NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
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Operator: Welcome to the conference. Please note, today's call is being recorded. Please standby.

Suzanne Theberge: Good afternoon, everybody. This is Suzanne Theberge. I'm the project manager for the Neurology Phase II project here at NQF. Welcome to our Post-Comment Steering Committee Call.

Just to get started I want to run down the list of committee members into a roll call so we know who's on the line. And then, I'll go through the developers as well. And then I'll turn the call over to Karen to get started.

So, Dave Knowlton?

David Knowlton: Yes, I'm here.

Suzanne Theberge: Great. David Tirschwell?

David Tirschwell: Yes.

Suzanne Theberge: A.M. Barrett?

Female: I think she's coming, but (going to be) late.

Suzanne Theberge: Bill Barsan?

William Barsan: I'm here.

Suzanne Theberge: Jocelyn Bautista? Gwen Buhr?

Gwen Buhr: Here.

Suzanne Theberge: Gail Cooney.

Gail Cooney: I'm here.

Suzanne Theberge: John Duda? Jordan Eisenstock?

Jordan Eisenstock: I'm here.

Suzanne Theberge: Risha Gidwani? David Hackney?

David Hackney: Here.

Suzanne Theberge: OK. Michael Kaplitt? Terry Richmond?

Therese Richmond: Here.

Suzanne Theberge: Jack Scariano? Raj Sheth? Jolynn Suko?

Jolynn Suko: Here.

Suzanne Theberge: Jane Sullivan? Fred Tolin?

Fredrik Tolin: I'm here.

Suzanne Theberge: Mary Van de Kamp? And Salina Waddy?

Salina Waddy: I'm here.

Suzanne Theberge: Great. Are there any committee members that didn't introduce themselves and I didn't call?

OK, great. And now, for the developers, American Academy of Neurology, are you on the line?

Gina Gjorbad: Yes, Gina Gjorbad.

Chris Bever: Sorry, Chris Bever and who else?

(Rebecca): (Rebecca) …

John Duda: Sorry, John Duda just joined.

Suzanne Theberge: Oh, great. Thanks, John. Sorry, from AAN, we have Chris, (Rebecca), and who is the third person?

Gina Gjorbad: Gina Gjorbad.

Suzanne Theberge: OK, great. AMA-PCPI, do we have anybody on the line? All right, PQA?

David Nau: We have David Nau and Julie Kuhle.

Suzanne Theberge: OK, great. And AMDA, (Jackie) I think you said, you were on the line.

(Jackie): I'm on the line and Dr. Tangalos will be joining us in the 2:30 hour.

Suzanne Theberge: Great. All right, is there anybody on who hasn't introduced themselves yet? All right, great. I'm going to turn it over to Karen for a little bit more introduction.

Karen Johnson: Well, hello again. Thank you for joining us in this Post-Comment call. We really appreciate you taking the time out of your very busy schedule to talk over the comments that we received on the Phase II measure evaluation. We had quite a few comments and we were pretty pleased with the response from a public that we had in terms of the comments that were submitted.

So, I want to just give you a little bit of background. We've provided the memo for you and we couldn't go through the call pretty much in the order that the memo is written. And as I'm sure you know, we have a couple of major topics that we want talk about including control reconsideration of several of the measures. So, the developers and sometimes the commenters have asked that the committee reconsider some of the decisions that they made on these measures.

So, one thing that I do want to point out is that committee members, you're very much entitled to think about it, read all the information. But there is no requirement that you revote. So, as we go through the call today, we'll be gauging from you your desires about revoting or not, and we'll go from there.

So, if you do desire to revote some or offer or you know some subset of the measures, we will make that – we will make a note of that, and we'll send out votes via a SurveyMonkey tool for you to vote again if you want to. But again, there's no requirement. Because there are a lot of measures that you may essentially want to talk about, I do want to point out that as you know, it's only a two-hour call. We won't have that much time for discussion of individual measures.

So, we will probably ask for this really high level of discussion items if you have them, and maybe handle it that way. And it kind of depends on how Dave and David want to do this because they're going to be chairing our call and handing it over to them in just a couple of minutes. But again, we'll probably have maybe five minutes or a little bit more per measure if you need to do all of the measures that are in front of you.

I also want to note in the memo that I sent out, I tried to summarize for you particularly for the AAN measures the rationales that were submitted in terms of why the comments or think that you should reconsider the vote. And I just want to make sure that everybody is very clear that this is a summary of the stuff that came in, in the comment. It's not necessarily that we agree with all the points that were made in the comment, and it's not that we don't agree with them if those are meant to be purely a summary for your convenience and your information.

And finally, before we start, and one of our committee members, actually, Dr. Hackney, has suggested that because so many of the measures went down in this project on evidence, he asked if we could start the call and our chairs agree that it would be a good idea to start the call and talk a little bit about evidence and NQF's criteria on evidence and the section for evidence.

So, we've asked Helen Burstin to come down as she's our senior vice president. We've asked her to come down and address of these issues. So, Helen, if you are ready, we'll just start with that. And I think what we'll do is just to make this – so let Helen start. And then, if you have questions, I'm sure she'll be happy to entertain any questions you might have.

We'll do that and once we're done with that piece of it, we'll hand it over to Dave and David to start the call.

Helen Burstin: Great. Hi, everybody. It's Helen Burstin.

So, I was supposed to give you a bit of an overview of some of the specific issues which I am happy to do. So first, you know, this is then about the evidence requirement, how long is this going to feature. We did an evidence task force support now a couple of years back. This requirement has been in place now for at least the last year to year and a half – I would guess. I don't have the exact number. So, this came out in January 2011. So I guess it's been in the last year.

It has generally been followed fairly carefully. I think what we've experience is that – particularly for some process measures – well, we oftentimes have less concern about the, you know, sometimes the quality and quantity consistency. I think what we're finding is a lot of difficulties being able to – a lot of difficulty being able to demonstrate the link between process and outcomes. I think that's been the part that has been the hardest.

