim until the outcome measure is developed.

Eugene Nelson: This is Gene Nelson. Two cases in point, right now, organizations are being paid for reporting and soon they're going to be paid for performing and it's a run-in period for value-based purchasing. And that's a general issue happening right now to hospitals and other measures – not PROMS – other measures. And as Dennis just mentioned, this has been done in the past four (CAPs-like) measures.

Right now, another specific case in point is Meaningful Use 2 calls for ability in an electronic environment to take patient-reported measures in for a couple of different clinical populations such as MU 2, total joints for hip, total joint knee and heart failure patients. So, the first step – it's a stepping stone – is to be able to bring this into an electronic environment – the patient-reported information.

And then in Meaningful Use 3, the hope is that that can become an outcome measure. So, it's a stepping stone in as much as most EHRs cannot do this today. And there is an agreement between, you know, ONC and NQF to try to make sure that e-measures – e-quality measures are NQF endorsed.

So, there's some, I think, special issues. I have no brief against the point that Ethan and Kathy have made. In general, you want these to be outcomes that are meaningful and important and changeable and yet getting there may be a bit evolutionary.

(Karen Pae): So, I think it should not be presented then as an alternative. It should be probably presented, as somebody said earlier, as a step in the process and probably in a much briefer version.

Eugene Nelson: Yes.

Collette Pitzen: Karen, this is Collette in Minnesota. I have a suggestion. Maybe it should be worded as what we're doing for the functional (test) outcome measures that we're collecting even beyond the depression measures, we simultaneously collect the process measure that helps us assess how well is the practice doing in administering that tool to the population. And, you know, how reliably can we count on those outcome measures.

And we do have a couple of measures and meaningful use 2 that are measuring the outcome.

(Karen Pae): So let me – this is (Karen Pae). So, I've heard kind of two divergent thoughts here. One is that creating a process measure of just administering a PROM is the inferior pathway and the other is that it's a necessary step that we have to include as the main pathway that every PROM has to go through this step of having a performance measure on collecting the data before we can do an outcome measure.

And I – so...

Stephan Fihn: This is Steve, Karen. And I've been listening to this and perhaps there's a difference here. You know, one of the issues with the examples that Gene and others brought up, and we can argue about this to some extent but perhaps the clinical one.

You know, there was a sentiment, perhaps, you know, perhaps not prove to satisfy a lot of people and sometimes not enough to satisfy me. But there was a sentiment that the measures that existed were good. And that, you know – but hospitals didn't have the measurement in place and it would be unfair to them to impose this measurement upon them immediately and then ought to be given some time.

So, the example of pay per performance, you know, the thinking is we know – and basically, we now have evidence that it's probably not true, but at the time, we know that getting urinary tract infection in a hospital is a bad thing and probably could be prevented. However, hospitals typically don't have the measurement systems in place for which to do that. And therefore, we're going to give them some time to develop the measurement system before we impose the measure.

It wasn't really a system to develop the measure. It was really an opportunity to give them the time to develop the machinery to collect and report the data before they were held accountable for (inaudible) the data. You could...

(Karen Pae): And the experience.

Stephan Fihn: Correct. So, in this case, I think what I'm hearing is that actually the measures aren't really even fully developed yet sometimes because they haven't met all the criteria and therefore, we're using their sort of certification (inaudible) – we're confusing the sort of recognition or you know, the betting process with the development process. And I think the development needs to take place before someone comes and says, "We want you to do this."

Kathleen Lohr: Well, this is Kathy and I guess I would just say that if you give this much (credence) to let's have process measures in place before we really start to use patient-reported outcomes, we'll be having this conversation three or five years from now.

That it – it's misplacing the finite amount of energy that can be put to all this. And I would – I guess I would – I mean, I hear what you're saying about the real world practicality but at some level, a lot of this is aspirational and emphasis on let's get to real outcome measurement and the use of those data for these purposes is the principle goal.

And if the process, thus, needs to happen, fine. But it's secondary with respect to the emphasis and the energy that should be put to using PRO – developing the PRO measures and using them.

