NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
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1:00 p.m. ET

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

Katie Streeter: Hi everyone, this is Katie here at NQF. Thank you all for joining us today for our Standing Committee Post In-Person meeting conference call. I just want to go ahead and do a quick roll call. Is Dr. Rosenzweig with us here? Dr. Bailey.

Dr. Bailey: Yes, I'm here.

Katie Streeter: Tracey Breen? (Bill Curry)?

(Bill Curry): Here.

Katie Streeter: Vicky Ducworth? Jim Dudl?

R. James Dudl: Here.

Katie Streeter: Ingrid Duva?

Ingrid Duva: Here.

Katie Streeter: Starlin Haydon? Ann Kearns?

Ann Kearns: Here.

Katie Streeter: Sue Kirkman?

Sue Kirkman: Here.

Katie Streeter: Anne Leddy?

Anne Leddy: Here

Katie Streeter: Grace Lee?

Grace Lee: Here.

Katie Streeter: Laura Makaroff?

Laura Makaroff: I'm here.

Katie Streeter: Anna McCollister? Patty McDermott?

Patty McDermott: Yes, I'm here.

Katie Streeter: Janice Miller?

Janice Miller: Here.

Katie Streeter: Claudia Shwide?

Claudia Shwide-Slavin: Here.

Katie Streeter: (Jessie Sullivan)?

(Jessie Sullivan): Here.

Katie Streeter: And Bill Taylor? Has anyone else joined and I haven't called your name?

Operator: And just a second. I'm sorry, Katie, I didn't mean to step on you there. Just a second for some housekeeping announcement for our group today. Please remember all committee members have an open line for the duration of today's call. So please use your mute button when you're not speaking or presenting. Please make your computer speakers are turned down or off. And please do not place the call on hold. Back to you, Katie.

Katie Streeter: Thanks, (Joanne). Do we have Jim from APMA on the line with us?

Anyone from NCQA or APMA, our developers?

Female: Ma'am, does Jim Christina have an open line?

Katie Streeter: Yes.

Female: Jim, are you there?

James Christina: Yes, I'm here.

Katie Streeter: Oh, hi, Jim, welcome.

James Christina: Thank you.

Katie Streeter: So just to give a quick overview of how we want today's call to go. We have a tight agenda as usual, so we really want to stick to our time here. We have two measures; the APMA measures that we want to spend no more than 30 minutes on if we can. NQF staff will be jumping in as needed to make sure that we're sticking to our time allotment for those measures.

Karen, do you want to say anything else before we move on?

Karen Johnson: Ask again if we have any other committee members particularly (inaudible) on the line. OK.

Do we want to talk – when do we talk about voting? Please forgive us. This is our project team's first time doing voting our call. So we're learning how to work the software. And I think it will be pretty easy for everybody but were you going to tell us a little bit later on the call or is that now in the call?

Female: Yes, we'll clear it up.

Female: As you can see our PowerPoint has been up to help you learn slightly different than what we did in the in-person. To select your option, you would just go to the screen and press a little box next to high, moderate, low or insufficient. Whatever you feel would be the right choice. You can vote as many as you

want. Your vote only counts one. And the voting will open as soon I go to the slide that has this displayed.

You will have something up for your discussion but until you see this displayed you will not be able to vote. And other than that, the voting will go at the same as in person. We'll go in the same order (inaudible).

Katie Streeter: Thanks, (Inaudible). Do we have Dr. Rosenzweig on with us yet?

OK. Let's go ahead and asked Jim from APMA if he'd like to introduce their measure. We're starting with 416, if you can go head and talk about them both at the same time if you'd like.

James Christina: OK, great. Yes, thanks for the opportunity to discuss each measures. Just as a little background, the initial form that was sent in, there was some confusion obviously on my part and I don't know if this was just a lack of understanding that these measures were actually going to be evaluated like they were brand new measures. So basically, it was just a reproduction of the evidence that was presented when these measures were originally endorsed.

Subsequently, I sent some additional documentation as with regards to the evidence base. There is also some confusion whether these measures were part of the Physician Quality Reporting initiative and then Physician Quality Reporting System. They have been since 2008. And just for informational purposes, I included one of the quality data reports from CMS from 2012 to just show how frequently these two measures have been reported. And on that same page you can see Measure 163 which is a diabetic foot measure, had a similar amount of use as well.

The evidence base is going to be weaker for the evaluation of footwear, simply because there hasn't been a lot of research done to demonstrate the value of doing the evaluation of footwear, but the literature clearly sites that there is a large percentage of people with diabetes that wear shoes that are too small and that these are an important factor in the development of diabetic foot ulcerations, which is the leading pathway to eventually doing amputations.

About 85 percent of amputations are preceded by a diabetic foot ulceration. It is also – it reference the article from the – published in Diabetes Care that was developed by the task force on the foot care interest group of ADA. And this was endorsed by the American Association of Clinical Endocrinologists. They talked about inappropriate footwear and its relationship to the development of diabetic foot ulcerations.

Measure 417 regarding the neurological exam, there is a strong evidence base that identifying patients that have loss of protective sensation is essential in the prevention of diabetic foot ulcerations.

This measure is designed to follow again the ADA guidelines where they talk about there are five different types of evaluations you can do in a neurological evaluation. And it generally recommended two of them are done, the monofilament exam with an additional test being done, typically the vibratory test being done.

So that's just kind of to set up the measures. We did do testing that we outsourced to (Intelligent) and we have included that testing information as well.

Katie Streeter: OK. Thank you, Jim. Claudia, you are the primary discussant for this measure. Would you like to briefly walk the committee through the numerator/denominator, kind of the overall summary of the specifications for the measure and then …

Claudia Shwide-Slavin: Sure.

Katie Streeter: … evidence and we'll stop there and open it up for discussions of the committee.

Claudia Shwide-Slavin: OK. Well, basically the numerator is the patients who were evaluated for proper footwear and sizing, at least once in 12 months. It was defined as evaluation for proper footwear for the foot examination documenting vascular, neurological, dermatological, structural, biochemical finding.

The foot should be measured using a standard measuring device in counseling on appropriate footwear should be based on risk categorization. The denominator is all patients aged 18 and older with a diabetes diagnosis and the denominator exclusion are for people that are bilateral amputee. It's a process known as measure.

And do you want me to go through the evidence part of this?

Katie Streeter: Yes, if you can discuss the summary of the evidence, please.

Claudia Shwide-Slavin: Sure. Basically, there was not a systematic review that was submitted with the original information and as the measures steward just explained we did get some additional information afterwards. The evidence provided links to evaluation of proper footwear was reduced also, but it didn't link the footwear with patient outcomes and also did not really define what a proper footwear exam was. But the two studies that we did initially get were really conducted very differently.

And then the subsequent review information that we got. Even though it was a systematic review, it did state that none of the public studies reported on the predictive values defined associated with foot trauma such as inappropriate footwear and improperly cut toe nail. So it wasn't really a part of what was being considered in the review. And that's part of the (inaudible) because we do know that poor fitting shoes are associated with an increase of ulcer. But there's nothing that we have that establishes that shoe size will be accurately assessed for that, that assessment will lower the rate of ulceration.

Katie Streeter: Great. Thank you. Laura, do you have anything to add?

Laura Makaroff: No, nothing to add. That's great, thanks Claudia.

Katie Streeter: All right, great. Let's go ahead and open it up for a committee discussion. Seeing that we're not in the room, I will just kind of count on you to speak up or if no one speaks up I may just start calling names, if you have anything to add in this conversation.

Karen Johnson: And it might help too if you would say your name the first time that you talk (inaudible).

Bill Taylor: Can I suggest we say it every time so we can keep track of who's who?

Karen Johnson: Yes, that's even better. Thanks.

Katie Streeter: Any comments on the evidence?

Bill Taylor: This is Bill Taylor. So it sounds like this evidence that poor fitting shoes cause trouble but there's no evidence that if you find out what proper sizes that that leads to better outcome. Is that fair?

