NATIONAL QUALITY FORUM

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

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

Katie Streeter: Hi everyone. This is Katie Streeter project manager here at NQF. Welcome to the Endocrine Workgroup #3 Conference Call. We thank you for participating in today's call and for submitting your comments on the measures before this call.

Before we begin, let's do a quick roll call. If you could please state your name so we know who's attending.

James Christina: Jim Christina, APMA.

Katie Streeter: Hi, Jim.

Sue Kirkman: Sue Kirkman, UNC.

Claudia Shwide-Slavin: Claudia Slavin, American Association of Diabetes Educators.

(Freda Luis): (Freda Luis), (inaudible).

Jessie Sullivan: Jessie Sullivan, Hudson Health Clinic.

William Golden: Bill Golden, Arkansas Medicaid.

(Kazaya Cook): (Kazaya Cook), Acumen.

Katie Streeter: OK and I'd now like to introduce Karen Johnson who is our new senior director who would be participating in this project.

Karen I'd like to turn it over to you.

Karen Johnson: Thank you Katie. Hi everybody. I'm Karen Johnson. I am, as Katie said, the new senior director on this project and just to catch you up on things we had to do some internal shuffling, so Reva who I know you all know and love, is still around and she's still going to be kind of keeping her hand in with this project but for a – in kind of the day to day activities, I'll be the one who's kind of overseeing the project.

So looking forward to getting to know you guys and getting to know your measures a little better as we get through this call.

And some of you are aware but maybe not others, we do these workgroup calls for a couple of different reasons. One is to do a preliminary go through of the measures and this is, you know, a – an evaluation at least specifically the developers on the line and then gives you a chance to ask any questions that you might have with the developers kind of outside of the in-person meeting.

These workgroup calls also seem to, tend to serve as an educational function. Sometimes folks who are new to the NQF process, are a little bit less clear about our criteria and this call just to get practice and seeing what we are thinking and using our algorithms, that sort of thing.

So as we go through the days, if you have questions about the process, you can definitely ask and we'll work through our measures today. We're going to switch around just a little bit and start with measure 417, the peripheral neuropathy, neurological evaluation measure. So what we would ask several of you to do is be the primary discussant for the measures so if we discuss it we'll just give a very brief overview of the measure itself and then we'll just go straight into the various criteria.

So I'm doing the lead discussant, well, if you would just very briefly. Mostly states to some extent the things that the developers do provide and then even

more importantly especially based on one of the comments that were submitted for the pre-evaluation if you could just kind of summarize the comments that were made. And as we go through, let's just start with the evidence of criteria. So introduce the measure and then we'll do evidence first and then we'll proceed on. So …

Male: Are we going to …

Karen Johnson: OK.

Male: Are the team members going to be seeing the comments that have been reviewed and submitted?

Karen Johnson: Are the committee members? Yes. Those were uploaded – when were they uploaded in?

Male: Uploaded, OK.

Karen Johnson: They are in the – there's one document and I think they're called whatever the measure number is underscore all so, 0417 underscore (all) and that contains their measure of information that was submitted by the developer and then some front material that contains the staff evaluations and then the comments are embedded in that section. So it's just there and (Lindsay), are you bringing this up on the screen?

(Lindsay): I am.

Karen Johnson: OK. OK. And let's see. I think Dr. Sullivan, we asked you to be …

Jessie Sullivan: Yes. Can you hear me?

Karen Johnson: … our primary discussant. You want to go ahead?

Jessie Sullivan: Yes, sure. So, you know, and I might have missed something. I also have started to realize we had a – was there a webinar link for this? I'm on the phone but not on the webinar, so …

Karen Johnson: Yes, there is a webinar link but what we're showing in the webinar is the staff review and the comments section as well as any …

(Crosstalk)

Jessie Sullivan: OK. So I was really looking forward to having Bill go first so I could listen to how he did it, so. But I'll do my best …

Karen Johnson: Do you want to hold off? I was – I'm sorry. I'm under – I was under the impression that you maybe had done this before and you might not mind and we knew that Dr. Golden was going to be a little late.

Jessie Sullivan: I don't mind.

William Golden: Well I'm here.

Karen Johnson: So why don't we go back to plan A then and have Dr. Golden go ahead and do this, that's fine.

Jessie Sullivan: That's just fine.

Karen Johnson: Then do that if you're OK then, Dr. Golden?

William Golden: I have trouble getting into the website. I'm in a different office because I was seeing patients this morning and I'm trying to get in but that's why I could see my comments.

Female: So which number are we doing?

Jessie Sullivan: I can definitely go ahead. I got this document on the (inaudible), try to get in, that's fine.

So just, because we haven't all met, my name, my legal name is Janet Sullivan but I go by Jessie so that sometimes confuses people. So I'm Jessie Sullivan. And these measures were submitted by the American Pediatric Medical Association and the title is Diabetic Foot and Ankle Care, Peripheral Neuropathy Neurological Evaluation. And it is a measure of the percentage of patients 18 years or older with diabetes who had a lower extremity

neurological exam when risk categorization is performed and plan established at least once within 12 months. And I guess that's why – no, let's see – you want me to go through things, so I think that the statement of the measure is not a straightforward but I felt that I dug into it a little bit that perhaps the specifications don't quite address everything that's in that numerator statement.

So the measure type is a process measure and the first question we're asked to answer is the quality of the evidence. So did the measure developer submit a systematic review of a body of evidence and based on the criteria that we were asked to use, there wasn't a systematic review with the quantity quality and consistency of the evidence but they did cite a 2006 guideline and I did, read that guideline and that guideline was a consensus expert opinion guideline that had a very extensive list of records with it that they – that they don't have a systematic review of the evidence.

And does the evidence link neurologic exam of the foot? This categorization and treatment plans to specific patient outcomes and I did read and not my own comment but the comment of everyone else (inaudible) comment then it sounded like those of us who submitted comments felt that, you know, that the evidence doesn't support that there is evidence that an exam, this categorization and treatment had impacts on outcomes.

There was some evidence that there is review submitted that is more current than 2006 from 2013 that describes some evidence that podiatric foot care, improved outcomes and specifically one article that describe the structure diabetics foot program as reducing the rate of ulcers and amputations but I think it would be a bit of a stretch to say that this measure was measuring the degree to which patients who are experiencing a structured diabetic foot program.

The next question is gap in care, is there definite (inaudible).

Oh, go ahead.

Karen Johnson: So, let's go ahead and before we go on into the gap in care, let's just open it up to the community members to see if anybody has any questions or any concerns or if anything they want to talk about before we go on to gap.

Jessie Sullivan: Oh, lovely good, OK.

Sue Kirkman: So this is Sue Kirkman and I don't know if it fits under the evidence discussion but my issue with this measure is that it's – it really just focuses on the neurologic exam and yet it says that it's sort of talking about the neurologic exam and risk assessment and the treatment plan. So, I mean that just seems like a real disconnect to me but it's just measuring one specific thing and yet it purports to be measuring an entire you know, process that includes much more than just the exam.

William Golden: Yes, I would agree, this is Bill Golden. Looking at a number of these foot measures, what are the interesting things, I looked it up to date and they rated a comprehensive foot exam having a level 2c evidence which is not particularly compelling for effectiveness and it's interesting because to prevent ulcers and actually have some grading scales now to prevent ulcers, you know, you get into issues of foot deformities and many of these measure don't even mention the notion of and looking for things like nail deformities, foot deformities et cetera.

The other piece that is interesting is it didn't talk about what do you do with people with preexisting neuropathies? So we'd talk about sex later but they don't have exclusions of people with preexisting neuropathy.

Karen Johnson: OK, anybody else have anything about evidence? So in thinking about applying the evidence algorithms and I wonder if you can, I wonder if you can bring that up or not. Where would you guys rate if you were rating like you know, what would you or how would you rate the evidence for this measure using your algorithms?

Sue Kirkman: I think it's low. I mean it has to be low based on what's presented.

Karen Johnson: OK, so it is – you're getting there by saying no to the (inaudible) QPC is not provided and then going from there to this rating that was done having the low grade, is that how you got to where you got?

Sue Kirkman: I'm sorry. Yes, I think so. I don't have all the documents open on my computer. So I don't have the algorithm in front of me but I think when I reviewed this, this is Sue Kirkman again. It sort of came out low because it's just sort of based on a guideline that is not really evidence-based guideline. It's not based on a systematic review.

Karen Johnson: OK.

Sue Kirkman: And even the evidence that's presented was not necessarily evidence for this particular intervention.

Karen Johnson: OK.