Female: That's why there's a middle ground. I think Karen painted a very black and white choice. But I think the middle ground is absolutely to target the outcome measures when they're available and when they meet the criteria. That's the – that's the desired end point and that's what we should be aiming for.

There may be some patient-reported outcomes for which there are no measures at this point. And they may be areas of importance to consumers that a process measure might signal to the developers that we have an interest in seeing outcome measures in this area. And it could be a point of departure for the development.

The process measure may suffice. It's certainly not the endpoint but it may be an interim step. So, we should signal strongly, I think, that we're looking for outcome measures and those are the ones we really want to see. But I think it's within the realm of possibility that there will be an area that people are interested in having measured for which there are no outcome measures.

And instead of taking that whole – that whole area off the table, if there is a process that we could use as an interim step, we might consider it.

(Karen Pae): And that was the intent of having this as a side bar versus in the main pathway. That there would be potential circumstances where that's needed. But I mean, we'll definitely, if people have suggestions on how better to display that...

Female: (inaudible).

(Karen Pae): Yes. it may be – and what I'm hearing here and certainly not only to see the (inaudible) but what I'm hearing is certainly, Joyce, as you're saying, the emphasis is the – the emphasis is going down, the ideal or the superior pathway building on the inferior considerations that Steve has (put on), the emphasis in the writing and in the visual is that we have an ideal path.

And however – and maybe that's just language as opposed to documenting it schematically. However, there are times when we don't have outcomes. And particularly when these things are meaningful and useful and important to

consumers, that as intermedian step, that we would go this process route with the goal of not only strongly signaling to measure developers upstream but that, you know, emphasizing this is an interim.

So, I think what we'll do is based on this really important emphasis and we'll go back to the not only to the test but also to the visual representation to (inaudible).

Male: So, what's an example of something that we go to the alternate path? Would it be something like patient-reported comorbidities or patient report of a procedure being done and then you'll look for some associated action. I mean, what are you thinking about here?

Female: Yes, I actually would like that answered. I don't know what we're talking about here.

(Karen Pae): OK. So – this is (Karen Pae). We have some examples here at NQF. So, the measure – the performance measure is simply what percentage of your patients, for example, renal dialysis patients were administered the KDQOL – quality of life measure for renal patients?

So, it's simply are you administering that PROM...

Male: Oh, a process measure, I see. Yes. Yes, yes, yes. Right. I think that that makes – so that makes a lot of sense.

Female: But you could say that in five sentences.

Male: Yes. How many people are being – how many people are undergoing a symptom screen or whatever? What support – yes. I think that's...

Collette Pitzen: Karen, this is Collette again. I just wanted to be clear. I would hate to see a process measure be required before you would bring an outcome measure forward.

(Karen Pae): I agree because there's a – they take a lot of – as you know, just to be clear, if it's a process measure coming though NQF endorsement, it has to meet all of our criteria.

Collette Pitzen: Right.

(Karen Pae): So, if you can go directly to an outcome measure, you, you know, it keeps the resources for performance measure development and testing to where we most want it focused.

Female: I think...

Linda Wilkinson: This is Linda. I think Kathy is making a very strong point and I want to support that choice. I do think that from the front lines of (QI), if we decide to use the PRO, our first step is to reliably – to go ahead and correct the PRO. So, to me it feels like it's – somebody said this is a step or something step – it's a step in this process and as such, you might want to emphasize that, you know, good reliable collection of it across the board is important before you're able to use the measure really effectively to determine, you know, as a performance measure. But probably not much more than that.

Female: This is...

Male: I wondered – remember when I was talking earlier about the confusion with the – the paragraph on patient engagement. Whether that was the intent of the paragraph was to say at some point, the measure of patient engagement maybe the percentage of people who are actually completing the PROM.

Female: Right.

(Karen Adams): Right. So if we looked at –yes, we've looked it. OK. This is helpful here. I think, what do we – we shared with you our – all our calls are open and we do have some public participants who (would speak to us) virtually as well as on the line. So, we did want to have this – an opportunity for any of our public experts who are following if they'd like to comment and then we will move on to the key implications/recommendation piece.

This has been a very helpful discussion and we will certainly make sure that this gets back to you.