We also recognize that, you know, measures are at the tail end of evidence development. And oftentimes, the evidence development isn't done in a way that provides that kind of information particularly about the quality and quantity and consistency of evidence.

So, we have, you know, specifically built in those exceptions to be able to allow committees to run a – think it's appropriate to either bring forward evidence that the developer didn't bring forward that they think is important to consider. But also, when they are really in scenarios of measurement where they believe for example, it's going to be incredibly difficult to get that

evidence if the evidence is not yet there that that evidence exception could be invoked.

So, this (inaudible) under a section to take the form of mandate and I try to fully understand perhaps we can have some input there on exactly what people mean by that when the evidence is not there. And I think this issue of evidence with only expert opinion is something we would really to the steering committee for guidance on. We are very closely tracking the IOM report that came out last year on the evidence of – on the evidence requirements for kind of a practice guideline, which also require the quality and quantity and consistency of evidence.

So, we've tried to stay true to that but we also recognize again, as I mentioned that that measure developers are often kind of (inaudible) at the mercy of the – of the guideline developers. So if the guideline isn't done using a systematic review with the ability to specifically quantify quality, quantity and consistency.

We are in lack of an expert opinion and that's why we pull together committees like you to see when there are opportunities to consider an area that is so important that the benefits to patients would significantly exceed the risks, and you would want to potentially invoke your expert input there.

We have had some other panels do a combination of things. You know, certainly, for the most part they have not taken – they have not taken a lot of measures for which the evidence is not clear. There have been some examples of exceptions. For example, our palliative care committee invoked the exception for measures around spiritual counseling for patients at end-of-life knowing that that would be a difficult evidence base to gather, and certainly a place where we thought the benefits significantly exceeded the risk.

And there have been other examples of that. I will tell you that a couple of measures were also similarly invoked on our recent (GIG) pilot. There was a great deal of discomfort about the degree of the use of the exception when it got to our Consensus Standards Approval Committee and in fact, several of those were ultimately turned down.

So, I think we are still in a bit of (inaudible) there's no question. We are trying to feature these criteria for consistencies sake. We added those two exceptions in explicitly to deal with it, but I think it really does come back to the committee to determine how comfortable you feel that some of these areas where the evidence is lacking are so important to clinical care that that potential exception should be invoked or is there evidence that the developer did not bring forward, that (inaudible) forward that would have strengthened the evidence based on the measure.

David Hackney: So, this is David Hackney. It just seems to me that a lot of the guideline developers who were disappointed where developing their guidelines and being quite happy with expert opinion without the kind of evidence and randomized control trials, outcomes evidence that we've been asking for. And that's what they were upset about. They said, "We think this is a good guideline, why aren't you endorsing it?"

And it sounds like you said that for the most part, the NQF committees have not been doing exceptions in those cases, but sometimes they do but I think, it sounds like we were behaving in the mainstream for NQF when we said we need evidence for this. Is that right?

Helen Burstin: That is a very fair characterization. And I guess, the question would be for some of these – that this states that we don't have any measures. And they are obviously high priority conditions, you know, this is where I think the clinical and broad based expertise of the committee comes into play. So, it's whether you know – for some of these areas or they're important enough – clinical areas that were raised towards the exception should have been invoked. I live it up to you.

David Tirschwell: Helen, this is David Tirschwell. It seems like much of the objections that were raised on many of these measures come down very much to that that there is an admission, that perhaps there is not great evidence linking the measured item with the outcomes but that is important enough that the developers consistently thought the exception should be invoked.

So, I realize you're deferring somewhat to the expertise of the committee, but when NQF designed this process and included exemption to evidence, there were some specific words around that – in the documents that I think that we reviewed, that I think it would be important for us to just to have the NQF perspective on when you all thought that would be the appropriate thing to do.

Helen Burstin: You mean on a measure-by-measure basis, David?

David Tirschwell: Well, and just in general, I mean …

Helen Burstin: Yes.

David Tirschwell: … you know, the – you know, it's a little – I guess, it's a little vague as to when the exception should be applied. You mentioned one criteria where the, you know, the benefit clearly outweighs the risk.

Helen Burstin: Right.

David Tirschwell: But it seems like another thing that gets factored into the equation is whether the burden of collecting information is worth the potential benefit that there's no evidence for and I feel like that gets a lot of consideration in these decisions also.

Helen Burstin: Right. Although feasibility is a later criteria, so we'd really want you to separate out the evidence questions from the feasibility. We would get to that and at the end of the day, you would, you know, assume that all coming together – at the end for your ultimate recommendation on the thought.

David Hackney: This is David Hackney again. I guess my concern about the – we don't have evidence but we know we're right attitude is trivial for all of us to think of examples of things that everybody thought was right that was wrong. And that – my mandate was my word that once this becomes a widely accepted standard, then ensures – use it to evaluate the quality of care being given. It gets published as a metric of how well some – a given entity, individual, hospital whatever does in taking care of patients with this condition.

And it's essentially a command that you must do it this way. And if there's good evidence for that that's wonderful. But if there isn't good evidence, patients might be better off if people didn't do it that way. And I think at the point that you're going to essentially require compliance by the mechanisms I mentioned, that we need to be really, really sure. And it's hard to be really, really sure when you don't have evidence.

Karen Johnson: Yes.

Helen Burstin: So, those were all – all fair points.

Karen Johnson: And again, even if you are, you know, invoking a section if the – whenever possible, you'd want to make sure expert opinion was systematically assessed. And it can't just be, you know, it would need to have some demonstrated process. You know, brand – using a brand of appropriate scripture and modify, identify whatever the process was during both the, you know, more than just one or the other reason to invoke the exception.