Claudia Shwide-Slavin: Fair, except – sorry (inaudible) on my background noise, I can't mute it out right now. The – yes, that's fair and the problem is that we, even though we don't have the evidence we do know that that's true, so it's – we're in a bind here.

Bill Taylor: We know that it's true that if we have people check shoe size that there'll be better outcome.

Claudia Shwide-Slavin: No, we know that improperly fitting shoes increase the risk of ulceration.

Bill Taylor: Right.

Claudia Shwide-Slavin: But we don't have any evidence of that and we don't have a definition of how that footwear is being evaluated consistently.

Robert Bailey: So this Bob Bailey and I guess the question would be then, what I'm hearing is, is that you would need to raise this insufficient with exception, is that correct?

Female: That's my feeling.

Bill Taylor: Or we could rate it low?

(Lindsay): Yes, this is (Lindsay) from NQF. If you feel that there's no evidence supporting the measure intervention your options really are low, insufficient or if you believe that there is an exception warranted (inaudible) with exception.

Starlin Haydon-Greatting: This is Starlin, are we allowed to consider the experiential evidence?

Katie Streeter: Certainly, we bring each other as experts in the field and so we certainly ask that you bring together your knowledge of what's happening in the field to see if (inaudible) to the evidence that warrants a national performance measure that is in use sort of accountability purposes and improvement purposes.

Sue Kirkman: So this is Sue Kirkman. Is there any evidence that most clinicians know how to do this? So just thinking of physicians in general. I don't know of any evidence that physicians know how to do this. They know how to do foot exams, but I don't think they know how to measure the feet using a standardized instrument or assess whether the shoes that are not …

(Crosstalk)

Claudia Shwide-Slavin: In the state of Illinois, we have the sources but before we have an actual license that do the (inaudible).

Sue Kirkman: Right, this is Sue again. It sounds like this could be any clinician or clinician group.

Female: That's a very good point though.

Anne Leddy: This is Anne Leddy speaking. In my practice I find that the podiatrist to whom I refer my patients do this type of evaluation in a very consistent way. I see these measures of supplying certainly the podiatrist but I don’t see them applying to providers in general.

Female: Hey, I'll just jump in. We do want to keep the discussion focused on the evidence for the measure. So again, really just if there is evidence for this

invention we'll get to the specifications when talk about reliability and validity.

Sue Kirkman: OK, thank you.

Ingrid Duva: Hi this is Ingrid. I have a question for clarification just to back up for a minute where we're talking about the evidence. It is in the guidelines from the American Diabetes Association to do the measurement or just to do the foot care?

Anne Leddy: No, just to do the foot care evaluation.

Ingrid Duva: OK.

Anne Leddy: So the footwear itself is not mentioned but it is mentioned in additional information that was sent to us since the meeting in the references about a backing up of recommendation in an article that would then guide the use care that was just mentioned earlier. The foot care interest group did say that footwear evaluation was recommended. It's not in the current ADA recommendation.

Ingrid Duva: OK and I asked that question, this is Ingrid again, because when you're ranking the evidence based on expert, you know, kind of consensus it's talking about those experts not necessarily – maybe us but if you consider the American Diabetes Association the expert. Thanks.

(Bill Curry): So this is Bill. When you say the ACE has a recommendation to evaluate footwear, do they include measuring in a standard way the size of the foot for our footwear stint?

Anne Leddy: I'm not familiar with the ACE recommendation. This diabetes care article that was (inaudible) was the first time that I have heard about this. So and I just looked at that information today for the first time. So I don't know if it's in the current state guideline.

Bill Taylor: And this is Bill Taylor. Are we supposed to evaluate every pair of shoes the patient wears or just once they have (inaudible)?

(Lindsay): Jim, would you like to take that one?

James Christina: Obviously, all you're going to be able to evaluate is the shoes that they've worn in. But obviously, part of the consultation with them would be that if they're – first of all, if they were at risk and if there were factors that put them at greater risk you could make general recommendations in terms of the type of shoe the height of the toe box. You can review with them generally what a proper shoe fit is as well as far as having enough firm in the front part of the shoe, having it fit properly around the heel.

So obviously, you can only evaluate what shoes the patient brings in but you can certainly question them as to the type of shoes they wear and the type of activities they wear the shoes for.

Claudia Shwide-Slavin: This is Claudia. I think the podiatrists are educated in how to do this. I don't think that anybody else is. That does not mean that other healthcare professionals could not be educated. Diabetes educators and you know, other support personnel could very easily be educated but it's not something that's currently being done or that we have evidence on.

(Lindsay): Hi, this is (Lindsay), I'll jump in. It sounds like we're moving more towards specifications at this point. Are there any other comments in particular about the evidence being helpful to this intervention? Please go ahead and make them but if not, I will just for everybody to vote on this criteria.

James Christina: This is Jim Christina again. Can I just make a general comment when you're talking about evidence linked to outcomes, particularly with the diabetic foot, it's such a multi-factorial problem that I don't know that you're ever going to find specific studies that can look at specifically doing one intervention on the diabetic foot and seeing what the outcomes are going to be because there is such so many factors involved that it makes it almost impossible to do that type of study but it doesn't necessarily limit the importance of the doing certain things.

The other just general statement and this is more for my clarification, I didn't know that quality measures had a requirement as to who could perform them. I thought the thought was that if a quality measure helps improve patient care,

that's what's important. And just like a dilated eye exam my only be done by a limited number of positions for person with diabetes, it doesn't reduce the importance of doing that exam.

(Lindsay): Yes, then you request on that second point and we'll have a greater discussion about that when we discuss these applications for the measure. But for now we are limiting this conversation to the evidence to support this intervention.

Are there any other comments from the committee? All right, let's move toward the vote on one end.

Female: Voting is open.

Female: Cool.

Female: You're biasing my vote.

Male: Yes, that's right.

(Crosstalk)

Female: I love that it's so demographic right on there at this time.

(Lindsay): Last call, if you want to change your vote, change it now because we're going to close voting in one second. All right. We'll stop there. We got to do it.

Female: The result would be (inaudible).

(Lindsay): Insufficient with exception so we'll continue discussion of the measure. Claudia, have you seen the performance gap?

Claudia Shwide-Slavin: Yes, so there was kind of conflicting information, originally, it looked like the measure was not new but now with additional information unless there have been in use by podiatrist but it does – that is the only place that we've seen to be documenting the care.

(Lindsay): And was there any information provided on performance gap?

Claudia Shwide-Slavin: No, I didn't see any information on performance gap.

(Lindsay): OK. Laura, did you have anything to add?

Laura Makaroff: This is Laura. I don't have anything to add (inaudible).

(Lindsay): Comments from the committee. Again, this is focused on whether or not there is a demonstrated performance gap that would warrant a performance measure.

Patty McDermott: This is Patty McDermott. So is there any, if there was, if this measure is being used at podiatry, was there an average compliance? Is this something all podiatrists are doing or not doing?

(Lindsay): Jim, would you like to answer that?

James Christina: Yes, it's only being used in the PQRS system which is a voluntary system but I just want to correct that in the PQRS report this measure was reported by almost 20 different specialties, the anesthesiology, cardiology, chiropractors, clinical nurse specialists, critical care, epidemiology it should the list goes and on. It was not only reported by podiatry in the Physician Quality Reporting System.

Also, about the gap in care, again, there's not going to be evidence that this particular part of the foot exam is not being done but there is a gap in care of foot exams being done and that's documented. That's been documented in multiple places.

Again, they're not going to document necessarily the specific components of the foot exam. But there's only 55 to 60 percent of people with diabetes are getting the foot exam you can assume that there is that gap of visitor being evaluated for proper footwear.

(Lindsay): Thank you. Any additional comments from the committee?

Female: This is (Inaudible). I see patients at work site which are manufacturing work site and we every month check their bill code work boots and there's – I think this is an important measure as Jim pointed out but it's not specifically shown in the evidence and a gap analysis but gets all wrapped up into the foot exam.

R. James Dudl: This is Jim Dudl. Jim, if you do have some experience in this maybe the next time – this seems like it's insufficient but the next time maybe you could present the overall gap. That at least would be of some interest.