OK. I'm going to ask the operator, please. If there's anyone from the public who wishes to come on to the line to ask a question or make a commentary, please queue up to do so. Or optionally, certainly you can send in through the web.

So, let's pause a minute for the public comment.

Operator: If you would like to ask a question, please press star then the number one on your telephone keypad.

And again, that's star one to ask a question.

And there are no questions at this time.

(Karen Pae): OK. We just checked our web chat. So, for those who are on the line, please, we welcome your thoughts but we will – we will (move along), OK.

All right, again, in the interest of time and certainly if any other thoughts occurred to you after this call, please send us an e-mail whether it's a general comment or specific edits, we definitely appreciate that. So we wanted to move in to the next section of key implications and recommendations related to the NQF criteria.

And what we intended to do here is identify – and some of this relates back to those guiding principles, some of it relates to the pathways, some of the other things that we talked about are unique issues with PRO-PM and how those relate to the NQF criteria.

So, again, I'm not going to walk you through this because I know some of you have comments and we have limited time so we'll just get right to anyone's suggestions or comments that we can address.

Lori Frank: This is (Lori). I think this table is helpful but it does reflect the illness orientation instead of the wellness orientation with regard to PRO but that others have noted that the problems associated with the PRO administration are stressed and some of the strengths of PROs perhaps aren't emphasized enough.

And I would just caution the unique issues with PRO-PM column be reviewed carefully and wording changed when the issue isn't really unique necessarily to PRO.

(Karen Pae): OK, yes.

Female: I have one note on the table under feasibility. And I think this may show up in the text, too. But you put down the cost of proprietary PROMs and that's definitely an issue. But are there other costs that might be hint to that? not that I want to undermine using PROs but if, in fact, within the next few years, we really do move much more to computer adapted testing and using PROMIS-like instruments that really give you, you know, the same information, way fewer items and so forth.

Are there costs here of the need for having more computer access for people and that sort of thing? And, I don't know, Gene might be able to comment on that with respect to the electronic medical record stuff. But, I just thought that perhaps there are some other costs that might be mentioned even if what they end up doing is reducing the overall cost of administration of these instruments.

Male: I think that's an important point. I think that our cost to build the infrastructure through which these data are going to be collected and whether those – that infrastructure exist already in a (inaudible) or whether it's going to have to be built or modified by the organizations that provide, you know, the EHR Incentive Program. I think that's an open question. At this point, I don't think that infrastructure exists.

(Karen Pae): All right, (unique to PRO)?

Eugene Nelson: This is Gene. I think we saw in the two international cases two very different ways of building PROMs in. And one was in England. A separate – really a separate apparatus, a bit CAPs-like, has been constructed to add on to care delivery alongside it. A way of getting patient-reported outcomes.

The initial data is to be collected at the point of care but then the follow up data is collected by an independent data collection patient with – part of data collection organization.

Whereas in the Swedish case, literally, the process of care has been modified so that the patient reports feeds into each visit with the clinician and can be used also to monitor how things are changing in between visits to a clinician. So, it's designed into the flow of care in a more integral way.

So, they both have (flaws) obviously but the design in versus the add on approach is quite different in the potential usefulness to the patient and the clinician and getting the assessment matched to the treatment plan and using it to monitor the impact (of three) in planning outcomes that are relevant are quite different in those two approaches.

Female: Well, those sound like ways to highlight perhaps some benefits. And maybe part of the problem with this Table 1 is that this is called "unique issues". And "issues" always implies, oh, you know, problems, barriers, challenges, something or other. And maybe it should be something more neutral like "aspects".

Female: OK.

Female: So that if there are particular points to be made that fall on the benefit side of the equation instead of the, you know, sort of the harm side of the equation, you could draw that out. Or you could even do it with three columns and one is just the standard NQF criteria and one is challenges, at least, potentially unique to PRO-PMs and benefits potentially unique to PRO-PMs.

Where you can reinforce this idea that you're getting a lot from using these kinds of instruments to get at measurement because they not only may play in to accountability and performance and improvement, but they provide some value back to the people who are – particularly if you're feeding the information back into somewhere, giving it to them in ways they can use it. It benefits directly to the respondents.