Male: How about this, by the way, you talked in generalities about incredible prevalence, incredible list of known numbers. And when you start looking at the numbers, the numbers are a lot more discreet. And then finally, I guess the question is when you talk about evidence for this measure, the measure is not very specific or targeted. It's hard to understand how the evidence applies because this – I think Jessie said there are numerous steps with this measure. So it's hard to tailor the evidence to all the different steps.

Claudia Shwide-Slavin: This is Claudia. And, you know, I felt across the board while we know that when someone does develop an ulcer that it is extremely expensive. All of these measures didn't provide to show how we, you know, how we present getting to that point and you know, this is just one example of not giving us the proper steps and as everyone else that there is not enough evidence of what happened, you know, to get there. The statistics that people that actually, you know, end up with the exams and the – in the ulcer.

Jessie Sullivan: Karen, this is Jessie, I'm so sorry I got disconnected for a minute so I missed – forgot a couple of things that were said.

Karen Johnson: OK.

Claudia Shwide-Slavin: There is also when somebody has an exam, there isn't any indication of exactly what has been done and if they're consistently being tested.

Jessie Sullivan: Well, this is Jessie, I thought there was one area where I saw it was some concern about what evidence they did get because in that measure described, the exam is having sized component that were all neurologic components but in the evidence in the 2006 guideline, they have slight evidence that you don't need to do all those things that you didn't get the – that you can forget neuropathy based on history in a monofilament exam. So what they left you have to do is reflexes, vibratory proprioception, sharp/dull and monofilament.

The guideline that they decided that you don't need to do all that and then I think because we're saying, the measure doesn't in the – when Telligen evaluated the measure, it doesn't really capture that component. So if the five components were necessary, you don't have to (inaudible) like capturing them and if the evidence doesn't support those five components are necessary, you certainly wouldn't want to require them. And I thought that that was a disconnect with the evidence and the way the measures was constructed.

Male: In another side, I took a look for the evidence about the monofilament exam, you know, the one paper that I saw was references back to '95 but there are other ways of doing tests that are less cumbersome requiring less equipment that haven't shown to be equally effective. So the monofilament test itself is not necessarily evidence-based as the preferred strategy.

Karen Johnson: OK, well that's a lot of great discussion. So in the – it sounds like in general pretty much, you agree that the evidence rating will be low. In the in-person meeting, how it works or how it will work is that we will go through the individual sub-criteria in both, on each one of the main sub-criteria. So the entire committee would discuss the measure just like you've done and then we would ask everyone to vote on the measure. And then depending on the vote count, we would decide whether to continue evaluating this measure or just stop.

So evidence is one of the measures that we, one of the sub-criteria that we call a must-pass. So basically, it needs to pass with a pretty high margin or else we would guess in the in-person meeting, we would just stop the evaluation. So if you guys were, if this were the in-person meeting at this point we would stop and not go forward with the evaluation of this measure. And it would just be not recommended for endorsement. But because this is the workgroup call, we do want to go a little bit further in discussing the measure. So we will – let's just go ahead and talk a little bit about gap, so, OK?

Claudia Shwide-Slavin: I have (inaudible) go on …

Karen Johnson: Sure.

Claudia Shwide-Slavin: This is Claudia. One of the things that I know way back when and it's probably from '95 was something called program LEAP I think was lower extremity amputation prevention and that was when the monofilament was started. And I was just curious if anybody, I didn't have a chance to go back and look and see if there had been any evidence back then to establish that an art being, done in diabetes education and diabetes exams. But the fact that there's just expert opinion now makes me wonder if there was ever any evidence to begin with when we started doing this.

William Golden: The up to date article I found and again I'm in the wrong office right now, did have a reference to a test of the monofilament technique that dates back to like '95. In the article that was just reviewed in 2014, basically is that refer to this one paper which was I thought kind of interesting and because I felt I have another paper that came out in about two years ago about a different technique using very simple touch type activities that had a similar operating characteristic.

So, the real question here, is does a monofilament test to detect neuropathy, yes, but it does have by the way, it's very specific but not very sensitive, that's the other thing. But finally the other question is, is that the only technique to be used that does have certain amount of burden and I don't think there is evidence out there to show that that is the preferred or the guideline-named or

say national performance metric mandate to ensure that that is the only way to detect neuropathy.

Sue Kirkman: So, this is Sue Kirkman, I mean I, I think this discussion is going to come out with a lot of these measures because there are three or four that are all related to foot care and, you know, that is that – all the papers that I've seen or it's almost all, it's multi-factorial, you know, kind of intervention assessment, you know, compared to a control group. And then – and maybe they show some better outcomes although it's been hard to show, you know, true reductions and amputations for example, but, you know, but they're – there just aren't any studies that are going to pull out one particular little piece of the foot exam or foot care education or treatment plan and just be able to show that it by itself, you know, it by itself or it added on to everything, you know, it's going to make a difference compared to everything else.

So, I think, it's – and I think foot exam has sort of become so embedded in the, you know, kind of, almost standard of care for people with diabetes that it's going to be hard to ever have, you know, really strong evidence. And so that to me, that was the issue with all of this foot measure, is that, you know, I don't think we have very good evidence for any other particular components of the pathway and I'm not sure that we ever are in the future, but on the other hand I'm not sure that that means that we should drop all foot measures.

Jessie Sullivan: This is Jessie. I'm really glad you raised that because I feel the same, I think it's really important that we do look at the evidence and on the other hand I think that there's a lot of things that we do in quality improvement where we know that it takes a lot of different activities to move the needle and sometimes you can't really sort out, that, you know, just anyone component by itself will do that, but that you need to do them together. And sometimes having a logical path maybe a reason to have a measure.

So, if for example, I'm not saying this isn't it, if for example there is evidence that for patients at risk, a structured diabetic foot care program can reduce the amputations than a measure that helps you identify the patients at risk, I think, would be worthwhile even if there weren't evidence that just identifying

patients at risk in and of itself is good outcome because you couldn't apply the structured foot program if you haven't found patients at risk.

William Golden: You know, as a follow up on that, and I agree with (inaudible) comments but if indeed, you know, I mean, examining or having an assessment of, you know, vascular neurological and structural integrity of the foot which by the way none of them do, you know, the question is if we put in a national standard and it becomes homework and burden and it's not easy to collect, you know, there are other things that the office need to do in the care of a diabetic.

So, if we start to have these kind of measures which are time consuming that are not well-based and we're going to be taking energy away from other activities. So, it's going to be one of those kinds of balances to. I agree it would be good to have some sort of foot measure but not one that just had the people's work.

Female: I agree.

Female: Right.

Female: Yes, Bill, I totally agree with you, right. In the – when we get to the – what I said about the danger of this so, unintended consequences, this measure might be, it just that, that it's an opportunity to us that you do this instead of something else, I totally agree with that.

Female: Yes. And I think, you know, we might be jumping ahead here. But, you know, I also feel like this particular measure is pretty duplicative of the measure about foot exam, you know, which include pulses, you know, other things about measuring. We need such a specific neuropathy exam measure if the other measure is going to continue.

Female: So Karen …

(Crosstalk)

Karen Johnson: Yes. It's been a great discussion on – so I think a couple of really good points came out and one just has to do with the idea that we are talking about

endorsing national consistent standards. So, we do realize that there are a lot of many important care processes that have to, begun, but one of the questions that you're answering is do those kinds of things going to rise to the level a national performance standard? Knowing that you have the data collection burden and opportunity cost and that sort of thing. I'll just remind you that NQF in general has a higher article preference for certain kinds of measures.

And basically, we prefer measures better either health come measures or measures that are very proximal to outcome measures. So, sometimes measures that are – cannot be far really from the outcome they are just by definition as you said, you're (inaudible) a lot of evidence for them. So, as standing community members we are impressing you with basically the oversight almost of our portfolio of the diabetes measures.

So, those are the questions that you have to think yourself, you know, if, you know, what kinds of things would really push the needle as she said in terms of improving care and it might be, you may decide we these – the measures aren't quite what we need and if not, then we definitely want you to opine on what kinds of measures would be used.

So, again things to think about kind of as a big picture as you are going through the definition as well.

So with that, why don't we, for measure 419, I'm sorry, 417. I think you guys have (inaudible) on several things and this gap, I believe it – there wasn't much provided in the way of gap that there was a little bit of a discussion on the specifications themselves.

So, maybe we can just go to the reliability section and specifications and also to make sure that everything that you wanted care in terms of the specs for this measure, is brought out so that we can make sure that we summarize in the meeting as well as we possibly can. So, I'll hand it back to you Jessie to talk about the specs and reliability, that part of the (inaudible).