(Lindsay): Any other comments from the committee members about the data demonstrating performance gap? Everybody (inaudible) to vote? I'm taking silence as a yes. So we'll vote on performance gap. Voting is open.

Tracey, I understand you're having some computer issues. I don't know if you feel comfortable saying your vote or if you prefer to e-mail that to me?

Tracey Breen: Thanks, I'll shoot an e-mail to you.

(Lindsay): This is (Lindsay).

Female: OK, last call. If anybody wants to change their vote, this is the time. OK, so the final results are zero high, three moderate, four low, and seven insufficient.

Katie Streeter: OK, we will stop discussion of the measure at this point. The measure was not recommended due to the lack of demonstrated opportunities for performance gap.

And just as a reminder of our process, this measure will go out for member in public comments and you'll have an opportunity to discuss any comments received at that point in time.

And we will move on to Measures 0417, Janet or I'm sorry, (Jessie), you are the primary discussant for this. If you would walk us through the specs and then high level overview of the evidence then we'll open it up for discussion.

(Jessie Sullivan): Sure. Similarly, this measure has been explained. I've submitted (inaudible) the developers was just considering somewhat submitted subsequently (inaudible) to look at that. This is the measure (inaudible) care of peripheral neuropathy …

James Rosenzweig: Hello?

(Jessie Sullivan): Hello?

James Rosenzweig: Hi, it's James Rosenzweig.

Katie Streeter: Hi, Jamie, we're just beginning discussion of Measure 0417. (Jessie) is walking us through right now.

James Rosenzweig: OK, thank you.

(Jessie Sullivan): OK. So the denominator is all patients aged 18 and over with a diagnosis of diabetes mellitus and the numerator statement is patients who had a lower extremity neurologic exam with categorization performed and a sequenced plan established at least once within 12 months. And then it goes on to define a lowest extremity in neurological form consists of documented evaluation of moderate and (inaudible) including (inaudible) detection.

This is what the numerator statement as we reviewed it and we've subsequently been told that as it was implemented in PQRS, (inaudible) numerator specification that that talked about only the (inaudible) of those components that (match) the measure that was submitted to us.

The evidence that was submitted is not an outcome measure; it's a process measure. The (inaudible) that was submitted is not (inaudible). There was (inaudible) of potential evidence submitted to – that would allow us to consider diabetes foot morbidity and even mortality related to diabetes foot morbidity as well as important issues and then extensive issues, a lot of evidence. So there's some evidence submitted that there is a gap in terms of people with diabetes having their foot examined.

(Inaudible). There wasn't any logical – a logic model submitted but I think that (inaudible) from what was submitted (inaudible) say comfortably that neuropathy increases the risk of ulceration, ulceration is a significant problem. It's logical to (inaudible) if you don’t diagnose neuropathy is when you miss the opportunity to present ulceration so an exam to find neuropathy is logical even though I don't believe we have evidence submitted. So maybe that's (inaudible) open up for discussion.

Katie Streeter: Thank you. Laura, do you have anything to add?

Laura Makaroff: The only thing to add right now (inaudible).

Katie Streeter: All right. We'll open it up to the committee. Do you have any comments on evidence for Measure 417?

Bill Taylor: This is Bill Taylor. So once again we have evidence that the condition of having neuropathy is bad and puts you at risk for having an ulcer and all the terrible complications that come from. But we don't have any evidence that doing the neurologic exam is actually connected with the outcome we're interested in which is fewer ulceration, fewer amputation, fewer deaths. Is that right?

Female: Well, I mean I know we have to work with the evidence presented but I can tell you from personal family experience, my father has type 2 for I don't know, quite as long as I've had type 1. He has peripheral neuropathy and has caught a couple of ulcers in part because the doctor did a foot exam and he had no feelings. So I mean just because we haven't studied it in some sort of systematic review doesn't mean that we don't have evidence from practice.

So I don't know what the process is in terms of evaluating evidence based on NQF guidelines for the community. But I don't think that we can completely cast away what we have learned as a community in the group of providers and patients of what we know works. I mean randomized control trials aren't the be all and all of clinical practice.

(Lindsay): This is (Lindsay) from NQF, similar to the last measure, if you feel that the documented evidence is insufficient you do have the option of using your collective expertise to vote to move the measure forward in position with the exception to evidence.

Claudia Shwide-Slavin: This is Claudia. I know there wasn't the evidence presented here but I remember back in the 1990s (elite) program presented significant evidence about neurological evaluation reducing the risk of foot ulcers and you know that was maybe the mid 1990s right after (DCPP) and maybe the

reason why there hasn't been since then was that it was so thoroughly documented into practice.

R. James Dudl: Yes, this is Jim Dudl. I don't I think the monofilament has a fair amount of good evidence that if you're at a certain level that you will have an ulcer and if you take precautions which are not defined here but you could, that it leads to non-ulceration so I think there is evidence but I'm not sure it was presented.

Claudia Shwide-Slavin: No, and this is Claudia. On the AADE website, the worksheet used for evaluation and grading are all available if anybody wants to look at them. I don't know what people definitely save but that's where I get them.

Bill Taylor: This is Bill Taylor. The question about our process, what do we do about evidence that the developer didn't give us but we hear about from other committee members?

Female: Yes, if you're aware of evidence and you feel that it's evidence that would then allow to measure to meet our evidence requirement we certainly would ask you to at least send the reference to both our staff and to the developer. But as far as voting would go we would ask you to vote in position with exception to evidence.

Anna McCollister-Slipp: Again, just from – this is Anna, just from a patient perspective, I mean if I went to endo or took my father to an endo and they didn't do this test then I would probably assume that they're not. I mean depending on the specifics of the need of that meeting I would assume that they're not particular quality. That would be my evaluation whether CMS needs that or not.

But I mean I think this is pretty standard as the process measure. It's when outcome measures, the process measure.

(Lindsay): Any other comment on the evidence from the committee? All right, let's move to a vote.

Female: OK, last call.

Female: I don't have any – for some reason it's not letting me vote. I don't have this vote screen, I suppose. I don't know why.

Female: OK, if you're comfortable saying your vote over the phone we can record it that way or you can e-mail it to me.

Female: OK, I'll just e-mail it to you.

Female: And if the box never appears as any point for you, you can also refresh your session by pressing F5 or refreshing your browser.

Female: OK. We have zero high, two moderate, one low, 12 (inaudible) and we move to the next – 13 position evidence with exception.

(Lindsay): We'll move on to 1B. (Jessie), would you like to introduce the performance gap?

(Jessie Sullivan): Yes. I guess I think (inaudible) before I even say this but there is evidence that there is a performance gap in performing foot exam (inaudible) but national rates are around 50 to 60 percent.

(Lindsay): Good. Laura, anything to add?

Female: This is (inaudible) for the measure gap around sort of the (inaudible) but I'm not sure about this (inaudible) measure.

(Lindsay): Can I open it up to comment from the committee?

Anne Leddy: Well, Anne Leddy, those of us who are clinicians know that this gap exists. We know that the care of diabetic patient involves the regular foot exam and associated education. So although we don't have a demonstrated performance gap, it really does exist at least in our experience. So can we use that personal experiential evidence to vote on this measure?

Karen Johnson: This is Karen. I think you have to vote as you feel the truth is in you own life. So as you said as a clinician, if you feel like that there is a gap even though it looks like that data were not actually given in the submission form then you could go ahead and do that.

Those of you who maybe don't know the literature or not clinicians, you can decide if you would vote insufficient or if you will potentially take the word of the clinicians on the call.

James Rosenzweig: Hi, this is Jamie Rosenzweig. I was not in the impression that there's a lot of evidence showing that there's a performance gap. But there are large number of people who don't get their feet examined during their exams. In many cases, they don't get their shoes taken off. And I thought we discussed – there was a previous foot measure that we discussed this with. I thought we thought that there was a reasonable amount of evidence in that one. I don't have the information in front of me.