Female: OK. (Inaudible).

Collette Pitzer: Karen, I'm sorry, this is Collette. I need to exit the call. I'll be happy to follow up with e-mail.

(Karen Pae): OK. Thank you very much.

Collette Pitzer: Thank you. Bye-bye.

(Karen Pae): OK.

Dennis Kaldenberg: it's Dennis, I do think it's important to emphasize however that there are costs to organizations to collect and manage these pieces of information. And any time that a new measure is required, an organization has to put in place personnel and infrastructure to manage that information.

And that is a burden to the organizations that have to do it. Now, the benefits may be great in addition and I think then, it becomes a question of can you demonstrate to the organizations that have to collect this information that the benefits that will come as a consequence will offset the burden with respect to data collection and management?

(Karen Pae): OK. Thank you.

OK. Other...

(Ethan Basch): Hi, guys. It's Ethan. I apologize but I have to run as well.

(Karen Pae): OK.

(Ethan Basch): I'm happy to follow up with anything that would be helpful. But it's a great, great job.

Female: Thank you.

(Ethan Basch): Thanks. Bye-bye.

(Karen Pae): So...

Kathleen Lohr: This is (Kathy). It's – I don't want to reopen the conversation earlier but I'm concerned about the phrase "proxies" appearing in this table.

(Karen Pae): OK.

Kathleen Lohr: Because it's not really developed elsewhere as it appears here. And so I just would caution – I think we know that we need some guidance around that but I don't think the term is the right term.

(Karen Pae): OK.

Female: Well, it might be helpful if you have an abbreviated reproduction, if you will, of what's in Appendix B in that table because I'm under the impression that – or you could refer people back to it but "proxies" are, you know, that – anyway, in measurement...

Female: (inaudible).

Kathleen Lohr: I understood in the (inaudible) here but I just know that there was some question about whether (review want to) tolerate proxies and that's the only point I was making that the issue isn't just use of "proxies" but it's the number of issues about analytical modifications given and, you know, about – I'm sorry, I didn't mean to reopen it. It was – the term – it's loaded, according to this conversation.

(Karen Pae): OK. Thank you. So, this section was intended to try to reflect the discussion we've had in terms of recommendations related to NQF evaluation of a PRO-PM that would come in. so, for example, on page 11, the translation from that discussion that we had earlier in the guiding principles about person-centeredness is that when NQF evaluates these measures, we would be looking for evidence that the measured outcome is valued by the target population.

So, that means, you know, for those who were going to be providing the information on, you know, what did the developer do to validate this with something of value to that population? And so, you know, and that's how this

is structured to kind of go through based on the discussion and how that relates to our criteria.

So, the next section is about evidence. That's whole discussion about actionability and that the health care provider can actually have some influence on the (inaudible) outcome. And how does that relate to NQF criteria and what we would be looking for.

Female: (inaudible).

(Karen Pae): Go ahead.

Patricia Brennan: The third bullet in the bottom of page 12, to me, either needs to be rephrased or eliminated.

(Karen Pae): OK.

Patricia Brennan: Because either it's making a general message to the NQF that they should be always considering the actionability of the relationship between the interventions and the outcome. Or it needs to be – and to explain what this "approach", quote, unquote, might be meaning in this context.

(Karen Pae): OK.

Female: (inaudible).

(Karen Pae): Go ahead.

Female: I'm sorry, go on.

(Karen Pae): No, go ahead.

Female: Were you going to answer Patty?

(Karen Pae): Well, I was just going to say – and definitely other people can weigh in. there seem to be – you know, when the discussion about actionability about PRO-PMs, there were quite a few comments also made about," well, we actually

feel this way about any outcome measure." And that's what the genesis of that was. That I think it bears further discussion.

Female: It might be a separate message to the NQF to clarify.

(Karen Pae): OK.

Female: I think...

(Karen Pae): OK.

Female: On the second bullet, Karen, I think that it's not clear whether you expect the measure developer to do the systematic assessment and grading of the evidence or whether you just need to – if we...

(Karen Pae): OK.

Female: ...how that's going to happen.

(Karen Pae): Right. OK, thanks.