Jessie Sullivan: OK. Well, Karen, if I can just before I do that, I just want to make a comment about the priority because I do think that that does for measures less and significant health with high prevalence, high severity, and high cost. I do

think that this measure and the other measures make a good point and provide evidence that diabetic treatment of the diabetic for ulcer, preventing ulcers medication is a priority.

So, I just would hate for that not to be reflected in our discussion, I'm not sure that these measures have been (inaudible) there, but I probably want us to not say that and I guess I'd be interested, but just before moving on – other people (inaudible) with that was not the case.

Sue Kirkman: Yes, this is Sue Kirkman. I mean I kind of commented on all these foot measures. But I do think it's really important problem and it's certainly an area that, you know, requires a lot of focus. And it's probably one of the most preventable complications of diabetes. And the other thing that I wanted to say is, you know, we know that amputation rates, you know, for people with diabetes are falling. But on the other hand, disparities in imputation are continuing so they're sort of following in parallel if you look at black sorts of white for example.

So, I mean I think it's a little bit why I'm – I'd be concerned if we just sort of said, oh we don't need any foot care measures anymore which I don't think what anyone is saying. Something is working whether it's performance measure or, or not, you know, something is working to improve settings. But there still a lot – still a lot of improvements that need to be made.

Male: What we need is a foot measure but maybe a better foot measure?

Sue Kirkman: Exactly.

Karen Johnson: And we will definitely make that's, you know, your – your feeling about (inaudible) ulcers being a priority won't definitely make sure that comes through in our notes.

Female: OK. Well, you asked me too from my comments about, about the specification. So well, it's clear that this measure was then initially specified for PQRS and its G codes that are specified for the numerator. And as one of the other committee members pointed out earlier on the call. That the G codes describe that a neurologic exam was done but without specifying the side

component, but did not mention risk stratification or treatment plan. Even though the statement of what the numerator means is that it includes with stratification and treatment sign. But there actually are no specifications about this stratification or treatment plan, so – so those measure specified doesn't really address the statement of the – of the whole statement of the numerator.

And then beyond that I was – I was concerned about the – that the data sources. Because the measures that's specified for administrative data and clinical record including registry and electronic medical records and paper medical record, but there are no specifications addressing the criteria for meeting the measure except the administrative code that the G code that was provided.

So – so well it said it can be met other administrative measure that not specified for that so I think at the minimum they will have to take out the – or suppose to be accurate it has to say this is only specified for administrative measures. I guess – I guess our – I guess that was the main thing that – that was my summary of what I thought the comment set on to open it up to see what other people thought.

Female: Yes, I agree I thought it was – I thought it was unclear what is – what is exactly being measured.

Female: OK.

Female: OK.

Karen Johnson: I guess if in terms of time is – is there are, you know, like really burning questions that you want to ask the developer or anything like that, we can just go on and we can talk about reliability and validity testing. Again later, you know, and I want to be cognizant of time that I want you to be able to (inaudible) any issues or concerns you had about those, sections of the (inaudible).

Jessie Sullivan: Sure, OK, so this is Jessie, as I said reliability and validity testing. I did have a question for the measure developer. So I have a little bit I wasn't sure I quite understood what happened and – and I'm sorry I meant the call, (inaudible) or

Karen it was the new book I just – as I was traveling I guess I wasn't able to clarify because (inaudible) said that the measure was not in use but the reliability testing work done using comparing 2011 PQRS submission to the clinical record.

So, implement it from PQRS in 2011 and then – and then discontinue them and now it's going to be used again, so I just – I want – well I have a couple of questions so let me just ask a couple of question and then open it to developers. So that was one what is the (inaudible) they use. And then if the measure wasn't actually used in PQRS, we don't see any of the results of the PQRS reporting.

So I was quite concerned that we didn't see what the results of the measure were. And when I read and I might be misunderstanding this, but when I looked at the table display being the – that testing, it sounded to me like there were no negative results. So you were comparing what people had submitted in PQRS to what you found in the chart. And that was pretty good correlation for the most that was found in the chart, we thought was submitted to PQRS but there were no failing records submitted to PQRS. So because there were no failing record submitted to PQRS, then there must be a bias in the measure because in the supported document it said, you know, that the neurological exams are only done about 60 percent of the time and you wouldn't expect that to be 100 percent so, I wasn't sure if I was understanding correctly how the testing was done.

Male: Yes I think that, that goes, you have a good point Jessie and this goes to all of these measures. Where what is required to pass the measure and many of these measure have multiple steps of an exam. And if somebody puts in the chart normal exam in my book that wouldn't pass the measure as described. So we don't know what criteria they use to say when they validated the reporting that there was an acceptable performance of the steps as specified in the measure. I think a lot of these measures have that as they kind of almost they don't flow.

Female: That a good point because the medical record probably just has some sort of a check (log).

Male: Right and I don't, I'd be surprised if – I have always patients had a documentation at the neurologic exam was done, the vascular exam was done. I mean, you know, there were several discreet tests here that it's really almost the composite measure which adds to the complexity and probably the question here is, what is the – what's the testing that's accurate and the reliability of actually measuring this performance is actually (quested).

Claudia Shwide-Slavin: You know, this is Claudia and just in daily practice when I meet with patients and I ask them if they've had a foot good exam or a neurological exam if they have neuropathy. And if they say yes and I ask them what was done. I don't get consistent responses and I do ask those questions.

Female: Well, I will just say Bill that when Telligen tested this measure in their comments, they note that the components were inconsistently found. And they advised the measure developers to specify what all the components necessary so I think that you're right that it's not clear what criteria Telligen require to say that the chart met the measure. But – but I wanted to go back one step beyond that and maybe again I'm misunderstanding that, but isn't it a problem that all of the charts they were reviewing were passes? Because of that in alone show that there was bias in the measure?

Male: For the testing, yes.

Male: Do you want to response to some of your questions?

Female: Yes, no, I was, yes I was really hoping to share how (inaudible) I realized I maybe am misunderstanding.

Male: Yes, I think there is a lot of misunderstanding first of all this has been in PQRS systems since 2008 and continues to be PQRS. So that that could have – I don't know why it's a measure not in use, I think that that was a misunderstanding I thought it was indicating other than PQRS and I'm not aware of other programs that may have adopted this measure. So it's maybe in use in other programs so we haven't gotten any feedback on that.

But this measure is and have been in use in PQRS since 2008. In response to your question about, I don't know if I have to go back and look at what was submitted. But if you look at the PQRS measure as it's detailed, it describes a neurological exam. It describes two of the five components that's typically required. And that most commonly are vibratory and monofilament are considered to be the most consistent by the evidence to be consistent with neuropathy.

So when they did the testing they were looking – looking for two of the five components where they should have been. That's the way the PQRS measure is described. Further, this testing was done in podiatry offices. Podiatrists do and document this consistently. So if a podiatrist did this exam, you're going to find pedal pulses documented. You're going to find structural deformities documented. You're going to find the – the actual exam documented as well as some biomechanical findings.

That's typical documentation for podiatry. That's who we had access to to get testing with. That's the reason you're seeing probably 100 percent. So is there bias if you just evaluate podiatrists with this? Yes, but we didn't have access to anyone else. That whether we could use, that we knew we're using for.

The other part of this is that, the gap in care is because we developed this measure. Obviously podiatrists are going to report on this in the PQRS system because at the report could get certain things and this is one measure that works for them. But the rest – the gap in care is the gap in the rest of the medical professionals to take care of people with diabetes and ideally yes we'd like to have a composite foot measure as Dr. Golden described. That takes into account every component of the foot exams. Neurological, biomechanical, structural, vascular, history previous ulceration which is a huge component in determining amputations in at risk patients.

So yes that would be the ideal. This was developed when everything started initially with PQRI and there was a rush to develop measures. One of the other things that wasn't clear to me is the measure developer to APMA was that we were supposed to be redoing these submissions. I thought this was a review of already endorsed measures, and there was a lot of confusion as to

what we were supposed to do. So we didn't do a current literature search to see it. But one of the things you touched on is that the evidence base isn't there. We have tried for the past three years to get – we've gone thought the Medicare center for innovation.

We've gone through private insurance companies to robust. Let's do a comprehensive diabetic food exam, let's risk stratify the patients and let's compare those patients with their outcomes in terms of ulcerations, hospital amputations to those that just got the standard care that what's already offered. Nobody will take us up on doing a research project like that. So the – to develop – it's a catch point too, we can't develop the evidence base even though we know that there's value to this. And we've shown value to this, both through the study that was done through Thompson Reuters that was retrospective look which isn't as effective as doing a prospective study.