Female: Yes, (inaudible) NCQA measures discussed during the in-person meeting.

Female: It says in the developer rationale (1B1) and I don't – this is somewhere in the measure information it says occurrence of yearly foot examination, Jaime, consistently below 60 percent in the study. That's a pretty high evidence gap.

(Lindsay): Any other comments?

Female: (Inaudible).

(Lindsay): Any other comments?

Robert Bailey: Yes, this is Bob Bailey and I guess this is the question for the developer. So was the evidence not included here because the thought was that this was going through re-endorsement and there was not a need to do so or is it because there wasn't enough evidence to present?

Male: It's the former that you presented. It wasn't aware that we needed to reestablish that there was a gap in care for this particular measure. But I did include in the supplemental information there was noted when the NCQA and (TCPI) where looking at their overall diabetic measures. They talked about the incidence of foot exams being in 55 percent.

So there's almost every study that you'll reference when they talk about foot exams, I believe in the Healthy People 2010 data as well, it comes in somewhere around 58 percent. So it's consistently at 60 percent or below.

Robert Bailey: Thanks, very helpful.

Male: And just to comment, that 60 percent refers to foot exams within the past year not just foot exams per visit.

(Lindsay): So, are we ready to move to our vote? All right, taking your votes once again, let's vote on 1B performance gap.

Female: OK, voting is open. OK, last call for voting. OK. We have seven high, nine moderate, zero low, zero insufficient.

(Lindsay): All right, let's move on to discussion of 1D. (Jessie)?

(Jessie Sullivan): No, I think we've already commented on this. I think that even in the initial submission that significant evidence was submitted that (inaudible) condition that we've had large numbers of people, resource use (inaudible).

(Lindsay): Does anyone have any new or additional comments to add to that?

Sue Kirkman: This is Sue Kirkman. I mean the only thing as I recall that we're supposed to be talking about not just the condition is important but that the measure would be important in changing the outcome. Is that right? You could sort of say that about any measure for diabetes or any measure for amputation.

(Lindsay): What you're referring to is really covered on their evidence and this is much more is the topic area, high priority.

Female: Well, that's not what I remember from the meeting. I remember – because you could really just say that for any diabetes measure then because diabetes is such a high priority condition that no matter – even if a measure would not – could not possibly affect the outcome because it's a high priority disease then we have to say this is high priority. I'm not saying that about this measure but …

Female: This is (Inaudible). Just to clarify just a little bit on even if you didn't want to say it's diabetes only, I think the foot – you guys have already agreed that the foot exams are important because of the severe complications, the number of amputations and ulcers and that sort of thing so that with data – you know, that would get you the high priority there.

Female: OK. So it's that the intervention is likely to have a high priority rather than the condition.

Male: No, I think that the condition has a high priority to be addressed, that was my understanding.

Female: (Jessie), this is (inaudible). That's also my understanding but I think we're saying not just the diabetes is important but that diabetic foot ulcers are important so it's not just diabetes, it's specifically (inaudible).

(Lindsay): Yes. This is (Lindsay). That's correct. It's really the specific outcomes targeted by this intervention, that's a high priority topic area.

Female: OK, whether or not we think the intervention itself or the measure itself is likely to impact it. I mean again, I'm not saying that for this intervention – this measure per se but I guess I'm just confused.

(Lindsay): Yes, no, just to clarify. If you think that the intervention is not going to affect the outcome, that would really be under the evidence for the measure.

(Crosstalk)

Female: Let's just move on because we've already decided it's a high impact condition.

Male: That's we're voting on, it's a high impact condition. It has nothing to do with whether we think there's evidence that doing the exam actually impacts that, right. That's what we're voting.

(Lindsay): Correct.

Female: The voting is open.

Female: All right, last chance for you to put your vote in.

Claudia Shwide-Slavin: This is Claudia. I lost my connection. I have to get back on but I want to vote high.

Female: So we have 17 high, zero moderate, zero low, and zero insufficient.

(Lindsay): All right, we'll move on to discussion of Reliability 2A. We're discussing here the precision of the classifications and then also the reliability testing results to comply about the developer. (Jessie)?

(Jessie Sullivan): Right. So can we have those both together but could we (inaudible) classifications (inaudible) would be the position so I have some trouble with the position of the specification. Even just the numerator statement, patients who had a lower extremity neurologic exam with categorization performed and a treatment plan established and yet the technical specifications say nothing about which categorization or treatment plan.

So the specifications are just that a neurologic exam is done not that there is risk categorization and a treatment plan. And then (inaudible) has said earlier and this is – that there's a difference between specifications we were given and the specification (inaudible) PQRS which is then defined neurologic exam of these five components and even the people who did the testing said that there was confusion about how many of those components do you need to meet to score. And I understand it's about (inaudible) that you need two, but specifications don't say that.

So I think (inaudible) a lot of positions have used specification that I found a little troubling.

(Bill Curry): So actually the PQRS guideline reads the following for the numerator. This is (Bill Curry). Lower extremity neurologic examination consists of a documented evaluation of motor and sensory abilities and may include reflexes, vibratory, proprioception sharp-dull and a 5.07 filament detection. The components as listed are consistent with neurologic assessment recommended by the task force of the foot care interest group of the American Diabetes Association.

They generally recommend at least two of the listed tests be performed when evaluating for loss of protection sensation. However, the clinician should perform all necessary tests to make the appropriate evaluation. So the sentences consist of a documented evaluation of motor and sensory abilities and may include, it doesn't say that they have to do two or they have to do five. It said they generally recommend two.

But if you did one you would meet the intent of PQRS as I interpret the PQRS. And so as the specification is written here it looks like they want the clinician to do all five of the tests.

(Lindsay): Jim, would you like to clarify?

James Christina: Yes, the initial and the way the measure was originally written is that as it reach, however, when it came to doing the getting into the PQRS system there are consisting questions about how many of these have to be done and that's when there is clarification as to what is considered the standard for doing the evaluation is certainly from this – from the way it is being used in impracticality, it is as it is written in the PQRS measure. It is not how it was originally submitted. And probably that should have been a change that should have been noted on an update to the measure.

But I thought PQRS and NQF worked kind of together on these things because we have calls on a consistent basis with one organization and I got the impression that two were working hand in hand but I guess that they're two different, two separate things going on. So the specification should probably be reflected as they are written in the PQRS measure. That's the way …

(Crosstalk)

James Christina: That's the way they were written in the electronic measure as well which was submitted to NQF.

Female: Yes and Jim, just to clarify procedure reference, we actually – we don't pull information over from PQRS. We rely on the developers to provide us with the most up to date specifications in the measure.

James Christina: OK, thank you.

Karen Johnson: Thank you. Can you go back and this is Karen, can you go back and speak to the list categorization nation and treatment plan section – statement of your numerator?

Male: Yes. Again, they have to remember this is the initial development of these measures back in 2007. And the idea was to make it almost like an intermediate outcome measure. I still believe that risk categorization is important and the implementation of a treatment plan based on it categorization is just probably what's most significant and actually affecting a change in the outcome for the patient.

But, that was more of – just show the intent of the measure back when it was written. Again, it does it hasn't become part of the requirement to meet the measure in PQRS. And when they did the evaluation and the reliability and validity test and they were just looking to see that and neurological was done. They were not looking to see if there was risk categorization and treatment plan included.

Female: So, just in terms of process for NQF we really need committee members to vote on the measure and specify for – I think there are two difficulties. One, it sounds like you're on the same deck; if you had to do it over he would probably give different specifications. And, if I understand you right then you're saying that the testing that was done is not done, was not done with the specifications that you have provided for the committee but actually to something else.

(Bill Curry): That's correct but I don't think that we're – if you look the other foot care measure that was passed to testing that was done for that was probably different as well because that measure change, 056.

Female: As a risk of opening this up just because I do know we have NCQA on the line, (Mary) would you like to comment on that?

(Mary): You know I don't know the answer off the top of my head about the testing that was done for that measure. So let me look at the forms tonight and get back to you.