David Knowlton: This is David Knowlton. I also think that we've done – I said most is a (inaudible) represent (inaudible) and consumers when the NQF standards are unquestioned where they are based in some sound science and not subject to the naysayers. So I'm – I advocated this committee and will advocate today for strictly improved (inaudible).

Suzanne Theberge: OK. Any other questions for Helen about evidence or the exception or any other of our processes in terms of what we need to think about today?

William Barsan: Just one, this is Bill Barsan. So Helen, when you mentioned about getting an expert opinion at all for a modified (inaudible) approach or whatever, that would be something we would have expected the developers to do, correct?

Helen Burstin: Exactly. And so, I guess that's one of the questions as well I think back to you know your discussions with the folks from AAN is, you know, I guess some of the central facts – the guidelines that were used, and the process that was used to determine that those guidelines have moved forward. What kind of process did they use to determine those where there wasn't significant evidence?

William Barsan: Right, right, OK.

David Hackney: Helen, one more question. And I know that in preliminary responses in some of these comments. It's repeatedly mentioned that a standard of care does not necessarily equate a NQF – to equate to an NQF endorsable performance measure. Can you contrast in your mind what those – what the difference between those two might be?

Helen Burstin: I'm sorry, David. The difference between which – between which two?

David Hackney: The standard of care like you find in abundance in guidelines …

Helen Burstin: Right.

David Hackney: … versus a NQF endorsable performance measure.

Helen Burstin: Yes. It's been I think something that has been a major discussion point for several years now. And I think there are some instances where standard of care measures continue to be endorsed, but less so especially if they don't have a relation to outcomes. There are times when we're somewhat surprised by the low rates of performance on things that would considered – be considered a standard of care. And sometimes, those measures, they move forward just because of this significant gap.

David Tirschwell: And finally, Helen, this is one other thing that came up and it may not relate to the evidence criteria, but it does relate to NQF criteria for endorsing a measure. And you can put it in the right category for us all, but pure documentation measure …

Helen Burstin: Yes.

David Tirschwell: … I know that NQF does not have a particularly positive outlook on a pure documentation measure as opposed to something that involves doing something.

Helen Burstin: Yes. I mean, in general, most of those tend to be, you know, fairly basic kinds of measures. We need to be a little careful because so many of – so much of

what we do in the process of care is documenting by a process. So, I think what we try to avoid are measures that would otherwise be almost a check box, where it is the such a simple yes/no checkbox that you're not really capturing any of the complexities of the carrier providing.

Yes. And actually our CSAC guidance specifically said, avoid specifying measures that can be met primarily (free) documentation without an evaluation of the quality of the activity. So that's often the checkbox kind of measure.

David Tirschwell: Oh and it – and which of the four areas that each measure has evaluated on would the question of whether it's, you know, just a checkbox measure and doesn't evaluate the quality of the activity. Which would that – would that be under evidence or where would that be under? Feasibility, usability?

Helen Burstin: It's probably a combination of evidence and validity, so that – you know, that the measure concept being very robust until you actually see how the measure is actually structured, and then, you may question whether that is in fact a valid representation of what you're trying to capture.

David Tirschwell: Sure. OK, thank you.

Karen Johnson: OK. Well, if there are no more questions specifically for Helen. She's going to hang around for a little bit longer, so if something comes to mind you can always ask. But now, I think Dave and David – I'm going to turn it over to you to take us through the rest of the call.

David Tirschwell: OK. You know, the way I envisioned this going and the staff can feel free to interrupt me or Dave if you have a different opinion. Although, there are a lot of individual measures that they're listed at the beginning of the memo. And I guess I thought we should at least open the floor to each one to see if anybody would like to bring up a discussion based on their review of the comments that would lead to at least the possibility you think of us considering revoting on a measure.

Does that sound OK with everyone?

Suzanne Theberge: That's good for me (inaudible) by.

David Knowlton: (Inaudible).

David Tirschwell: OK, I'm not hearing any …

David Knowlton: Yes, this is Dave. I agree too. I had you on my phone, yes.

David Tirschwell: OK, very good. Well, I'll just jump in and maybe about half way through, I'll let Dave start introducing the measures. Dave Knowlton.

The first one that's on the list and it's on page five of our memo is measure 1953, seizure types and current seizure frequencies where the description is that all visits with a diagnosis of epilepsy who had the types of seizures and current seizure frequency for each seizure type documented in the medical record. And it's noted that this measure did not meet the importance criteria mostly based on the lack of evidence connecting it to the outcome.

So, it's not that the committee was arguing that seizure frequency isn't important. It just wasn't clear that documenting that you had asked about it and written it down was going to have an impact on the seizure frequency.

Any committee members have any comments on that?

Jocelyn Bautista: So, this is Jocelyn Bautista. And I think that's exactly right. I don't think anybody argued that it's not an important part of care, but it's just one step in the process, not only do you have to document and ask about seizure frequency, but you need to act on it. And so, it sits along, you know, NQF requirement that we pick the process that is most closely related to the desired outcome.

So, I don't feel that there is any new evidence presented and all the comments that would make me want to revote on this measure.

David Tirschwell: Does anybody else have any comments? OK, then. I suggest we move on to 1954, which is a related measure – also related to epilepsy. And Ramon Bautista was the primary reviewer, he's not on the call today, but he did send in a letter that I can summarize a little bit. But essentially, this one is for all

visits with patients with diagnosis of epilepsy who had the etiology of their epilepsy or are epilepsy syndrome reviewed and documented if known, or documented as unknown, or a cryptogenic.

And this one also failed on the importance criteria. The evidence – there were zero votes that there was evidence linking this to improved outcomes. And again, although I think especially epileptologist or a neurologist in general believe that having the right epilepsy diagnosis has a potential strong impact on patient outcomes whether this measure as it was described was going to get us there, it was felt that there was really know evidence linking that.