As well as the study that came out of Duke. It involved an incredible amount of Medicare patients. It showed when there was foot care particularly podiatry care on the team process. You had a greater outcome and a reduction of the amputations. So there's a lot obstacles to developing a truly effective measure. But just – just so you understand that a lot of these was that I didn't know that this was going to be like – this is being treated like it's a new submission to me. Which I wasn't aware of that – so I thought this was a review of existing measures. PQRS data I'm not sure how we access that from Medicare but there is data – these are measure – these are measures 126 and 127 in the PQRS system. So there's data going back to 2800 (inaudible).

Male: Oh a comment, you know, a review here with me, while we want to continue the endorsement. But it – when you describe, you know, the number of components, the task, the testing, does the measure and its specification say you only have to pass two of the components to that? Or do they expect you to do all the components?

Male: No, it says it's this – well – we'd have to look to see if it's in the original measure we described – but that one we described a neurological exam, we described the bio components instead that you have to do two of the (inaudible).

Male: That wasn't clear to me on that, OK.

Female: But yes – it's not and what has been given to us. I don't believe that in this specification we're looking at. It sounds like part of the problem with some confusion about what …

Female: Yes.

Female: … we were supposed to be looking at.

Female: I agree.

Male: The other question is, you know, this was designed for podiatry. Should this be in place for every patient and every primary care office, regardless of the risk status of the patients? Because you would assume in a podiatry practice, you'd be getting some – a referral bias, so you'd be getting the higher risk patients.

Male: Well, I think in an ideal world, kind of like the dilated eye exam which probably the primary cares aren't doing. In an ideal world, it's part of the diabetes group, there should be a comprehensive diabetic food exam included. And I don't think that's something that the primary – that the primary care physician has the time or the interest to do. But it should be completed. I mean it's one of the problems I see with how the whole system works. You should – as a primary care physician, you should only have to determine whether or not this was done. You shouldn't have the responsibility for actually doing it just like for the dilated eye exam.

I would assume that that's mostly done by optometry, ophthalmology not being done by the primary care in the group measure for diabetes and PQRS. And I believe it's an NQF endorsed measure as well.

Male: Does your measure exclude patients from needing an annual assessment if they have preexistent neuropathy?

Male: It didn't, that might be something to consider, but no, it is set up for to be a yearly exam for the patient.

Male: You know what? That's an issue, and it doesn't risk stratify patients who are in a particular risk one way or the other.

Female: Maybe it's a – maybe we can also ask you too. As long as we're talking at some specifications about age which we didn't bring up earlier. This is especially to the ages 18 and older. And I know that's a convenient denominator and all that I'd say about that and this is at the health plan level where (inaudible) in many measures. And it's certainly easier for me to do that if I have a group of measures, like a group of diabetes measures that all the same denominator.

So as an implementer of measures, I do not want to see additional denominators for each sub measure. But it seems to me that if the risk of ulcer and amputation in the 2016 review, it said that the risk increases dramatically. I think it was at age 40 and I don't know, you know, that – or the literature that – I'm guessing that it's somewhere older than 18 whether it really becomes the risk or just a built point and the other clinician's point about not wanting to do harm by getting clinicians to focus on things that aren't that important so that they can (inaudible) those things that are important. Is 18 really the year that the age that this needs to begin? Unless they're thought even to be starting at an older age?

Male: There was not at that time for us to start in older age. I will tell you there's recent – there recent article that was just out believe in diabetes care that actually talked about the higher incidence in type 2 diabetics, younger patients of – some of these complications such as neuropathy. So I think there's a change in demographic to the people that have diabetes and there also seems to be some evidence that some of these complications are occurring at a much earlier age than expected. So I don't know that I would necessarily change that age range.

The other issue is that when you talk about, you know, you talk about the diabetic food exam, NCQA measure that's harmonized to be the 18 to 75. Well patients over 75 are probably in greater risk for issues of diabetes particularly because they have probably more concomitant peripheral arterial

disease and you're excluding the group of at risk patients, you're saying, well, we don't have to look at their feet if they're over 75 which doesn't make – I understand the reason because it's in the group and doing some of the HbAc1 control causes some unintended consequences in older than 75 but now you're excluding group of patients that's at that risk for something in the measure, so in the group …

Female: No, I totally agree with you when we get to that measure, I can, certainly would.

Karen Johnson: OK well this is Karen and I think the developer's discussion about the PQRS is basically a discussion about why we thought that it was not then used. So that part is good to know. I think in the interest of time, is it OK with everybody else if there's no other burning questions in this measure, let's go ahead and focus on measure 0056 the diabetes foot exam.

And Dr. Golden I think that one is yours.

William Golden: Yes I think so. I'm trying to find, where are the comments that was submitted here, I have to look at my notes. I felt like it's into the website.

Female: Yes …

Male: Folder …

Karen Johnson: Sorry they are underneath each major groupings, so criteria one important measure report. Evidence and gap and disparities and priority are all listed under there. And then after that is all the different comments that cam through on that group of criteria.

William Golden: Yes, I am getting warmer.

Jessie Sullivan: Karen, while Bill is looking, I tried a webinar in the – it's had the link with the wrong address. Could someone just send the link out again if that's possible?

Female: Sure we'll go ahead and resend that, who is this speaking?

Jessie Sullivan: So Jessie, Janet Sullivan.

Female: OK we'll go ahead and send that to you.

William Golden: That was interesting I see my – I see something under my name and its empty. Did you all get my comment? I did put something in, but on the website it looks like it's empty.

Female: (Inaudible) in comments, oh.

William Golden: I'm just having trouble today, OK. Well anyway.

Karen Johnson: And this may clear you, Dr. Golden what are you looking at, are you looking at the doc …

William Golden: Number 38. So I mean there's committee, preliminary measure evaluation.

Karen Johnson: OK, can you get you get the file that's called 0056 underscore (all)? Do you know how to get there?

William Golden: Oh yes, yes OK that's – yes, that's just the original.

Karen Johnson: Yes, but we've – included the – all the different workgroup comments in there. So it's a – there were rows that said pre work group comment that were empty (inaudible), and now, they're not empty.

William Golden: Do I get a piece of cheese once I get this stuff? Now, I have to re-log in. Now, you have a very (inaudible) website.

Karen Johnson: The share point? Yes. I'm not going to argue …

Female: I just got lost out of it too in the middle of the …

William Golden: Now, let me in. So, I was logged in now (inaudible) see it. Oh you know what? Do you know what I'm finding? If I don't download the – I can't open it (inaudible), I have to download it to my desktop. It's pretty goofy but not as goofy as the travel arrangement. Oh no. OK.

Anyway, I think in terms of questions, this is the national quality, (inaudible) this is a national quality NCQA measures and the – and it's in use and I think

that's – it also talks about had comprehensive, basically the numerator said, "Patients who receive a foot exam, visual inspection, and sensory exam was monofilament and post exam during the measurement period was denominated with anybody with 18 to 75 type 1, type 2 diabetes." So, that's the numerator.

The specifications or a little more detail and the evidence basis is very similar to what our previous discussion was where, you know, the evidence is not as good as it should be that I mention that's not a reason of you labeling that kind of thing, the level 2c. And again, the evidence for a monofilament exam as it preferred and demanded standard for care is not very strong either. And if you notice in the evaluation, it talks about a pulse and a neurologic exam and it really doesn't queue into structural integrity like nails, calluses and other deformity.

So, in general the evidence supporting the material as stated and as specified is not very strong.

Karen Johnson: OK. Any other committee members want to add to, what Dr. Golden has said so far? Can you disagree that's or questions about the evidence from this measure?

Sue Kirkman: This is Sue Kirkman, I mean, it's just a similar comment to the prior measure I think. think a lot of the evidences for, you know, foot exams, plus risk reassessment and high risk people going in to some sort of comprehensive program and that, you know, I think it's just hard to pull out, you know, just a foot exam and show that – compared to no foot exam, you know, that outcomes are better and so again, it's kind of a similar problem with the prior measure.

Karen Johnson: OK.

Sue Kirkman: And this is certainly – a certainly a necessary component of risk assessment that sort of makes sense but it's along that evidence pathway but I just think it's hard to kind of prove that it's the foot exam itself.

Karen Johnson: OK. Let's go on to gap.

Male: (Inaudible) my comments in here by in terms of gap, in terms of – is there a failure to perform? I think the answer is yes. I don't think anybody is going to argue that foot exams could be better. I do – when I look at the literature, a lot a literature that gets quoted is 20 years old which make me uneasy about just how large the gap is. There is – well that's disparity. So, yes, I think that there is – that foot care could be better and the degree to which it could be better is unclear.