Female: Yes. And, so the committee will provide that information to you at a later date. And just as reminder of our process, we will be discussing all the comments to be use and measures again after the comment period ends, so any additional information that may come to life during this we will provide to you and open in up. So certainly (inaudible) conversation of measure 417.

(Bill Curry): This is Bill, we need to open up, you mean, we get to vote again based on what we learn in the interim?

Female: If you hear something in the interim that you believe would lead to a change in your vote; you can ask to re-vote on measure yes.

(Bill Curry): Does the individually say each one of us say, I change my vote on this or do we as a group. How does it work?

Female: It would be a motion for the committee to re-vote on the measure, so we would ask at the (inaudible) call if anyone felt the need to reconsider their vote and if there was a majority in support of a motion to revote, we would solicit your votes on the measure.

(Bill Curry): Great. Thank you.

James Rosenzweig: This is Jamie. I just like to comment to the, I mean, as it is written, it seems like the measure is quite imprecise. I mean, the previous measure we had discussed actually specify the using monofilament and the big – the question or discussion was whether or not the monofilament was a suitable test to be used. Whereas here they're giving you a large number of different options and it just seemed very – it seems like with their experience they should have able to narrow it down when they re-wrote the measure.

Sue Kirkman: And this is Sue Kirkman, I actually as it – it was presented it says to do all five. That may not have been the intent but does the neurologic exam is, you know, and it lists (all five would end working them).

Karen Johnson: So this is Karen, I think the specifications, there's a lot of changes. It's not a minor change that we would ask and give to make at this point with specification still. I think what we really have to do is vote on the text as provided in this submission. And, depending on how it might end as (Rosy) said. We have an option that we discuss and come up most comments have to remind you that this is a pilot project where we are allowing developers to bring forward measures a little bit more often than we use to.

So if you voted lower insufficient on reliability because of the specs as it's written right now potentially Jim could bring it back in our next cycle with specs change to more reflect with going on with PQRS if that's what you desire. So there are a couple of options available.

Katie Streeter: This is Katie, should I – should we say something about the testing before we vote?

Female: Yes, please.

Female: Yes.

Katie Streeter: So that we've already got up on issue that is helping which I haven't realized before. So there's testing, you know, I guess I realized that (inaudible) in my mind. So the testing was done with the PQR as specifications that are not exactly the same as this presentation for listening. Again you guys has something to say but also maybe can turn me a little bit. So when I looked at the test result before (inaudible) so we were (inspected) that in this case because the way the testing was done was to compare the electronic submission to PQR to what was found on that chart review.

We will accept to use a – or whether these – the reliability testing and the validity testing with the plain testing. And so this can tell some of the – that was submitted to PQRS versus what was found in the chart. And there will be a very, very high agreement that other concern that there was a 100 percent compliance rate with the measures which can mean that either – there wasn't a gap when it wasn't important to be measured in it or the sample was not, or the bias sample.

And we have said in our meeting this was among podiatrist segment which provides us wouldn't examine the feet. But just earlier today you said that actually in PQRS, the measure was from that only support the other measure was submitted by dermatologist, neurologist, and a bunch of other people. But I guess I didn't wonder why you didn't value only do the testing and then podiatrist if in fact it would use more probably, you might have gotten (inaudible) that example which is testing reliability so that that would be going discussions about the testing.

Female: Jim …

Male: I guess the answer to that is I have – I have no access to who those providers are that CMS doesn't give the access to who use it or utilize the measure. So I can't test, and I can only test with people that are willing to volunteer to participate in the testing.

Female: OK. Well did you have anything to add to the discussion of reliability testing?

Female: That is everything we had.

Female: OK. Comments from the rest of the committee? Anyone? Any comments or questions for the developer?

(Off-mike)

Female: All right.

(Mary): (Inaudible) from NCQA, I just wanted to say that the measure that was asserted had been tested into different specification. But I can't imagine how that could be. So maybe Jim and I should talk off-line to figure out what he – what exactly he meant by that. Because the measure that was used in our program is what we present is, for validity testing is the data binomial, you know, evidence from the actual use of the measure. So there's no other specifications that has been tested. And what we brought you is the measure as we have or using in the program.

Katie Streeter: (Mary), thank you for clarifying, I will be back conversation off-line and committee members if there's anything else that we need to add in this conversation we'll bring that you during the comment period.

Any other comments on reliability from the committee?

All right, let's move to a vote. Voting is open.

All right last call for voting. OK, the final vote is zero high, three moderate, 12 low, four moderate, 12 low, one insufficient, thus the measure does not (file).

Katie Streeter: All right. Thank you committing members. Thank you, Jim, and Jim our staff will follow up with you about some next step.

(Jessie Sullivan): Katie before we live this is, I think when we were meeting in person, we said that it wouldn't be – maybe be possible for the committee to express the developers what they might like to see whether it be possible stuff to do that for a moment?

Katie Streeter: Sure, let's take five minutes and do that, I'm going to give up to five minutes. So feel free to go ahead and offer some commentary.

(Jessie Sullivan): OK. So I'll just start by saying what I would like to see as a measure is a measure of a comprehensive treatment program. Because from that the evidence that I saw and let me submit that of what makes a difference. And that would mean, we wouldn't be able – does not – because it looks like there's not evidence to see what parts of those sometimes this program we're meeting or not you'd have to, like take the evidence and implement the program as they specified in measure, but that's what I would – also that I would like.

(Bill Curry): So from an operational – this is (Bill Curry), from operational standpoint I would be – take a fair number of patients who do not a neuropathy documented on screening such as monofilament who would not be able to go to a podiatrist for instance for a comprehensive evaluation because their insurance would not pay for that in many cases because they don't have neuropathy documented. But …

(Jessie Sullivan): But I guess I was assuming that it would be for patients who have neuropathy that there's a comprehensive, (case) treatments program for our patients with neuropathy.

(Bill Curry): So the – as I look at these measure they intended to increase screening for neuropathy. And so, would that be a separate measure all together to bring. And I don't disagree with you. I think it's a great idea and it would be great to implement. But as I look at this measure, it's to improve the screening for a neuropathy to prevent the complications down the road. If I were looking at this measure to come back, I would like it to mimic the PQRS.

And in the PQRS they talk about the five testing. They say main food. They don't mandate that they're all included. They don't mandate it more than one is included. They say generally, you know, more than, you know, two should be done but they don't mandate, it's my interpretation that the two are done. It's one. And they talk about the risk stratification and they talk about follow up plans for how frequently the patient should have their feet examined if they have which (adversary) of complication from their diabetic neuropathy. But that's not mandated as putting them in the numerator either.

So – And I really want to see this as a measure and I would be – I would like to see if it could be congruent with the PQRS measure.

(Jessie Sullivan): Well, I guess there's a lesser harmonization with you because we already have a – there is another neuropathy screening measure. So I guess I just say to me we need one neuropathy screening measure and then we need to measure to address how one manages neuropathy once it's been identified.

Anna McCollister-Slipp: This is Anna again speaking from the perspective of the patients who have neuropathy. I absolutely like this measure. I mean, I think we do need to consider, you know, specificity, you know, and consistency amongst the different measures. So I think I would certainly love to be – love to see it being resubmitted with the comments of the committee taken into consideration.

And I'm a little surprised but if you don't by your statement, I mean maybe I shouldn't be surprised. Btu insurance companies don't cover referrals to podiatrist if you don't have documented neuropathy from a filament test because I've passed for filament test every time but I have significant episodic pain. So if that's the case, then I would certainly love to see some sort of a measure that uses some sort of pain assessment because I think a lot of patients experience pain and they don't actually recognize it as being neuropathy.

I don't really understand what it does for many years and that was certainly the case with me beside excellent care.

(Crosstalk)

James Rosenzweig: This is Jamie. I just wanted to mention that the monofilament test to identify clinically significant neuropathy that might cause an ulcer or an infection. But it is not sensitive enough to be able to identify all neuropathies that are present. So it's not …

Anna McCollister-Slipp: Right, I recognize.