And it was also quite a bit of concern that this was going to be applied to non-specialists who it wasn't clear could really do this. I realize that's probably a feasibility argument, maybe more than the evidence argument.

Also, in the staff summary of the rationale for reconsideration, there's mention of this as a standard of care. But again, as we just discussed, just because it's a standard of care it doesn't necessarily mean it rises to the level of having evidence at the (B) and NQF endorsed performance measure.

Anybody have any additional …

Female: No.

Suzanne Theberge: Operator?

Operator: Yes, ma'am.

David Knowlton: Somebody put us on hold.

Suzanne Theberge: Can you mute the line that put us on hold.

David Tirschwell: I think they wanted me to (inaudible) page left.

Suzanne Theberge: Thank you.

Female: That's great.

Male: Hello there.

Suzanne Theberge: A reminder to everybody, please don't put us on mute during the call or on hold rather. Mute is fine, hold is what causes the music.

David Tirschwell: Jocelyn, I don't know – you're an epileptologist. Do you have any other comments related to that?

Jocelyn Bautista: No, I think the arguments are very, very similar to the last metric – these are very …

David Tirschwell: Yes.

Jocelyn Bautista: … important to do clinically, but they're just one step in the process. And so I don't see any new information that would make me want to revote on this measure.

David Tirschwell: Any other comments from committee members?

Chris Bever: Can the developer make a comment?

David Tirschwell: Well, I guess we'd ask the NQF staff for process question. Should we – should we query the developers along the way for each measure or what would be the right approach?

Suzanne Theberge: I think it's fine to hear from the developers. We did have to kind of be so full – overtime. So, we probably need to keep it brief.

David Tirschwell: Well, OK. Why don't – maybe we could have the developers which I think was the AAN. Just comment on the epilepsy measures to start.

Chris Bever: Well, I just want to make a comment on the linkage to outcomes and that is that the committee is asking for basically a study to determine whether care is better if you have the diagnosis versus if you do not.

So in epilepsy patients whether it matters, whether you know the epilepsy subtype. And I would challenge the committee to come up with a trial design that would be ethical and approvable to test that out.

David Tirschwell: I don't think that's quite what we're asking for. You know, I think evidence to show that this was associated with outcome would – could be as simple as a large chart review study showing that the cases where this was documented as suggested, leads to lower seizure frequency compared to cases where there's no such documentation in the chart.

And I think as we try to point – everybody agrees that that it's important to know these things. And it would probably help with seizure frequency, but it's the – it's that first piece linking that this is being documented in the chart will somehow make the difference is I think the part that committee wasn't seeing.

Chris Bever: So, I mean, I guess we don't need to get into an extended discussion of this, but if you actually did that – sort of a study would find that where the diagnosis is documented in the chart, it's a different sort of a treatment environment than one where it was not. Then there would be many other differences that might explain the difference in outcomes. So again, I think this is a difficult study to do.

And sort of (flies) in the face of, you know, how medical practice is done. Generally, we try to characterize what we're treating and choose the appropriate treatment based on a diagnosis.

David Tirschwell: I don't think anybody has any argument with that part.

Jocelyn Bautista: I think all we're trying to say is that NQF would prefer to see a measure that measures the intervention as opposed to documenting the seizure frequency. It is important. Obviously, it's very important to ask the question, to document it. But then, to act on it is even more important and is more of an effect on the outcome than just the documentation.

Chris Bever: I agree with that.

David Tirschwell: OK. I'm going to move on to the Parkinson's disease measures. Number 1973, annual Parkinson's Disease diagnosis review; all patients with

Parkinson's Disease who had their diagnosis reviewed including a review of current medications, and for the presence of atypical features at least annually.

And this again, failed on the importance criteria. Again, it's a – it's really the same question that keeps coming up over and over again. It's not that the committee did not think that having the right diagnosis was unimportant. I think we'd all agree that it is clearly important. It's just the details of just having to go through this process of reviewing the diagnosis, documenting it, then what. And it's sort of the "then what" where the potential quality of care is affected. And the "then what" wouldn't really be documented through this measure.

So that link from this documentation to the actions as Jocelyn was just saying was lacking. Who was the primary reviewer on this? Let's see. It was Michael Kaplitt. Isn't Michael on the call? No. Does anybody else particularly movement disorders – folks, have any comments on this measure?

John Duda: This is John Duda.

So, I want to start up by saying that in the – the AAN's comments about this and the other measures. I thought it was accurate to say that the – some of the neurology subspecialty areas involved in these measures were probably not terribly well represented on the panel. I think it was me and Peter Schmidt who have a lot of experience in Parkinson's disease.

And I think – and so I think that that was a fair criticism and maybe something to be taken into consideration in the future. However, I do think that the importance of this for the Parkinson's measures, this one included. The importance of the concepts brought up by the measures was not disputed.

I mean, I think the panel agreed that, you know, most of this assessing (inaudible) function and psychiatric function, and the diagnosis, and everything – these were all accepted as laudable goals for quality care, but that's not where they failed. They failed because of either lack of specificity in how the measure was going to be assessed or the evidence discussion that we've already had.

For this one, just – I think, you know, it was the checkbox concern that how do you other than putting a checkbox – it might be, if you expected a provider to write down all of the potential atypical features of Parkinson's it didn't say whether or not they're representing a given patient, you know, annually. That's a lot of burden. And other than that, I don't know how you document that they or have a checkbox that says, I reconsider the diagnosis.

I think that was the problem with this one and some of the others that, the specificity of how this would translate from a very laudable quality care guideline to a performance measure. That's been – was kind of the problem and I don't know that AAN response adequately addressed that. I mean, the importance of these measures was well recognized and if – and some of them I think were potentially – I forgot the voting and everything, but potentially able to go through the evidence with an exception. The evidence criteria with an exception, but they failed later on with the feasibility and things like that that was affecting (inaudible).