Female: OK. I know one of the things that the staff review had noticed is that in the three years of PQRS data that were presented. It was like the rates – the performance rates for – with survey study that – what do you think about that?

Male: Honestly, I don't really have a lot of phase that PQRS rates reflect the measure it specified. And so it's hard for me to say what that means.

(Crosstalk)

Male: What things that the existing measures are so cumbersome, that it will be very difficult to move the needle.

Female: Also, wasn't it actually the diabetes, the DTRPs where the data were presented.

Male: That was the testing, the measure hasting was in the DTRP which I would not consider to be a general population. So, yes I agree with that in terms of …

Female: Yes.

Male: … the measure.

Female: OK. Let's go down. I'm skipping over disparity and priority a little bit just because the disparity is important, but that's not really something that we look at in terms of would that make or break a measure. It's just something that we want to think about in terms of maybe how things are specified or tagged, in priority, I think we've all agreed that you know, diabetes is they, a lot of people have it and that or with the big problems in amputation so, I think we can kind of assume a priority.

Male: Yes, the only thing I would say though about the disparity is that the measure developer didn't provide any disparity data. And I'm pretty certain that amputations in black diabetics much higher than in white, so I'm pretty sure, there is a disparity.

Female: Oh yes. There are disparities by race, ethnicity and age and amputation. But I don't know if there are disparities and whether the exams are done more or less.

Karen Johnson: Does anyone on the committee have any idea about if there are disparities in the exams being done or is it mostly about the amputation?

OK. So, let's go ahead to the specification and see if there's anything that we need to discuss specifically about the specification, Dr. Golden?

William Golden: Yes. I'm here, the specifications and again I'm looking for my notes, but the specifications really are not clear about the monofilament exam, about the pulse, I mean there are several components technically to a path that's measured. And it is not clear from specifications as provided as to what you have to have documented, the past measures.

Karen Johnson: Is there something that you would like to address to the developer to see if they had any insight on that?

William Golden: If they had a comment, I'd love to hear them, sure. Yes?

What, you know, what I "normal exam" or "normal pulses" no neuropathy path or do you have to document monofilament would perform pulse, this pulse and that pulse was palpated and not palpated, those kinds of things.

(Crosstalk)

Male: No, we can never go in this pulse, I'm sorry. But we can never go in this pulse (inaudible).

William Golden: And in this issue, is that if it's not clearly specified what must be documented, then you don't know if the data are being reliably abstracted.

(Off-mike)

Female: Reva, or anyone from NCQA do you care to speak to that?

Female: Can you hear us? Hello.

Female: We can hear you.

Female: Oh, OK. So we need …

Male: … we need to try a couple other times to (tight up) but it wasn't working.

(Mary Burton): (Inaudible) is open. This is our (Mary Burton) from NCQA, I guess several things would have been mentioned. One, is regarding the evidence for the measure, so I wouldn't want to, have it not be said, but this is relying on 2013 updated guidelines from the ADA. And if the ADA is given a B rating in their system to that – not necessarily randomized control trial data but the cohort data that supports the foot exam as part of the overall care of the diabetic patient.

So, I want us to make sure that we were able to make that clear. Definitely in terms of the disparities in section 1B.5 of our submission form we have noted data from the CDC that shows that there are socioeconomic disparities in the performance of the foot exam, that people with the high school education or less have a much lower rate than adults who have greater than high school or college education. So, I think that that also I'm not sure if that forum was actually transmitted to all the members of the workgroup.

So, I wanted to make sure I said that. Then finally in terms of the specifications in how the chart review, you know, this is in use in our diabetes recognition program and so that clear – the question of whether this is, you know, clear, we have this constant of at least regular back and forth between the programs that are being evaluated (inaudible). And then have foot and (inaudible) stored for the recognition program. And in terms of their, you know, they'll ask of questions that they want to know how would they, you know, how – what would count in their chart review, the (inaudible). And so,

these specifications that we've come to are – reflect that in use measure. To me it's actually not. I'm not sure – then, lacking specificity because that requires a monofilament, a visual inspection and monofilament exam and a pulse exam.

So, I could certainly imagine and I'm not sure if this is what the question was going to that there could be, you know, you could talk about the dorsalis pedis 2+. Or you could say, you know, BP 80 both normal. I'm sure that there are a variety of ways the clinician can mark (inaudible) pulse exam but it's not clear to me that this is an area of great confusion where lack of specificity and agreement between the people who are taking care of diabetics and the rate and the people who reviewed that chart.

Male: So, (Mary) have you done any similar kind of assessment of primary care practices, family practice internal medicine but it's only in people with (inaudible)?

(Mary Burton): What an actual question. Because I think this recognition program is offered to practices that seek recognition for their care of diabetics. And so they've raised their hand, you know, this is something that is reinforcing some, by some insurance companies, by some states where they provided the recognition to the practice …

Male: Right. But the question is in general practice other than people who are volunteering to be in a recognition program have there been any assessments of its reliability?

(Mary Burton): Not my knowledge.

Male: Thank you. The other question is, do you have data that say that you have to do a monofilament exam to measure for neuropathy and primary, are people with existing neuropathies excluded from the measure?

Female: So, the question was, so that comes straight out of the ADA guidelines and we are not in a position to be guidelines developers ourselves but we are, you know, we rely on high quality guidelines which we had deemed this ADA

guideline to be and it specified these at the monofilaments. So, I think, you know, that …

Male: ADA guidelines are not always the most evidence-based but that's OK. But you have no comparison data to specify this particular technique.

(Mary Burton): I'm not sure I understand the question.

Female: Well I think there is some data that monofilament are more predictive of future ulcers than some other test.

Female: And probably that's why the ADA states that technique.

Male: But you're not sure.

Female: I mean I think in the, one of – it may have been in one of the other measures but there is a paper that looks at the sensitivity and specificity and positive and negative predictive value of the different tests.

Male: It is supposed to be sensitive, not always specific but not sensitive.

Female: Right.

Male: But there are other tests and other techniques that's why if (inaudible) to the universal standard of their alternative and less cumbersome ways of doing the exam.

Male: This is (inaudible) at NCQA, just for your information in our – we've had our testing forum on the estimates of benefit and consistency of cross studies and body of evidence of 187.7. We do include the sensitivity and specificity of the predictive value and then the predictive value of those screening tools, assessment tools.

Female: I'm looking at the 2014 clinical practice recommendations from the diabetes care and the reference on the screening is to a diabetes care article in 2003, peripheral artery disease. That's an old reference. I'm just wondering why they don't have anything more current.

Female: Well, I think again part of the problem is that I do think, you know, maybe it's because of performance measures but I think the foot exam has sort of, become an insurance part of the, you know, diabetes care environment and I think it's going to be hard at this point to say, let's do a randomized controlled trial and not do foot exams in 5,000 people and do foot exams in 5,000 people and follow people for five years and see whether amputation rates are reduced.

Karen Johnson: So, maybe let's get ahead just a little bit and talk about – I think there was a question about the – under the specifications and particularly related to validity, that (Jim) talked about the age inclusion, the 18 to 75.

Female: Are you asking me?

Karen Johnson: I'm sorry. I'm actually addressing it to Dr. Golden first, but then anyone in the committee and then of course to see what to ask the developers (inaudible) so they would …

William Golden: (Inaudible) that involve me one way or the other.

Female: OK.

William Golden: It's the measure, the measure to get a good swap of the population, you know, how am I going to worry about that one too much.

Female: OK.

Female: So, I actually disagree. This is Sue Kirkman. I mean, ulcers and amputations are so much more prevalent in older people, you know, I just think it's a – and it's a complication that can develop quickly and can really impair people's quality of life. So, I don't see any rationale for stopping age at 75 if we're going to keep the measure.

Karen Johnson: OK. Any other committee member's want to jump in on that, or – OK and then I'm going to just going to go into the usability …

Female: I'm sorry I'm setting a little trouble from (inaudible). I think you're going to have a question about that. Well, it would seem to, so I agree with Bill that,

you know, the big chunk of the population and as they measure implementer, I might decide for the convenience of doing the implementations that I want to have a single denominator and I'm going to use 18 to 75 for convenience. So I can have the same denominator and I will – if measuring – if foot exams are important, then doing its measure for that big chunk of the population will do good and more good than the harm by missing the older population. If the measure were specified to be 18 or – I guess I'm wondering why we couldn't have a, some way I'm saying that the measure was the acceptable, if it was used with either – depending from what context in which it was implemented.