James Rosenzweig: It's not …

(Crosstalk)

James Rosenzweig: … to have enough to actually screen for a neuropathy per se.

Anna McCollister-Slipp: Right.

James Rosenzweig: It's used as a practical test to identify patients who have neuropathy that's significant enough that makes them high risk.

Anna McCollister-Slipp: I understand completely. I would also know (inaudible) recommendations about what measures would be relevant. I would say severe neuropathic pain can be incredibly relevant to patients. So I don't know what kinds of assessments out there in terms of pain scales for neuropathy. But if we're only using the monofilament from an insurance company (inaudible)

monofilament test to assess what are not, there need to be future referral to podiatrist and I think that's pretty short planned.

So again, other commentary about whether (inaudible) the patients.

(Lindsay): OK. This is (Lindsay), it sounds like we've kind of reached the end of that conversation or (Inaudible) in summary, it sounds like this measure is something that our committee really wants to see again and our staff have kind of used comments and that that would be to work with (I.U.) on bringing the staff to review.

Male: OK. Great. Thank you.

(Lindsay): OK. At this point we do want to move on and have a discussion of harmonization for some of the measures reviewed during the in-person meeting. So we're (rejoining) our conversation on the last data, there is a need for discussion of the related hemoglobin A1c testing measures.

So sooner we'll be pulling up the slide now that shows a comparison of them and I'll let Karen walk us through this.

Karen Johnson: Yes, thank you, (Lindsay). And just to back up a little bit, you know. If (Kim's) neuropathy measure that we just discussed same task, then we would have actually gone straight into the competing measures discussion besides the NCQA measure is directly completing with that measure.

So depending on what (Joe) decides to do, we may go ahead and push that discussion out. But that brings us to the HcA1c testing measure. So just to remind you, we had three measures that talk about HcA1c testing. One was an actual was said and done and then the other two had to do with the level of the test.

And the two, 0575 and 0059, for some of those, the testing is actually embedded in that numerator, so what we would actually see these as competing measures. So even though the key measures are, you know, a little bit broader than just the testing measure, they are competing in a way that we define at NQF completing measures. But I will point out that 0057 which is

again the testing measure is specified for health plans only whereas the (safe) measures, or control measures are specified for health plans and for clinicians, individual clinicians are appropriate.

So, the question basically that we have in front of you to consider is, is there justification for endorsing 0057 to testing measures, the standalone testing measure given the facts that we have this other key measures. And just to remind you of your review and discussion the last time, the intensity measure actually (Kim) went lower on evidence than the other two and I think that was mainly because it is more of a result process then from the (inaudible) measures. And then it's also lower on performance test because the performance rate was fairly high. I believe it's somewhere in the – below nine.

So that was how your ratings scores are known. But the testing measure actually became higher on reliability and that was due I think in part because 0575 and 0059 as you recall, since they were synthesized for clinicians, there was the question about the seemingly low reliability for the clinician measure and if you see like folks had explained that they have used a possibly – they used data from their recognition program and that's why they thought just the reliability appeared well and, you know, accepted the argument.

And then also the testing measure actually scored higher by you guys on validity, feasibility, and usability. I think feasibility particularly it makes sense that the testing measure was test score higher because it's an easier measure. Again, the testing part is embedded in the other two. So the other two do require more work than collect that data.

So let me stop there and see if you guys want to discuss some more whether or not you feel that there is still justification for endorsing measure 0057.

Sue Kirkman: So this is Sue Kirkman. I mean I'm going to editorialize it. I've had the same thing at the meeting but, you know, I think there's a general consensus that we need new measures, we need better measures. And implicit in that is that we have to be willing to drop some measures. And to me this seems like a pretty obvious one that could be dropped. Came at performances already at about 90

percent and it's kind of embedded in some other measures that has been endorsed. And I was surprised that people wanted to keep it.

(Jessie Sullivan): This is (Jessie) and I said this before at the meeting so I'm not going to be – (inaudible) use of measure for us to identify people who have become lost to care. And I'm very concerned about having the screening measures go away because they really do help us identify the people who aren't seeing things.

(Crosstalk)

Female: Is there no other way to identify that?

Female: Right. That's my question. I agree with the first term. Of course, I don't want you to lose improvement data that can help improvement. But is there a way to collect it without it being an endorsed measure which then becomes mandatory?

Female: Well, the problem is that that we now have restrictions that come from the Office of the Attorney at the second general that prohibit us from using measures that haven't been, you know, that are standardized and nationally endorsed for difficult, so. It makes as much, you know, alarming, yes, this is measured as basically as any way if it was endorsed but just the second it's endorsed it makes it much easier for us to do it.

And then that also means that on different health plans, you have positions that are less of who is it being seen. They're defining it more or less the same way.

James Rosenzweig: This is Jamie. I think we already endorsed this measure, so the issue is whether or not there is a problem with harmonization with the other measures or if it's really competing with the other measures. And I don't think it is. It's basically a process measure and the others are intermediate outcomes measures.

So there are two different things and I think it still has use in specific populations that may not get A1c testing done. And I would virtually keep the measure.

Robert Bailey: This is Bob Bailey. I think the other major consideration here, if we talked about other potential ways to capture the population and recall that the medication adherence to anti-hypoglycemic agents did not pass or have another way to I guess identify patients that are not either fallen off the radar screen or not adhering to their medication.

Karen Johnson: And just let me be clear. This is Karen. For now we are considering this competing and that's why we're asking you to discuss whether or not this additional measure is needed.

If you decide that it is, then Jamie is right that we will go on to have a discussion about harmonization of the measures. And quite frankly, they all come from NCQA, they're already harmonized. There would be no harmonization discussion.

Ingrid Duva: So, this is Ingrid again. My question is so the patients who are not being captured they're not in the numerator for the greater than 9 percent of that those patients who do not have the test and patients who are greater than 9 percent. I though it was captured in that measure, I don't understand the difference.

Female: Well the difference is to understand what you need to do, but by the time they'd give a physician actionable data and you just say here's the patients who are doing poorly. They're not helping them to know, so then they have to look up in the chart of each of those patients to figure out which ones of them are doing poorly since they had a test that it was a high number versus the one who are doing poorly because they never came in. And it's much more helpful to give them new information, OK.

Among the failing population we have two groups, those who haven't been at all and there's those who have been in but has the wrong number and we do different things depending on the (inaudible).

(Crosstalk)

Female: Break up the data for you.

Female: I agree, but that's part of data driven performance and you have to figure out what cost is your specific number at your specific site. So that you can make your changes, but as a generalization if there's not, you know, great room from improvement then that's a specific site decision right? No?

Female: I mean, doesn't your health plan your – health plan is already given two different buckets of patients for the greater than 9 measure. So why couldn't they just gave you two different (look).

Female: Because (inaudible). Reporting to physicians on measures that are involved in the measure.

Female: But the greater than nine is endorsed. And it's got two different buckets of data.

Female: Putting it into a sub-measure isn't, this will be the sub-measure.

Female: I think it would just be looking at your data but.

Patty McDermott: So this is Patty McDermott, this goes back to the comments are used making early on about the fact that. And it seems to what some of this conversation is going is that if you'd simply – if you restrict the measures that are dealing with level. So that members where you know you have a hemoglobin A1c level available to evaluate with the (clinical) measure. And it's that's what (inaudible) say it's a cleaner measure rather than mixing in the concept of not being able to fine the test because this – it maybe a date of a missing data problem rather than the fact the patient really didn't get trusted.

R. James Dudl: This is Jim I think for the users whoever want to maintain this I really need to know what groups that helps because – yes I'm certainly with the larger groups all this data dissected and we know all the pieces. So, yes but it this it maybe that it's in the disparities in certain smaller groups that this is a major problem of figuring out which ones are over now and which ones are tested. Then I guess we should keep it, but I haven't yet heard which groups for sure this will benefit.

(Jessie Sullivan): Well this is (Jessie), I guess I can speak to that. So we're in Medicaid health plan and we have 50,000 (enrolled) and (inaudible) about half of our patients get there care from larger provided method community helps them towards that do have of electronic records and data system. And about of half of it are known with (dental care) some small private practices. Many of whom do not have electronic records and even those who had electronic records don't have to do with (inaudible).