David Tirschwell: Well, that's not – well, that's not – I mean, I understand what you're saying, but that's actually not an accurate reflection. It did fail on evidence.

John Duda: Well, this one, yes. But I was talking more broadly about all the …

David Tirschwell: Oh, OK.

John Duda: … anyway, for the – but, in this one again, was like I said, like it – there was a concern – there was a checkbox measure, right.

David Tirschwell: There was a concern about that. Although, once you failed on the evidence, theoretically, we don't even discuss the feasibility stuff …

John Duda: (Inaudible) it is what it is …

David Tirschwell: … but validity stuff.

John Duda: … and memo as well.

David Tirschwell: But I – but I, you know, I'm in complete agreement with that. Any other comments from the committee? Did – somebody's typing kind of load near

their phone. OK. Does the developer want to or I guess, actually, why don't we go through the other Parkinson's disease measures. And then, we'll ask for comments from developers.

Suzanne Theberge: Actually, David, if I could just interrupt for a moment.

David Tirschwell: Yes.

Suzanne Theberge: I got an email in from AAN that Dr. Bever has to leave a little early. So, I don't know if he's still on the line. But I know he had to leave around 1:30 or so. So if you …

Chris Bever: I'm still on.

Suzanne Theberge: Maybe we can let you speak now just before you have to sign off. I just saw (Rebecca's) email a moment ago, so.

David Tirschwell: Sure.

Chris Bever: Well, I mean, the issue comes down to the same one that we had with epilepsy, and that is whether you can adequately treat a patient if you don't have an accurate diagnosis. And you know, how do you do a study to look at treatment related to documentation of diagnosis and you know, I think …

David Tirschwell: Was it …

Chris Bever: … we face the same issues that we face with epilepsy basically.

John Duda: This is Dr. Duda again. I guess I disagree. I mean, I think it would be very easy to design a study, to take a cohort of patients and randomly assign them to have an annual – formalized annual assessment of diagnosis, and see if that alters outcomes at all. That ought to be (needing) a study to do.

Chris Bever: Easier in Parkinson than in epilepsy. I agree.

John Duda: And the same with a lot of these measures. I mean, you know, doing a formalized assessment of psychiatric symptoms with and that was a concern – what were to use, but you know, that would be an easy study to design and

conduct to see if these guidelines, which believe me – I believe in them – we, in our own quality assessments look at them as a guideline. But you know, it wouldn't be hard to take a cohort of patients and assign one – and have them randomly do an annual review of psychiatric symptoms if that made a significant difference in treatment or outcomes.

Chris Bever: It may not be relevant.

John Duda: (Inaudible) pay for.

Chris Bever: Right. It may not be relevant, but as a measure developer, we're kind of in the Linus/Lucy in the football situation where we started on this, you know, four or five years ago. And we're working in good faith to develop measures that met the criteria that were available at the time.

And the criteria have been altered over time and we're being held to the new criteria rather than the criteria that were in place at the time that we started the process. And I guess, we can go back and try to develop evidence and address the issues that are being raised now. But that raise is a question whether, you know, in five years when we come back to you, will there be at another set of criteria that we have to respond to. But I guess, again, that's probably not anything that you need to consider in your deliberations, it's not an issue at the level of your committee.

Male: Those of us in the (inaudible) filling out forms for other bureaucracies are sitting over here with that problem.

Chris Bever: Right.

David Tirschwell: Yes, and you know, I guess, especially if these measures are already being used in the Neuro PI stuff that the AAN is rolling out, I guess, it seems to me there should be some data coming in and maybe it shouldn't take five years to get some results. But maybe, I'm too optimistic.

Chris Bever: We will have some data from that and it may not take five years.

David Tirschwell: That'd be great.

Female: I would say, we have data much before that. I think the issue that Dr. Bever was waiting – is waiting for is there to be either another call for a neurology project or for a (seeming) committee to be formed for our neurology measures to be reviewed.

Helen Burstin: This is Helen again. You know, we'd be delighted to try to bring in the neuro measures again, you know, certainly shorter than the three years until the (maintenance) time. We're just you know, (inaudible) waiting on some federal funding to see if that can be done. But we'd love to for example keep a more open process where people can submit when measures are ready.

I also assume these measures will likely be in (Pcare-S). We also might have an opportunity to gather some of the data on the docs who are reporting and kind of bring that forward at the next (federation).

David Tirschwell: Great. Well, I'm just going to proceed along with the other Parkinson's disease measures, 1982, there's Parkinson's disease Psychiatric disorders or disturbance assessment. And this one, in fact, did pass with evidence exception despite the fact that there was no consensus that there was evidence linking this to outcomes yet, despite the fact that it passed on the evidence exception.

It then did not pass because of a lack of precise specifications related to the tools that were going to be used or not used or that they weren't specified, and exactly how this would be – how this was to be done. It was thought to be too unclear.

Is Jane Sullivan on the line? No, she's not. So, any other committee members want to reconsider this measure? OK, without anybody piping up, I think we'll continue along. There are still two more, excuse me, three more Parkinson's Disease measures. And maybe, I'll go through those and then hand off to Dave Knowlton.

Again, that similar issues related to the evidence question, 1983 is Parkinson's disease cognitive impairment or dysfunction assessment where all patients with a diagnosis are assessed for cognitive impairment or dysfunction at least annually. And John, do you have any comments?

John Duda: I think just the comments before, you know, applies well. You know, many of these have similar issues and I support – I encourage the – the developers. And I think his last point was accurate, but like I said, I can't really do anything about the changing target for these performance measures. But you know, I think that some of this – if – like the last one, like I said, it got through the – at the except – I think I voted through with an exception, but – exemption, but failed further down. And those (inaudible) I think could be more remediable in the short term by the developer.