OK. And then the next section is about reliability and validity and basically I think, what we've heard throughout the workshops is that we need to have a reliable and valid PROM and then we need to also demonstrate that we have a reliable and valid PRO-PM. So that's what the gist of this is supposed to be. And welcome your comments and suggestions.

Patricia Brennan: This is Patty. I want to stress that this, to me, is the critical section of the paper, for me at least. And there's nothing in the text about PRO-PM at all. It's just in the recommendation.

(Karen Pae): OK.

Patricia Brennan: And the list in the recommendations of the measure specifications for PRO-PM looked to me like measure specifications for PROM, not for PRO-PM.

(Karen Pae): OK. So we need to make sure that we're really clarifying PRO-PM. Thanks.

Female: And I think it's OK to say – to show your hands here that this is an urgency and there are – this is where issues of design, of systematic administration of rigors of application really can affect the validity of the PRO-PM, and so, rather than acting as if we should know how to do it, we might say there may be many roots to demonstrating this and that each time a promise used in a different manner to create a PRO-PM, there may need to be a different method developed for making that PRO-PM.

Female: OK. OK, any other comments there or we can keep moving through and we can always come back. The next was...

Male: I would make a comment about the third little point under recommendation.

Female: Yes.

Male: It seems to me that an assessment of validity using phase validity is probably the weakest form that we could have.

Female: Right.

Male: And in some respect, I view that as a backdoor to push through a measure that maybe last valid and might be appropriate, so it's just a concern.

Female: Yes. It's been expressed about not just about PRO PMs but other measures, and I – but I – we can certainly address that or at least highlight that as particular concern.

Female: I had one – this is another one, the structure reactions, but I actually think you should number this recommendation and somehow make it clear. They come at the end and maybe the introduction to this whole section should say, we're going to find a set of constructs and some discussion of it and at the end of each of those we'll come about with a recommendation because you know, it was just a little tricky on some of these pages, you know. Did it go with what's coming or what already had been written, so...

Female: OK, thank you. That's helpful. All right. So the next section that we – that's addressed quite a bit was missing date and response rate and you know,

certainly we've talked about the PRO, and again, I think this is probably where we need to make sure everyone understands what we're talking about, that the PRO-PM measure specification should include how missing data are handled.

And I think there was some discussion that having response rate to company the performance measure as potential and this really needs to be analyzed in terms of information that's available and the measures are submitted for evaluation, but I'll stop there and see what suggestions you have.

Female: In some of the circumstances, risk adjustment, missing data, certain to those kind of measurement problems. Rather than say how it should be done, maybe there's a way to convey the idea that there are options, you know, some of (inaudible) paper and all kind of hinted at that, that there's more than one way to skin a cat and people should put forth what they regard as the best approach or may be the better of a selection, you know, a couple that are acceptable or good or whatever. But it's not just do it this way.

Female: Right. OK.

Male: It may be important to specify some threshold under which missing data would make a measure unreliable, and I'm...

Female: What I'm asking here for how the measure developer proposes to address missing data.

Male: I think that's...

Female: We were already helping them to consider the...

Male: Yes. I think – yes, I think you're exactly right.

Female: Yes.

Male: But I think at some point, they have to account for what threshold is appropriate in the use of this for the presenting.

Female: Well, that's fine. My point was simply to try to convey the idea that different measures may have one best way to handle certain things, but there are

probably more circumstances in which a given measure, you could tackle some of these problems in more than one way and developers just need to be clear about what they're recommending, but it might be a couple of different ways.

Male: I understand, that works.

Female: Great. OK. And then, the last section was specifically about feasibility and it seems that at least to consider the burden to individuals as well as the measure's entity, and you know, for most of our performance measures that are not PRO-PM, the data collection burden is really on the healthcare organizations.

And as we've talked about this, also we'll have some potential burden to the healthcare organizations, but also could have some implications for the individual, but you know, this is not real specific and if you have some suggestions then of how we might address this.

Female: Is this intended to guide developers?

Female: Well, the primary audience is first and foremost to guide NQF and our steering committee, so we'll start evaluating measures, but obviously, it translates into what information we're going to ask for developers, which translates to what they're going to need to do.