So, if you were only doing a measure of food exams it doesn't make any sense to cut off the age of 75. If you're doing this suite of diabetes measures you're going to run into trouble with A1C above 75 so there might be a reason why you want to do the suite going to 75 and includes foot exam.

So it seems to be like an implement question but then implementers could be in the position of saying they're not using an endorsed measure because they've used a different age range, is there any way around that or we just (stock) with that being a problem.

Female: I think in terms of looking at NQF endorsement, we really are trying to have you look at the measure as specified in the attribute to the measure. So try not so much to think about how it might be implemented other than or, you know, is it able to be consistently implemented across, you know, various populations and practices in that sort of thing. So there's nothing really in terms of the endorsement side of things to let you think too much about the implementation other than what we're doing under feasibility and usability (inaudible).

Female: Well then, it seems to me Bill that as a standard, there's not really a specification for saying the standard for foot exam and the age 75.

Male: OK, OK.

Female: All right so I think we've got through most of the points that were unclear for this measure but I will open it up to the committee members again if there's

anything particular under feasibility or usability in use that you want to bring out?

Jessie Sullivan: This is Jessie again. I just wanted to raise again, we discussed this earlier with the other measure that the share of doing harm by saying we don't need a measure of foot exams when we don't know the degree to which the fact that we have had measures of foot exams may have contributed to a decline in amputation. And I don't think there's any way we're going to know that. But I would feel uneasy about things that we shouldn't have any measure of – I wish I had a better measure but in the essence of a better measure, in (inaudible) about things, we should have no measure.

Male: Yes I take a different tactic, I think a bad measure is potentially concerning is having I just think it's – we are demanding a major practice standard that may not be implemented or implemented poorly, you know, gets back to the (Berenson) article. It becomes homework assignment that you somehow make the chart look happy rather than actually doing appropriate and meaningful pair. So I think that there is a real issue as we move any of these measures forward.

About making sure that the measures are meaningful for the clinician and actually becomes something they value as a core component of care.

Female: (Inaudible) I think that's a pretty good (inaudible).

Karen Johnson: OK and, you know, from NQF perspective just to remind the folks sitting around the table and the committee are going to be with, you know, coming in with lots of different backgrounds and expertise and, you know, we're going to have participants at the table and consumers at the table. So it will be interesting to hear, you know, how these issues are perceived by the various folks. And I think we'll probably see something similar in the in-person meeting as we've heard today in the work-group calls in terms of some of that earned questions and, you know, it's in the end of the day when you vote on your measure, you just have to vote based on, you know, what you personally feel in terms of the usefulness in the measure and how it will work to guide improvement.

So, these are all great questions and great things to be thinking about. So we have about 40 more minutes, which is great because we have two more measures to get through. And I'm thinking, our next one should probably be measure 416. That one is the footwear measure. And I believe Claudia, that one is yours.

Claudia Shwide-Slavin: OK. Yes this is the developers of the American Podiatric Medical Association and it's about foot, ankle and ulcer prevention by evaluating footwear. The rationale is because people really have their feet exam done on a regular a base system. And so this is where we got the 60 percent, below 50 percent consistency in the exam and the high cost. So, there have really not been studies that have looked at this, the evidence that was presented in here were two studies.

One was done in the U.K. and one was done in the VA and the studies also were not done the same way and the U.K. study pointed out that there was a difference between measuring people sitting and standing and it didn't seem to be any way to capture that in the documentation. There's a process review and again there was no, just like with the other one's, there was no like review. And no link of the measures of footwear to patient's outcomes to lower the rate of ulcer formation.'

So that's sort of the summary of the comments from CMS.

Karen Johnson: OK committee members would you like to spend time on that summary? Any other concerns that probably you didn't bring out or things you want to talk about a little bit more in detail?

Male: The only comment, when you – the only data I saw about the performance gap, about the lack of foot exams. The couple of references I had seen in some of these documents was middle 90s or early 90s. But anything newer than that or is that similar?

Female: Is that a question for the developer?

Male: (Inaudible) that was the only thing that concerned me with some of the performance or lack of exam, right. I saw some references that went back to

like 1995. I was just curious if there was, it has still a numbers that people are using in those quotes.

Female: I think, you know, for this particular measure this is not even what, you know, maybe non-podiatrists would consider part of a standard part of the foot exam. You know, I don't think any, I mean outside of the world of podiatry, I don't think primary care doctors are going to be, you know, measuring people's feet and you know, seeing if their shoes that – so I think the only evidence that was granted was the evidence about that people frequently wear ill-fitting shoes and that people with ulcers are more likely to have been wearing ill-fitting shoes than people without.

(Off-mike)

Female: So there's evidence for the problem but I don't think that there is any evidence for the intervention that's being measured.

(Jeff Alice): Now this is (Jeff Alice) concerned about (inaudible), I just wanted to ask the developers what they thought about that because it sounded like some sort of when I was guideline their guidelines. It sounded like there was more evidence for measuring foot pressures when people have neuropathy. And then also there was some recent evidence cited about podiatric care and the structured foot program, but not specifically about measuring shoe size, so I would like to hear what the developers wanted to say about that.

Male: Basically, probably the most significant study is that VA study that was done that linked the higher incidence of ulcerations with the improperly fitting shoes. There aren't a lot of studies on how the shoe fits related to people with diabetes and neuropathy. So there's not a really huge evidence base for it but that was pretty compelling evidence when you have five times incidence of ulcerations with the improper shoe fit. I mean the obvious problem here is somebody with peripheral neuropathy doesn't know when they're wearing a shoe that's too small for them. That's more of the incidence of it is to check the shoe fit, not so much to check – measure the person's foot but actually to check the shoe that they put on their foot.

The other problem you run in to with trying to do any of these types of study is there's no consistency with shoe sizes and (inaudible). So you can measure a patient that's size seven, size seven might be too small, might be too big, it's really – actually physically examining how the shoe fits a foot.

This measure also talks about doing structural evaluation so if you have patient that has structural deformities such as bunion deformity or a hammer toe deformity then the size that should fit, the style, the shoe that they're wearing, in other words they may have to have shoe that has a high toe box to accommodate the foot better. So from an evidence based point there's not a lot of research that's been done on this particular thing but it does show up as consistently putting a patient at greater risk if their shoe does not fit properly and they have neuropathy.

Female: One of my concerns was that, if the shoes that has to be evaluated where's the training for how – how a person evaluate shoes that, and what instruments is going to be used to the evaluation of a shoe fit outside of a podiatry office.

Male: I can't really, I'm not sure how to answer that because I'm not sure who – we talked quality measures related to having equality measure done for the patients. And the person that does a quality measure has the capabilities to do the measure. So I'm not sure how to answer your question specifically on that. If you can't do this quality measure, then you probably shouldn't. And you – if you think the patient should be evaluated you should probably refer it to the person than can do it.

Female: Well if this was going to be done in let's say a primary care office, to my knowledge is a primary physicians haven't ever been thought about checking how the shoes fit.

Female: I understand that you're saying that just as a primary care doctor would refer to an optometrist or ophthalmologist for a dilated eye exam, primary care doctor would refer a patient to someone who could to this exam, if this exam will lend to us better outcome.

Male: Correct.

Female: OK.

Female: So then are you essentially saying that everybody with diabetes should be referred?

Male: Personally, I think everybody with diabetes should have a comprehensive foot exam and part of that should include evaluating how their shoes fit them. Yes, now whether that needs to be referred probably it does. I think that would have an incredible impact on reduction, ulcerations and amputations and it will be incredible cost savings in the long term. The problem it that no one will pay for these types of services. So you …

Male: So when you said, that it would be a cost savings. Cost savings at every diabetic (inaudible) or a risk stratified?

Female: Yes, I mean I can't imagine that, you know, the 21 year old was relatively recent on type 1 diabetes needs to be referred to a podiatrist. So I mean – I mean that's my concern is that if you're saying this measure, you know, if its primary care can't do this which they can't, then they should refer to podiatry or essentially saying that everybody over the age of 18 should be referred to a podiatrist. And I don't think there are enough podiatrists in the world.

Male: There probably aren't enough podiatrists in the word but if the cost of doing a yearly evaluation on a patient with diabetes versus the cost of it just one of those patients develops an ulceration that leads to an amputation, it's not even comparable.

Male: I would just – I would like to see some numbers on that. I think that would (inaudible).

Male: (Inaudible) is we have them, it's – yes and we have the numbers so it's just that the cost in so many terms per patient that undergoes an amputations is just in terms of social cost, in terms of their …

Male: Oh, OK. You can make a hangnail look very expensive, depending on how you can calculate the cost, so.