David Tirschwell: OK, thank you. Any other comments on measure 1983? OK, 1985 Parkinson's disease querying about sleep disturbances. All patients with a diagnosis of Parkinson's disease or caregivers as appropriate who queried about sleep disturbances at least annually.

And again, really in an identical fashion failed on the evidence criteria, not because we didn't think sleep disturbances are important in Parkinson's disease. I think all agreed that it is important, but just linking the annual query with an improved outcomes that was – there was really no evidence presented for that link.

I don't know, is Jack on the line and have any comments? I think, maybe, Jack is not on the line. Any other folks have any comments about 1985?

OK. Finally, the measure 1988, Parkinson's disease rehabilitative therapy options. All patients with a diagnosis of Parkinson's disease who had rehabilitative therapy options discussed at least annually. This one did pass again with the evidence exception. It passed it on the evidence part or the importance criteria through the evidence exception, but it did not meet the scientific acceptability criteria for untested measures specifically as related to precise specifications.

There was some concerns about exclusions and basically, I just didn't see my guess clearer enough to the committee to move forward.

Any comments from the committee?

John Duda: This is Dr. Duda. I've kind of the same comment. It seems that this – if the powers to be desired should be amenable to redesign and pre-submission in a form that it should be ought to pass that test.

Male: Yes. And I would just add that Helen's comment about the possibility of reworking a measure application and getting it reconsidered in a timeframe that was less than three years would be a fantastic goal because, you know, based on the fact that at least a couple of these Parkinson's measures passed with the evidence exception, I don't think the committee can be really folded in saying that we never – we never use that and we didn't figure it was important. In fact, we did a couple of these measures failed later for issues related to specifications. So, you know, I think that addressing these issues and trying to resubmit when it's possible would be great.

Any other comments? Does anybody want to suggest we open up any of these Parkinson's disease measures for re-voting?

Any further comments from the AAN developers related to the Parkinson's disease measures?

Chris Bever: I don't think I have anything additional to add.

David Tirschwell: OK, thank you. Dave Knowlton, do you want to go through the next few?

David Knowlton: Sure. The next item is 2029 – Dementia – Counseling regarding Risk of Driving. I actually was a reviewer of this measure. The measure did not meet the importance criteria. The measure involves with percentage of patients regardless of age with the diagnosis of dementia with a caregiver who at counsel we got in the risk of driving and they alternately used to driving at least once within a 12-month period.

But at that time, you will recall the committee questioned the need for this measure, all deserving that the counseling regarding the risk of driving was included under a previous measure that we fitted through 2028.

Does anybody have any suggestion that this be reconsidered at this time?

OK, 2029 – I'm sorry – 2111. The measure is Antipsychotic Use in Persons with Dementia. Percentage of individual is 65 years of age or older with dementia, receiving antipsychotic medication without evidence of psychotic disorder-related condition. The measure did meet the importance criteria but did not meet the scientific acceptability criteria particularly the validity criteria.

There was some discomfort about this, you would recall in our discussions. But (inaudible) that has provided some additional information, which I think those of you have this document can see.

Is Gwen on the call, Gwendolen Buhr?

Male: Dr. Buhr is not on the call.

David Knowlton: Anybody else? Excuse me?

Female: I think Gwen is on the call. Gwen, are you still there?

Female: She's on mute.

Female: Are you unmute Gwen?

Gwendolen Buhr: Hello.

Female: There you are.

Gwendolen Buhr: Hello. Yes, OK. I can't get my phone off mute.

Female: We know the way.

David Knowlton: Gwen, do you have any comments on this other than what we already had? This is around …

Gwendolen Buhr: Yes, I don't think any …

David Knowlton: … measure 211, the Antipsychotic Use in Persons with Dementia.

Gwendolen Buhr: Yes. I don't think anything new. I think it failed on the validity measure and the comments, I think, just another round the fact that they were using claims data and then follow what they could do. I think our discussion is centered around that if dementia is under diagnosed then they were going to measure it based on diagnosis or drugs for dementia and we thought like that was wasn't going to be valid because we might be missing a whole bunch of people or even getting people that didn't have dementia with the diagnosis, so.

David Tirschwell: You know, it's interesting …

David Knowlton: Go ahead, David.

David Tirschwell: David Tirschwell. Just reading the comments related to this measure, one of the comments referred to, I think it was from a health plan which this measure was – that was the level this measure was to be implemented, that then they had commented that they had been sending out reminders related to the use of antipsychotic in patients with dementia for a number of years now, which suggests to me that already in their database they have the ability to see whether doing something like that might affect the use – the frequency of use of antipsychotics and might have been really interesting additional evidence that might had helped with the questions and might have even help with validity if they had done the appropriate analysis.

So, it seems to me that they might be able to reevaluate their submission and possibly continue to pursue this measure also.

Helen Burstin: David, this is Helen. David Nau from PQA is on the line. And they did provide a fair amount of additional analysis. I wasn't sure if Gwen had seen those. But I wasn't sure if David one – if this is the right time to allow David to say anything; kind of a lot of David on this call, David Nau.

David Tirschwell: Yes, that's right.

David Nau: Hi, this is David Nau. I guess with the very last comment about evidence, I guess I'm not understanding what additional study the committee would have like to have us do. I guess I have not seen the connection there.

Female: Yes.

David Tirschwell: What I was referring to the validity criteria about whether it's the right patients or not and the fact that an intervention along this line if it had led to an improvement in some outcomes might have helped us believe in the validity of the measure to some degree and showing that the use of the mailings led to lower rates as well as showing that some other benefit less mortality. For example, if your health plans are big enough, you might have the power to show that sort of thing and of course that was the – that's the literature benefit that we're shooting for with this measure is the fact that mortality is increased with the use of these meds in dementia patients.