Female: I don't know if someone else reads it differently, but as I read through the entire paragraph several times, it made me feel that it was saying only that you just can't count on a reaction because other than saying whose responsibility it is, each sentence seem to highlight variabilities, you know, that might occur.

And I'm not sure what the response of the developer to that in terms of gaining more confidence in the acceptability, what they were going to provide. I didn't find guidance there, and maybe this isn't a place for it, but if there was some way to indicate ranges or benchmarks or something to hang on to in designing your response, I would have...

- Female: Right. And that's a good point and we would – if we could be more specific about what we would be expecting to see or evaluate, if people have some ideas about that, we'd like to hear that. And I think and I'm sorry about this, but with the time, we need to ask once more if there's any public comment, and definitely would like to hear from the expert panel if they have some suggestions about this or whether...
- Female: I might send some wording to consider.
- Female: OK. Thank you.
- (Linda Wilkinson): This is (Linda). Yes.
- Female: Yes. Thank you, (Linda).
- Female: OK. So, operator, will you check if we have any comments from our audience.
- Operator: If you would like to make a comment, please press star then the number one on your telephone keypad.
- And there are no public comments at this time.
- Female: Are there any on the web?
- Female: No web comments, thank you.
- Female: OK. So, we can – we have just a few minutes left and everything gets future directions but we think, you know, if you have suggestions for that, we'd love to hear those offline as well or in this last few minutes, If anyone has any comments about any of the things we've talked about, are future directions included or more on this feasibility, we want to...
- (Kathy): This is (Kathy) and I don't have any comments. I just wondered if you could reiterate what happens next.
- Female: Great. We had backed it up for you, so thank you (Kathy) and as Karen said, what we'll try to do in the future directions is capture some of what we call the

burning issues. We don't have them resolved just yet, but please we welcome your comments there and I know (Patty), you would help set that up.

I know that we did dedicate part of the last meeting really freshening up the pathway, but we do from that as well. So we welcome any offline comments there. Just so that you know, the paper is going to public comment, the 23rd of October.

We will make our best effort to incorporate what we've learned today, which has been very actionable. So thank you in concept with what's they're guiding principle. They really exist and has been very concrete things that we can hopefully tackle and do respectfully.

Just so everyone knows that we will be getting back with you, of course, virtually once the public comments come in to get additional guidance and feedback. So, this isn't the end of our journey just yet, but we want to thank everybody on the call because you certainly gotten as much closer to what could be a very useful product. So...

(Joyce): I just want to you to tell us please what your deadline is for receiving comments to be included in the public draft?

Female: Thank you, (Joyce) because that will be – Karen will have to...

(Joyce): Right.

Female: We should – can we send a note up the committee because we want to – we want to be able to camp back with a little bit, (Joyce).

(Joyce): That's fine. I think that we should know so that we can be respectful of your deadline.

Female: Great. Thank you. Thank you, (Joyce) and sorry, we weren't prepared but we'll camp back and we'll send a recap of this...

(Joyce): Right.

Female: ...so that we know.

(Joyce): Right.

Female: Thank you.

Female: And that just brings out that I want to acknowledge and thank all of you for working with us with – I know, very short time frame for this project and we are terribly grateful that you've hang in there with us when we've given you short time frame, but we will get back to you on that.

Female: (Patty) and (Joyce) (inaudible) to the group as we sign off?

(Patty): I just want to be sure that the same meeting that's scheduled for next Wednesday on my calendar at this very time is not going to be held.

Female: That's correct.

(Patty): Fine.

Female: We'll double check (Patty), but that was probably some...

Female: I don't have that on my calendar.

(Patty): I think it's a triple schedule on my end here.

Female: OK.

Female: I think it was a tentative date at one time.

(Patty): Well, there you go. You freed up two hours of my life, thank you.

Female: You know what? I just do want to thank you, the staff because you know, just as we've been hitting to our deadlines, you guys have been really amazing and thank you for your very, very nice work. We really appreciate it.

Female: Amen. Amen to everyone.

Female: Thank you.

Female: Bye.

Female: Bye bye.

Female: Bye

END