Male: Why you have – and take those away. It's just a pure medical cost of undergoing ulceration, hospitalization, amputation compared to the cost for a single yearly exam.

Female: But again I mean I think especially for …

Male: That's not for this measure, (inaudible) not what this measure really addresses.

Female: I know but if you're saying that really this – what this means is that people should be referred to podiatry, I mean there has to be some risk stratification. You can't, you know, you're going to do an awful lot of exams and measurements and so forth on really, really low risk people. And I mean, you know, we need to focus effort on high risk people and some sort of risk stratification. So I mean it's perfect for this measures, it's really to say that everybody should go to a podiatrist (inaudible).

Male: No, that was never the purpose, no, that was not the purpose of the measure. If you're asking me an opinion, that was not the purpose of this measure. This again this is to identify patients that are at risk for developing ulcerations relative to improper shoes. If, yes it – all the patients forget someone to do an initial exam to do the risk stratification that would be wonderful. And that's what should occur.

Male: And for the committee members, I've just sent you the members, a risk stratification scale with percentages of risk for ulceration and amputation that you can look at.

Female: So if you see that while we're really sort of discussing this, the problem of the lack of evidence that shows that this exam and this age group would improve outcomes and I'm not saying it's not true, I just – I'm just saying that we don't have firm evidence because if we did have firm evidence that would be a reasonable measure and they – even if there weren't enough podiatrist, it would still be the right thing to do if there were evidence that this was the exam that could prevent amputations, and that it would be applicable to all people with diabetes over 18. I'm thinking that the problem goes back if we don't have good (inaudible) but that's actually the case.

Female: Is this another one of those cases where we don't have the evidence because the study won't be done?

Female: Well this one is a little bit different because again I don't, you know, I don't think this is part of the sort of standard clinical care for people with diabetes, you know, most people with diabetes are taken care of by primary care providers. And, you know, I don't think they're doing this so it – it's a little bit different from the other ones where I think people sort of accept that foot exam with pulses and monofilament or whatever it is kind of standard of care and so it's harder to do a randomized controlled trial.

Female: OK.

Female: Well I know in the primary care office, the pushes just to get them to take off their socks so that he gets looked at. Because people often don't even, you know, take off their socks. And then if it doesn't get looked at.

Karen Johnson: OK this is, this is Karen again and I'm going to step in and just – to move us along mostly because of time, let's see, I think a lot of the comments that came through had more to do – maybe a couple of things, with the specifications themselves and I think this maybe a little confusing like the first one that we discussed. We're just not really sure about whether the measure is in use or not. So maybe, if we can real quickly hitting in the high points on the specs or the – the specs and see if there's anything we need to discuss there. And maybe we've already done that here, I'm not quite sure.

Female: OK, I think a high point really is that there's inconsistency and – in the interpretation. It said here, Telligen does not explicitly state how many components of a defined footwear evaluation exam at the present and that they found this to see and how this was interpreted. The measure does not specify aside being counseling required and G code, these are the measure don't mention risk stratification or counseling on shoe size. And I think these are all comments that have already, you know, been made. It just – it's just nothing really different in that.

Karen Johnson: OK. Do the committee members have any questions or anything else you wanted to bring out about specs or testing any of that stuff? And maybe if I

might direct a question to a developer, can you just clarify if this measure like the other one has been use in PQRS, if we've just misunderstood what you said in the submission?.

Male: Yes, that's correct.

Karen Johnson: OK so it's been PQRS since 2008 like the other one?

Male: Correct.

Karen Johnson: OK. OK if there's nothing else major about this one I should go on to measure 519 which is the patient education measure. And let's see. That one belongs to Sue.

Sue Kirkman: Yes, so this is a measure titled Diabetic Foot Care and Patient Education Implemented. The measure steward is CMS and the – it's an interesting measure because the population is people that are getting home health care.

So a percentage of home health episodes of care in which diabetic foot care and patient class caregiver education were included in the physician ordered plan of care and implemented for diabetic patients since the assessment. And the – this is an existing measure I guess it's been existing since 2009. The population excludes people, let's see. I got a little mixed up about the exclusion. So – so if that excludes people with bilateral amputation, then it excludes people where the home health episode ends and patient death.

But I don't – I think episode means the entire time that there's a home health. There's home health care going on. Since it's a process measure, it's collected electronically. These specific-formed OASIS forms which must be something about how data is collected by – by home health agencies. It is publicly reported. But the evidence that's cited is kind of a mixture of some guidelines and randomized controlled trials.

There is one Cochrane review that is about patient education, foot education and concludes that – that the evidence is insufficient regarding patient education alone. I mean that is a pretty good systematic review with quality ratings and so forth but that's their conclusion. And the other, you know, a

comment I think about the evidence is I don't believe that any of those studies were done in the home health population.

So I think they were all done in the ambulatory population. I don't know if you just want me to just keep going in the interest of time or?

Male: I have a question for our NQF staff. So if you look at these measures, and you know, I've heard some podiatry and we heard about that. The diabetes recognition program and now we hear one of our home health, are these measures to be assumed to be universally-applied or for targeted providers or has that been done in the past with NQF?

Female: In general, we don't look or consider measures that are – that should be targeted for – for providers per se. But we do understand that there are some measures that are targeted to particular subpopulation or even care settings, so in some cases, that will limit the provider – the providers that might provide the care. So to make it succinct.

Male: (Inaudible) settings, it doesn't mean a specialty office. It would mean an out patient as opposed to an endocrinology office.

Karen Johnson: Yes. We really think about it a lot if we think about, you know, hospital measure maybe as compared to a physician or an outpatient office. A nursing home specific measure that kind of thing is – is what we think of more what the care setting side.

Male: I just want to make sense of the ground rules, thank you.

Female: And this so but I just said one comment about that so that I mean just mentioning the diabetes physician or diabetes provider recognition program. That is not primarily endocrinologist but that and I don't know if the NCQA people, are some – some the majority of the people that have the PRP recognition or primary care providers. But it is a voluntary program so it's a little bit of a self-select population. But it's not – it's not measuring just specialist.

Female: This is NCQA and you're correct.

Female: So for this one, I'd presume it's measuring, you know, it's sort of measuring whatever physician is doing, is supervising that home healthcare and the – the other clinicians that are implementing the home healthcare.

Karen Johnson: And – and this is Karen this one is specified for the agency level, so it's not – it is just not really measuring clinicians that's really looking at the agency itself, so however they say that kind of oversight.

Female: But it is based on the physician orders and them being that …

(Crosstalk)

Karen Johnson: … the OASIS is an assessment data set that is in the home health so. And maybe that's something the developers need to weigh in on. I don't want to say anything incorrect for that one.

Female: OK.

(Kazaya Cook): Hi, this is (Kazaya Cook) from Acumen and one of the developers would you like me to clarify?

So the home health setting required a standard assessment which is called the OASIS. And that's where this data come from. That basically when a Home Health Agency completes the first assessment, they work with the patient physician to develop a plan of care that will meet that patients needs. The physician, you know, approve the plan of care, signs the plan of care and then the Home Health Agency implements that plan care.

Again with communication with CDAC on to the physician. So what we're measuring with – with OASIS based measures are actions taken by the Home Health Agency. But yes, the physician is involved in developing an appropriate plan of care for each patient.

Female: So do you want me to continue? I don't know if anybody else had anything to say about the evidence. In terms of the gap the gaps in care and opportunity for improvement, the average performance is pretty high. It's 93.4 percent or, you know, performing on this measure, there's a six – there a 16.7 percent

performance gap from the 10th percentile. So there's, you know, there's not a huge gap between the 90th and the 10th percentile.

There is – there has been some improvement since 2010, so that the developers presented the distribution of results from 2010 through 2013. And the results improved, for 2013 the result are above 90 percent at the 25th percentile. And they also presented data on disparities and it's above 90 percent for all the disparity stratification groups.

Karen Johnson: OK, does that lead you to think that there is a gap or?

Female: Well I mean – I mean I think – I think it shows that performance is already I mean it's quite high now. There not much of the gap there – there has been, you know, some improvements since 2010. But again it was – it was fairly high and it's quite high. And so that to me kind of raise the question about whether we could expect this to continue to drive improvement and care when performance is – is that 93 percent already.

Karen Johnson: OK, any other members have any thing to add on gap in care?

Jessie Sullivan: This is Jessie. Just as an example where I think that I don't know that the evidence supports that it's once doing there. But this was an example where I think if they stopped measuring this, it would no longer be done. I mean it's the reason that performances to (inaudible) it's because it's the required section of (inaudible) support that was required to do on healthcare.