And we give reports to all of our major processes, the large ones and the small ones listing the patient's name to be seen for diabetes, then it's on the claims that we have. And the larger centers that do have that was – they'll find that looks like helpful. So why they still send out with (hassle) I'm not quite sure why. So that's the question I have to ask them because they do have that information, but the small effect that do not have that information and they get it from (inaudible) and otherwise other than (touching) that information to them this is not something that they would be able to look at.

Male: Thank you.

Patricia McDermott: So this is Patty McDermott again and just close to be able to give a comment on home physician. I would suggest too keep the testing measure as it is. And then you specifically specify the (inaudible) onto level measures that's either being (above eight) or below nine. Only where you have lot result for that member here are more focused to you. So it's not a mixed tag. And, you know, with pertains to …

(Crosstalk)

Sue Kirkman: Sorry this is Sue Kirkman, I disagree with that because I think that (intensifies with) people not to check on patients that they know are poorly controlled. I think people can really gain that if you say you're going to exclude the people that weren't tested from the greater than 9 percent.

Female: (Inaudible) that’s going to show up in their overall testing (inaudible) at that.

Female: Well I don't know – I mean I just think, you don't want to gain – you don't want to give people the opportunity to gain a measure the way they could gain than greater than 9 percent one, if you excluded people that weren't tested.

R. James Dudl: You know, this is Jim Dudl, I totally agree with that the over nines are very difficult, they're also very difficult to get tested. And I wouldn't want to gain that.

Anna McCollister-Slipp: And this is Anna, I completely agree with Sue and Jim.

(Lindsay): Yes. This is (Lindsay) from NQF, my interpretation of your comments it sounds like we're coalescing on we would like to keep this three measure and then also the less than 8 percent and the greater than 9 percent. Is there anyone who feels accounted for that?

Sue Kirkman: I mean this is Sue I don't think we should keep testing measure, but – because I think we need to drop some measures and – but I maybe the only one and I think I was the only one that voted against it at the meeting.

Ingrid Duva: I agree with you, this is Ingrid.

Female: Do you guys feel we should do a vote or some kind of I don't know that would be – (Lindsey), help me with process here, do we want a – an official vote on justification for endorsing all three measures. If we did that vote, if there is – if it came out that there's justification for keeping off. Then every – all three will go through as it given in-person meeting. If the result to this vote was there's not justification then that would basically change your vote at for 0057 so that it will be do not recommend. So that – that's basically what we're asking.

Female: From the committee is there a motion to think about on justification for endorsing measure 0057 in the HbA1c measure.

(Bill Curry): This is (Bill Curry), I so move.

Female: OK.

Male: I just have a little problem with this, I mean we already endorsed the measure. And it seems to me that the issue of harmonization should be discussed during the discussion of whether do we endorse the measure and not afterward as far as I'm concerned.

Sue Kirkman: We were specifically told that we want that to discuss competing measures and harmonization at the main meeting.

(Lindsay): This is (Lindsay), I'll clarify our process, we ask you to evaluate each measure against all of the NQF measure evaluation criteria. We want to ensure that all the measures that are recommended for endorsement on their own merits meet the criteria. From there we ask you to discuss measures that are essentially related or competing to determine whether or not we need both of those measures in the endocrine portfolio of measures.

So it is that process that we would want to ensure – first of all if the measure on its own meets the criteria and then the second once we have two related or competing measures that do meet the criteria, the way from there is that both measures and whether or not they are both necessary in the portfolio.

Female: So but before we vote can we just clarify what a yes vote means and what a no vote means?

(Lindsay): Yes. So (inaudible) additional question guide if you vote yes, you are saying that there is justification for the screening measure and we will go forward keeping the recommendation for endorsement to yes for measure 0057. If you vote no you're saying there's not justification to keep this screening measure and we will not recommend measure 0057 for endorsement.

Anna McCollister-Slipp: Can I – this is Anna, can I just have some question. So, I mean and I hear what you're saying Sue, yes for requiring – as if measures around outcomes that require an A1c test that that inherently required you to do one. But what is the benefit of removing this one measure. I mean my concern would be that it has taken us a really long time to get people and patients aware of the need to look at the A1c as an important measure and at least be cognizant of the fact they had one and what their number is. So especially for the type two.

So I mean does that like have significant impacts on paper work I'm just trying to understand the burden of this measure as, you know, I mean I understand the concept that we can't keep everything always, but if this what just one more data fill to download which, you know, your doing export program or whatever the case maybe. Or is it something that's burdensome.

Sue Kirkman: Well, I mean I don't think it's particularly burdensome especially since you're collecting it any way for the greater than 9 percent measure. But, you know, I do think once some measure gets up to really high performance then the question remains, you know, why keep measuring and I mean there'd been other performance measurements like a beta blocker after MRI, I think maybe it's NQF still on those line they can clarify but I think that was actually dropped as the measure because performance became so high.

And, you know, I think if you're talking about the importance of A1c and what your member is I think the other measures are probably going to be more important. Said this whether, you know, whether someone had the test done. But, you know, I thinks it's a little bit of philosophical issue, you know, even if it's not that much additional work it's just that we – I just can't see that we keep adding more and more and more measures without ever dropping measures.

(Jessie Sullivan): This is (Jessie) I just like also to say something about that. I would actually – because I agree about the thing about the 90 percent mark up. As I've already said why I don't want this measure to go away but what I actually prefer to see is a screening measures with four components that look with the four diabetes putting measures together. And then that's actually how do you report to physicians I mean four of them.

And I've asked my team to pull together and the results that we have that I can show with the committee about, you know, when you look at compliance without those screening measures that can translate that even if this – even if the compliance rate is fairly high for each component when we look at all four of the rates really drop.

I will agree with that but if the choices this measure goes away completely and it's replaced with the, you know, from project measures then I really as I've said, you know, quite formally that we need this measure.

Tracey Breen: Hi this is Tracey – oh, sorry, go ahead.

(Lindsay): OK, just going to say the process of point of we certainly we'll have a conversation about whether our gap areas and measurement. So what you suggested is basically a composite measure not something that we have in our portfolio currently, so there wouldn't be that measure to replace it. It's certainly something that we could say that the steering committee recommends that this measure be developed and come in to NQF in the endocrine portfolio. I do just want to remind you that we are really limited to the discussion of the measures as are specified currently in whether there's value and keeping all three as currently specified.

Tracey Breen: Thanks and this is Tracey, I just want to say I agree with (Jessie) from composite measure eventually be much more useful pending (inaudible) while I agree with the philosophical you meant to, you know, we have to start down sizing some of our work. I don't know that we're ready to drop this as a process measure.

The outcome measures say different things and theoretically someone can get their outcome measures on their patient population the X percent of their patient for diabetes are in – are really high range and X percentage of your patient with diabetes are in a, you know, more well-controlled range.

But there's still the potential even though that's getting less likely except that we've done good work. There's still the potential to miss the over all process measure about how much you're monitoring your patient with diabetes and I think in higher risk population and understood committee they are still important metrics. So for right now my feeling is to keep it understanding that its potential flawed and something better should replace it eventually.

(Lindsay): It sounds like everyone is kind of coming to a point where they're ready to vote. Are there any new comments from committee members?

Yes and then I know we have NCQA on the line. (Mary), would you like to make any comments before we move to a vote?

(Mary): Thank you. I would I just like to say the different tools are needed for different purposes and I appreciate this conversation but I think I heard one misconception that I would want to correct. It seems just as somebody completed the NQF endorsement with requirement. And in fact unless there are some a magic I'm unaware of there's actually nothing about NQF as indicative to our facilities that use with kind of internal rule for themselves but by the legislation that has, you know, and regulation that has governed what NQF is doing.

There's no requirement that's something as NQF endorsed being use anywhere. At least we're to use our own measure in own program as we seem – that seems most useful. And just of at one other point, the beta blocker after M.I. had reached the point where the not only we're the best plans doing 98 percent. But the worst plan for doing 97 percent. And we've not reset point with the A1c (inaudible) unfortunately. That's all.