So, I guess I'm wondering if my – as my role as a committee member that might have helped me believe more in the validity of the measure.

David Nau: OK. I guess I'm not I would disagree, but I think in general I think that's where if the concerns are – many of the concerns we had heard and saw in feedback or about ability to really distinguish patients who may have psychosis but really it wasn't clearly documented but also the ideas around. The drug markers or dementia may be not being – not being specific enough which I think, you know, we provided the evidence that they were very specific to dementia.

So, I think we tried to address the concerns that we heard that were actually something that could be the best. I can't get if there's general concern that dementia patients aren't being identified in general. I think that's just the overlying problem where there may never be a (inaudible) measure that would meet that criterion.

So, I think our goal was to really narrow the focus of this measure to the patients who clearly were at the highest risk of adverse events, which was also with dementia, but then to exclude those patients who did have some documentation within the ICD-9 codes of psychosis or other behavioral disturbances. So, I guess that's where I think we have tried to address the concerns. But I said that getting the sense that those – there are still remaining concerns that just may not be able to be addressed at this time.

David Tirschwell: David, this is Helen again. Some of those – I think the commenter was actually from a PBM who was supportive of the measures, because they actually sound fairly high validity in the way they are using (inaudible) and finding high in the patient who had Alzheimer's as quoted. So, I mean, it looks those commenters particularly from the pharmacy side were quite supportive.

Female: And I can say the other thing in this comment was saying that when they did those – going back to the way that you specified the measure and the Alzheimer's drug, these comments also said that they pretty much agree that that's something that is a rare occurrence that Alzheimer's patients generally are not being described for non-dementia patient. Again, that kind of goes to one of the current (inaudible) measure in the first place. So, again, that was a supportive comment.

Helen Burstin: Yes. This is comparable for the kind of health plan level measures we've seen frequently using claims data. And we can't really hold the measure up to having had high impact yet, which should be ideal until it's really in use. So, we really have that threshold David for measures that are up for maintenance, so harder to do for a new measure.

David Knowlton: Sorry, what was that high-impact thing, Helen?

Helen Burstin: I think you were suggesting wouldn't it be great to know this is actually out there and potentially helping. And again, that would be something very logical at maintenance, harder with the new measure when the plans haven't yet implemented.

David Tirschwell: But in fact – well, I guess they're not implementing this overall plan rate. But the plan the rode in suggesting that they've been responding to use of antipsychotics in dementia patients by sending out notices to providers asking them to reconsider that which would be, you know, that would be the logical plan action if this was implemented.

Helen Burstin: Yes.

David Tirschwell: It seems that they could easily show the link on outcomes there. But again, you're right. This can go down on evidence so and I'm asking for more evidence. So, it's probably not the most relevant thing.

Helen Burstin: Yes.

Gail Austin: This is Gail. I think that this measure was really – we fairly split and it was mostly around validity and the questions concerned in my memory primarily whether or not it was valid to include patients who are being treated with dementia drugs as in the population and they provided evidence to support that that is a valid proxy. And I like this measure, because this is actually tied to an outcome where most of the measures we've been looking at today are not. So, I would vote for reconsidering it.

David Knowlton: OK. Are there other people want to be heard on that?

Gwendolen Buhr: This is Gwen. I think I agree with Gail that we should may consider it and they've given us evidence that I think people were concerned that that traumatic brain injury population was going to be included here and they've given us evidence that that's a really, really tiny person and went in fact to validity, so.

David Knowlton: OK. Karen or Helen, what's the process toward this? Do we just mark if this is reconsidered and (inaudible)?

Karen Johnson: Yes. I mean, it sounds like there's enough interest from the committee to revote. So, if that's the case, we will send out directly. After this call, we'll send out a SurveyMonkey so they'll – to revote this measure.

Helen Burstin: Including – we'll also need to include usability and feasibility …

Karen Johnson: Yes.

Helen Burstin: … they should vote on at the meeting.

David Knowlton: Say that slowly, Helen, because that was going to be my question. It eliminates to the issues …

Helen Burstin: I don't say anything slower, David Knowlton. Yes. I said we'll need to also ask you to weigh in just for the sake of, you know, if we have all the information, we'll ask you to reassess. I guess there haven't been any issues raised about evidence. I think we just kind of leave evidence as be. The issues that are really is the reconsideration of validity, so we'll ask you to reconsider the validity and then we'll also ask you to consider usability, feasibility, and over recommendation.

Karen Johnson: This is Karen. And we also put in a comment field for that. And, however, in that voting, if you would be so kind to put your rational for why you did or did not recommend the measure, we would really appreciate that. That would help us understand the committee's mind more than just counting to those.

David Tirschwell: Could I ask the NQF staff when we – when you send out with the link to the poll is if you could gather the information on any of the measures that we're re-voting on, you know, the committee's – the details of the committees initial decision and everything else all summarize in one place that would really facilitate our work.

Karen Johnson: Yes, we can do that.

David Knowlton: As well as the discussion on this …

David Tirschwell: Yes.

David Knowlton: … those of who missed it.

Karen Johnson: Yes. Well, we could send that …

David Knowlton: I'm a little concern about that myself that there will be people voting on this in the committee but did not have the benefit of Gail's comment or Gwen's comment.

Karen Johnson: Well, we'll send out the transcript and the recording tomorrow and then we'll send the summary Monday or Tuesday. So, you know, the folks who are on the call can vote and if they wish when they get the survey and the folks who

are not on the call will be asked to wait until they've reviewed the summary and the transcript. So, we'll get that out to you as soon as we can.

David Knowlton: OK. So I – we're done with that until we get this send out later.

Karen Johnson: Yes.