So I think the danger here is the one Bill raised earlier, the opportunity lost, you know, should the Home Health Agency better spend their time educating about something else that would make more difference from the time they spent educating about this and I don't pretend to know the answer to that. But I don't think the evidence was really clear but I do think that if they stopped measuring this, the agencies would stop doing it.

Female: But I also had a question and maybe the developer can answer those is, you know, I just want to assure whether this was just a check box, you know, it's kind of like, you know, it's sort of, you check it off in the physician orders and then somebody checks off. Yes, this was done and, you know, do we really

have evidence that, you know, it's thorough that you know, foot care education that's effective, that it's – or is it just, you know, yes I did it.

And if it's just, you know, yes it was done then I'm not sure that having the measure go away would necessarily change anything. You know, in other words I'm sure that first of all I'm not sure that there's – any evidence that is impact on outcome in the home health population but, you know, I'm also just not sure that there's really good education being, foot care education being done or is this just, you know, checking off a box to meet the measure.

Female: (Inaudible) would you like to (call).

Female: So the OASIS data set itself, you know, it has – it actually have two items, the first item is, you know, was this included in the plan of care and that is a yes, no or not applicable. And then there's a second item that, you know, was this implemented? We do provide fairly extensive guidance about how those items are to be completed through the OASIS manual.

And there's also, you know, training the CMS provider for home health agencies instead of state coordinators. In terms of, you know, what are they are actually doing certainly home health agencies are, they're basically the division of surveillance certification audits from health agencies on approximately three year basis.

So during the audit process, the auditor certainly can request, you know, to see the chart to see documentation on what was conducted and so forth. The OASIS item itself is a yes or no item but there are, you know, guidance that's provided about what it means to be providing diabetic foot care and education.

Female: And it's more that just in the chart. It says foot care education provided.

Female: I mean, I think you need to keep in mind that, you know, the question is about what was included in the plan of care and what was implemented. So, you know, what's being asked is, you know, were these things included in the plan of care and the guidance is sort of what counts. Like if you said you look at the person’s feet and acknowledge they have feet. That would not count. I'm

being extreme and so and, you know, we've had to read the manual to learn the exact level of specificity, I can't tell you kind of off the top my head.

You know, exactly what that guy is but, you know, there is guidance providers about what diabetic foot care and education means in the context of including it in the plan care.

Female: OK thanks. In terms of the priority, you know, it's a lot of what we talked about before that, you know, foot ulcers are a big problem and, you know, this one in particular talks about older people and the Medicare population and how their risk is extremely high. In terms of the reliability and the validity, you know, they do present a lot of data I mean there is this OASIS data set which is quite robust and they do present a lot of data on the reliability and validity.

In terms of validity there is some data presented that this measure correlates with other quality measures, you know, whether there's a statistically significant correlation and that there's a slight negative correlation with emergency room visits, so there is some suggestion that, you know, that there's correlation with other quality measures so that maybe it is a valid quality measure. I don't know enough about this field to know whether how meaningful that is. Because again I think you sort of get into the home work issue and if you, you know, if you're likely to complete your homework in one area you're probably likely to complete it on another.

There is some discussion from the measure developer from last that was initially proved about exclusions for the long term care episodes. And I guess that was suggested by NQF and I wasn't quite clear it sounds like the developers didn't feel that this actually did reduce a burden of measurement which I think is why the exclusion was included. But I don't know that they are asking that that exclusion be removed.

Female: The specification we submitted does remove the exclusion of long term medicine

Female: OK. So you would include that in the measure going forward?

Female: Yes.

Female: OK. And my understanding is that because you only measure this once. It's not like an annual measurement. So it doesn't really matter if it's a long term care or a shorter term care episode, is that right?

Female: It's measured at discharge or transfers that's measured at the end of the home health episode. And the look back here, it is actually only it's the previous assessment. So it's always a look back area that basically in most 60 days long. And there's a initially some concern that "What if the intervention was done in sort of the first part before that" but that would actually still be part of the documentation of the plan of care. So they still like capture it, you know.

So basically there was very negligible impact on the actual performance rate by including the long term episode and it did actually significantly increase the number of Home Health Agency to have enough episode of care to the eligible for public reporting.

Female: OK. In terms of – sorry.

Female: I was going to say a question. This is for the home healthcare. Is there another measure for the general population for foot care and education?

Female: Just one that we've talked about …

Female: Because back in CMS we really need it. Because it doesn't make sense to me why this, you know, why there is one for home healthcare but there isn't one for the general population. And yet we ask for the foot exam and the education?

Female: I guess that's kind of a larger question than whether to renew this measure.

Female: Yes it's much bigger question, that's why I kind of waited till the end to ask it.

Female: Yes. In terms of feasibility, it sound like it's an electronic reporting and it's a, you know, it's sort of a, you know, it's the developer mention that's a yes, no (inaudible) reporting so it seems very feasible. It is being used it's publicly reported so the people can compare one agency to another. And I didn't feel

that there were – because it's such as specific population I did not feel that there were really competing measures. Because the other measures seem, you know, sort of specific to ambulatory care and this is specific to home health.

Karen Johnson: OK. Does any of the committee members have any other items they wish to talk about this measure?

Male: I guess I have a question. So this is that there has to be diabetic education by the Home Health Agency. But if – if the patient had gotten education elsewhere, that would not be transferable is that how the measure is structured?

Female: Well it's foot care education. Yes.

Male: But even so, so if they went to a podiatrist in the previous five months …

Female: Right.

Male: … that would not count?

Female: I don't think so maybe the developer can clarify.

Female: Sure. So again the question is about, you know, where this is included in the plan of care and was it implemented. So, you know, I think our anticipation is that the all patients who are diabetic and not bilateral entities would have some requirements for foot care and education that would be, you know, appropriately included in the plan of care and implemented. The precise requirements are up to their physician and the home care agency.

So if the physician knows "This patient just attended a workshop that provided very detailed instructions, you know, he's probably only needs a refresher" or, you know, "I'd love to loop in his wife who is actually taking care of him while he's off his feet." So the idea is that, you know, because the item is only a yes or no that leaves flexibility to the physician to the home care agency to include, you know, education and care that's appropriate for that particular patient.

Karen Johnson: OK. Any other question about this measure or any other pieces to discuss?

OK, it sounds like you guys have done a really nice job. I can tell that everybody has looked and thought about these measures and has really had a chance to apply the criteria so very pleased about that. So I think I want to hand it over now Katie.

Katie, will you finish up what we need to do for the call and also I want to say thank you very much to the developers for being on the call and answering all these questions. We really do appreciate it.

Katie?

Katie Streeter: Sure. Thanks everyone for joining us today. If you did not receive the information from our meetings department regarding travel arrangements, please give a call or send an email we'll make sure that you have that information. Otherwise as far as next steps, NQF staff here we have one more workgroups to have a call with, workgroup 4 on the 18th and then we'll plan on meeting everyone in person at the end of the February also …

Male: (Inaudible) travel. I tried to use your airline system last night and frankly it was A, frustrating; and B, I can get a better set up and for less money if did it on my own so I'm just curious how does that work?

Female: (Inaudible) meeting staff, they have a little bit more information to give you. Sorry and who is this speaking?

William Golden: Bill Golden.

Female: All right. Yes, so we will put you in touch with them.

William Golden: OK.

Female: Also we'd like to ask if there are any members in the public that would like to make comments or any questions. If we can open up the line please, operator?

Operator: And all lines are open.

Jessie Sullivan: This is Jessie, I just wanted to say something to the developers, are they still on the line? Are they still listening?

Female: I believe so.

(Off-mike)

Jessie Sullivan: OK. Well I just wanted to say that I, I just wanted to give a shout out to the developers because I know that I've been on the both sides of this and I know it's been a lot of work, sweat, blood and tears go into developing measures and, you know, I think that the process of the last decade of figuring out that we need to have measures, we're developing them and figuring out what they are is it's a little bit painful and I think we're struggling with, you know, what's really worth doing and what kind of measures should be nationally endorsed.

Anyway I think it's – I think we're winning a lot and – but there's some pain involved and I just wanted to express an appreciation for the work and the thought that has gone into the measures and the trouble and the care that – I mean people develop these measure because they want to improve – because they want to do something to show that what they're doing is addressing issue to diabetes care so I just wanted to acknowledge that despite issues with the technicality.

Female: Appreciated.

Katie Streeter: Thank you. And if there are no other comments or question, this will end today's call. Thanks everyone for participating.

Female: Thank you.

Female: Thank you.

Female: Thank you. Bye-bye.

END