(Lindsay): OK. Thank you, (Mary) As a reminder when we vote on this if your voting yes, you're saying that there is justification to keep all three measures and 0057 will be recommended for endorsement. If you vote no you're saying that it's not justification for all three measures and 0057 should not be recommended for endorsement.

Female: OK, voting is now open.

OK, the final results is 15 yes, two no and so all (300) will be recommended (inaudible).

(Lindsay): All right. Thank you NCQA for joining us with that discussion and thank you committee members for your input there.

The next item in our agenda the discussion of gaps in the endocrine portfolio. On the first day at the meeting you all may remember Karen Johnson did a

very thorough discussion of what is currently in the endocrine portfolio, we did have some discussion from you all about the gap areas that were identified. We did want to take a moment to now you have evaluated all the measures so far.

You have an awareness with the measures in our portfolio. If you had other recommendations for futures areas of the measure development in the endocrine topic area. I know we spent most of our time looking at diabetes mellitus up until this point and only a few osteoporosis, I'll remind you there are additional osteoporosis measure and diabetes measure that will be reviewed in future cycles of this project. But (inaudible) be certainly we'd like your recommendation will be publishing them in the report and sharing them with their developer colleagues.

And now with that, if Karen, has anything to add, otherwise, I'll just go ahead and open up for discussion.

James Rosenzweig: This is James Rosenzweig, I would say that we should have some measures related to thyroid disease which is very common as well as all the use of testosterone. So those will be areas I think that would be a priority for NQF to consider.

(Lindsay): Yes and this is (Lindsay), I know Karen mentioned that for overview we don't have any measure adjusting those topic areas if you have specific intervention that you'd like to see process or outcome measures. If you would take any level of specificity you would like to give us.

Anna McCollister-Slipp: And this is Anna McCollister-Slipp and I know that this is some developing clients but I think given the fact that we now have things like continuous glucose monitors that are pretty accurate, it would be great to see if some measures developed and submitted around issues such as time and range. Since you can get to the a, you know, hemoglobin A1c of seven either by staying in range from most of the time or by going high and low and bouncing all over the place.

You know, the latter is certainly not desirable from a clinical or quality of life perspectives. So again just speaking from the perspective as a patient

specifically a type one patient I think that would be something that would be far more relevant and meaningful to many of us as a person hemoglobin A1C which is important they're just not physician.

Claudia Shwide-Slavin: This is Claudia and I think the impact of diabetes education was mentioned at the meeting but I just want to mention it again.

Sue Kirkman: Yes and I think there may be some measure under development that speak to diabetes education. This is Sue.

Janice Miller: Yes, this is Janice. Thank you for bring that up as, you know, I'm the one who brought it up at the meeting but I am very interested in pursuing that and if, you know, we could approach in the same manner in which we approach some of these other measures that there is insufficient evident but with an exclusion based on the obvious need for it and they based on any obvious performance gap.

Sue Kirkman: But there's actually, this is Sue Kirkman, there is actually quite good evidence for the benefit of diabetes education. So I think that the issue is really how do you determine, how often, you know, how do you measure, you know, when it was done or how it was done. But I don't think there's an evidence gap for diabetes education I thinks it's pretty strong evidence.

Male: I would agree with Sue, the issue is always is more related to the specification of how do you identify what diabetes education is to be how to measure it. And but I think there are measure that are coming now should be eventually considered by us.

Female: Excellent, yes I think it's the heterogeneity of diabetes education that was the problem that we discussed at the meeting as far the evidence. But I agree there is – there's sample evidence of its efficacy. But its that heterogeneity of that prevents this from really analyzing it in a systematic review type session.

Male: One other area that I would recommend for future measures to be considers are pediatric endocrine measures. We don't have any as far as I know.

Sue Kirkman: And this is Sue Kirkman, so I think also some measures of overuse or over treatment might also be useful to specifically in thyroid disease. I think there probably a way too many thyroid ultrasound to being done and some would argue that there way too many small thyroid nodules being biopsied. So, you know, there is a kind of growing evidence base about, you know, which nodules are high risk and which are not and I just think it would be interesting those think about developing some kind of over testing metrics measures.

(Bill Curry): This is (Bill Curry). If we move some effort to before the diagnosis of diabetes or when we move into pre-diabetes or metabolic syndrome conditions would that impact the care of our patient progression of disease and in the population. So I'd like to see something with consideration for pre-diabetes.

R. James Dudl: And this is Jim Dudl, I did mention it before but I think that we should consider looking it on MIs and strokes because there was some discussion about decreasing process measures, intermediate measures. What I found in our group is when we just focused on the intermediate and the process there were large treatment changes that we're available to us that we didn't make.

And when we started focusing on MIs and strokes we begin putting picture together. I think we might be able to get rid of the whole bunch of the process if we go right at the outcome.

Tracey Breen: Hi this is Tracey I'd also like to suggest that area of hypoglycemia amongst the elderly. And, you know, there's been data saying adverse drug events requiring E.D. visits and so and basically I think number one or two and so finally it's number two or four in that population I think someone could really look at that in terms of patient safety issue, in terms of how these events are assessed and if the treatment changes that made.

Sue Kirkman: Yes and that's to point this is Sue Kirkman the other thing is it may again it's kind of over treatment, you know, I think we should not say that, you know, a certain hemoglobin A1c is bad necessarily and people because you could get there without hypoglycemia. But there are some drugs for example Glyburide shouldn't be used in older patients with diabetes there are a number of guidelines that say that and so I think it would be useful to actually have a

performance measure that looks at people over the age of 65 and, you know, how many of them are on Glyburide

Male: The Gluyburide.

Female: I completely agree if you look it appears (inaudible) we clearly said and then if you look at why people are coming and those hypoglycemia the older are just so clearly getting it but I think there's a real performance gap there.

Female: Yes.

Male: Yes, the Beers list refers to that as well as the use of sliding scales that actually – scales in nursing homes.

Starlin Haydon-Greatting: Yes, this is Starlin and unfortunate thing about Glyburide it's generic and that's why it's pushed.

Female: But there are several other Sulfonylureas that are also now generic, so at least I found there's a real knowledge gap amongst clinicians to think they're giving their patient's a great bargain by prescribing Glyburide but there's several other generic options for them if they choose to go to Sulfonylurea road.

Female: You're absolutely correct.

Karen Johnson: So this is Karen this has been really good and we will definitely reflect this in our report. And let me just throw some food for thought out for you guys and if you want to send an e-mail or something like or something occurs to you after the call, we'd really appreciate it.

What I noticed is I don't think really anybody mentioned any kind of patient-reported outcome measures or patient experience kind of measures. So if anything like occurs to you that would be an interest as well for us include our report. So with that, I think we probably need to go to public and member comment, so Katie can you take this.

Katie Streeter: Hi, if we could open up the line and see if we have any comments, members of the public.

Operator: Thank you. At this time, if you have a question or comment, please press start then number on your telephone keypad.

And there are no questions or comment at this time.

(Jessie Sullivan): Karen, this is (Jessie), I just wanted to make sure that the two measure visuals that I had mentioned earlier were included with which would be composite screening measure and the comprehensive (inaudible) for patients with neuropathy as I mentioned earlier.

Female: Yes, we have that in our notes and we will include that as well.

Female: OK, so as for our next steps, NQF staff will continue working on draft report that summarizes your recommendation from the in-person meeting and from the conference call today. We will be posting that draft report April 3rd for 30 days NQF members and public comment period. We'll also be sending it to you a few days prior for review to ask for your input.

We'll then be meeting on May 20th via webinar to review the comments that we received and to come up with your responses to the comment. And in the meantime, if you have any questions or concerns, feel free to let us know. And otherwise I think that will be it for today, we thank you all for your time.

Female: Thanks so much.

Male: Thank you.

Male: Thank you.

Female: Thank you.

Female: Thanks.

Female: Thank you.

END