David Knowlton: And so, we move on to topic three, which is the measure 507 – Stenosis measurement in carotid imaging studies. And to note that the steering committee recommended endorsement of this unanimously, but there are six comments where we think we got in this measure which was (ordered). Two commenters expressed concern that the measure is a documentation measure and therefore limited to know use for accountability purposes. Another commenter expressed concern that stenosis is based on physician's judgment of patient's symptoms the development responded to the judgment issue.

I don't have a review of this but I was going to ask if David or one of the clinicians on the call wanted to comment on this.

David Hackney. Hi, David Hackney here. I reviewed it.

I think the comment that the stenosis is based on a physician's judgment of patient's symptoms is just some misunderstanding. I think they misread what it is because it has nothing to do with the measure and it's absolutely nothing to do with the patient's symptoms. It's just a definition of an anatomic method of doing the measurement. And specifically, we actually talked about whether it's relevant in people who are asymptomatic, but there's nothing in that proposal that says anything about the method you use it depends on the patient's symptoms.

The only other substantive comment was the suggestion that more than just stenosis severity should become standardized, but I don't think that was in anyway a criticism of the existing measure that was in front of us. It was the suggestion that it would be good to add others. So, I'm not sure if there's a lot that we need to do, we did endorse it. The only suggestion against that was that the, you know – with the documentation measure. But I think the feeling of the committee was it was important enough and there was enough evidence

that the one can interpret this result and make decisions on the basis of them that it was worth documenting and having as a documentation measure.

David Knowlton: All right. Anybody else have a thought or comment?

Male: David's response seems to be consistent with what the developers responded as well.

David Knowlton: Does anybody have any reason to want to change their mind on this?

Hearing none, let's move on. There was comment received for measures that were recommended for endorsement. They are measure 1814 – Counseling for Women of Childbearing Potential with Epilepsy, 2091 – Persistent Indicators of Dementia without a Diagnosis – Long Stay, and 2092 – Persistent Indicators of Dementia without a Diagnosis – Short Stay. Of the 22 comments, 19 makes press support for the measures. Of the remaining three comments, two suggested additional ideas for measure development and one question why patient in psychiatric facilities were excluded from the measure of denominator.

You see that developers' response on 2091, there really is no action required for committee on this comment (inaudible) verification and information. Anyone want to add anything to this?

OK. So we come down to suggested additions to measure gaps list. Karen, do you want to comment on this piece?

Karen Johnson: Sure. And you've already noticed in several of the comments, sometimes the commenters would say, you know, "We support this measure." But if you would recall it's also being (inaudible) developers we considered doing XYZ. In your in-person meeting, the committee gave us a lot of ideas for future development. So, what we are proposing is to take the comments for our future development that came into the comment period and just add them to the list in our report.

So, we've listed those out and we're suggesting that the committee would agree with these suggestions and we would update the report appropriately.

So, I guess the question there is just look at that with ideas for future development and if there's any discomfort with any of those, now would be the time to say it otherwise we'll just add it to the list and report.

David Knowlton: Does everybody have this so I don't need to read it. Everybody has this, I believe.

Male: Yes.

Karen Johnson: It's on page 16 of the memo and I think it's up on the webinar.

David Knowlton: OK. Is there any objection to these?

Hearing none, let's assume that they are good to go. Are there any additional issues not yet discussed that the committee would like to raise at this time?

Karen Johnson: So, this is Karen again. We pretty much with the AAN measures and the antipsychotic measures and such have pretty much to spend to almost all of the comments. But if there was any particular comment that was made that anybody wants to question and talk about over, we can do that now.

David Knowlton: Does anybody have anything?

OK, hearing none. OK, I'll just wait for people to get off mute if they need to.

Let's take some time – do we have an operator procedure for public comment or is this is an (inaudible), Karen?

Karen Johnson: Operator, can you open the line and see if there is any public comment?

Operator: Yes, ma'am. At this time, if you would like to ask a question or has a comment, please press star one on your telephone keypad.

Again, that was star one.

You have no public comments or questions at this time.

David Knowlton: Thank you, operator. Karen, next steps?

Karen Johnson: With that, I'm going to hand it over to Suzanne, who's going to keep us on track.

David Knowlton: OK.

Suzanne Theberge: All right. Thanks everybody for your time today. I will send out a survey after this call for you to vote on measure 2111 for the validity, usability, feasibility and then overall endorsement recommendations. With that survey, I will send the section of the report and the comments and the letter from the developer. Tomorrow, I'll send the recording and transcript and then early next week, well send out the call summary for the committee members that weren't on the call for that portion of the discussion.

Other than that, we'll just draft up some responses to the comments and send those out to you for you're review either end of December or early January then we'll just ask you to take a look at those and make sure that we have adequately reflected your thoughts on the comments and then the measures will move over to NQF member voting in mid January.

So, those are the next steps now and I think that's everything, unless Karen wants to add anything else.

Karen Johnson: I think the only thing is we were talking about when the deadline would be for submitting your vote on measure 2111 and I believe that is …

Suzanne Theberge: Oh, I'm sorry. It's December 21st, which is next Friday. We're going to ask you to vote by noon, Eastern Time, next Friday. So, we'll have time to compile the votes before the holiday week. So, please get your votes in as soon as you can.

David Knowlton: This is Dave Knowlton again. I also want to thank you, Suzanne and you John, of course, Helen, for taking us through and organizing our information so efficiently to get the committee meeting dealing with this step of discussion done in the type of time that we've got it done. So, thank you very much.

David Tirschwell: Agreed.

Suzanne Theberge: Thank you guys for being such great (inaudible). We've had a – we've had a lot of fun with this project and we've all learned a lot here. So, thank you for all your time that you've given us. We appreciate it.

David Knowlton: Thank you, all. Have a happy holidays. We are adjourned.

Male: Thank you.

Suzanne Theberge: Thanks, everyone.

Male: OK. Bye-bye.

Female: Thank you.

Suzanne Theberge: Bye.

Female: Thank you.

END