NATIONAL QUALITY FORUM

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

Katie Streeter: Hi good afternoon everyone, this is Katie Streeter, here at NQF. I'm with Poonam Bal and Lindsey Tighe and Karen Johnson. So welcome to our Endocrine Steering Committee Post Comment Call. Be fore we begin, I just would like to take a quick roll call.

Do we have Tracy Breen?

Tracy Breen: Yes, I'm here, thanks.

Katie Streeter: Bill Curry?

Bill Curry: Present.

Katie Streeter: Vicky Ducworth?

Vicky Ducworth: I'm here.

Katie Streeter: Jim Dudl? Ingrid Duva? Bill Golden?

(Off-mike)

Katie Streeter: Ann Kearns?

Ann Kearns: Yes, I'm here.

Katie Streeter: (Inaudible).

Female: I'm here.

Katie Streeter: Anne Leddy?

Anne Leddy: Here.

Katie Streeter: Grace Lee?

(Off-mike)

Katie Streeter: I’m sorry, was that Grace?

Katie Streeter: Laura Makaroff? If you're streaming or watching through the webinar, if you could put your computer on mute please. Anna McCollister?

Anna McCollister: I'm here.

Katie Streeter: Patty McDermott? Janice Miller? James Rosenzweig? Claudia Shwide-Slavin? Jessie Sullivan? Bill Taylor?

Bill Taylor: I'm here.

Katie Streeter: And Starlin Haydon-Greatting? Anyone that I may have missed, that joined after?

Claudia Shwide-Slavin: Claudia Shwide-Slavin.

Katie Streeter: Claudia?

Claudia Shwide-Slavin: Hi, sorry, I did got disconnected.

Katie Streeter: No problem.

Janice Miller: Hi, this is Janice Miller.

Katie Streeter: Thank you.

Ingrid Duva: And this is Ingrid Duva.

Katie Streeter: OK, great. OK, so I guess let's go ahead and begin. I'm going to turn it over to Karen, who will walk us through today's agenda.

Karen Johnson: OK, thank you Katie. So today, just to make sure everybody knows, our goal for today, as you know, we put out our draft report about just a little over a month ago and we set that out for 30-day public and member comment. And what we've done now is we've gathered all the comments and we have, internally, we have provided some draft responses to the ones that we could.

Some of the comments required responses from developers, some required responses from NQF staff. Generally those had to do with process or something like that. And then some require responses from you as the steering committee. So we've put draft responses out, we've provided those to you. And on this call there are some of the comments that really need some extra attention from you.

And so that's what this memo is about, it's trying to walk you through in an organized way, all the different comments that came through. So just a couple of things to remember before we get started, we – I pulled out the ones and organized them in the way that we want to discuss them today. But if there happens to be a comment and or a response that you would like to discuss in addition to the ones that I've called out specifically in the memo.

Don't lose that thought, we will come back to that towards the end of the call. So with that I think we will go ahead and get started. So what I'll try to do in this memo was remind you, because our meeting was actually three months ago. So it's hard to believe that it kind of really flown that quickly.

But the first measure that we want to talk about is measure 2468, adherence to oral diabetes agents for individuals with diabetes mellitus. And this measure, you will recall I think that you guys did not recommend this measure for endorsement. It went down on the validity sub-criterion.

And in our in-person meeting, you as the committee, basically the major difficulty with this measure was the patients who were on oral meds who or

switched to insulin and you weren't comfortable with how that was handled in the measure. So the developer has actually gone back, they've used that 30 day comment period to look at their measure and their data and they have actually brought back to you a re-specification of this measure.

So I think the easiest way to go through this would be to open it up to Kyle Campbell who is the developer for this measure. And just so you know, we did – we see three comments about this measure and they all agreed with your decision at the time. Do not endorse the measure.

So they think you guys hit it, in terms of the problem with the measure. So what we will do now I think is open it up to Kyle, let him describe to you what he had done with the measure and then you guys can discuss the measure itself and decide if you would like to revote on the measure. So you don't have to, but if you feel like that he – that Kyle and his colleagues have addressed your concerns, you are certainly free to change you mind.

So we'll hear from Kyle and then you guys will discuss. So Kyle.

Kyle Campbell: Hey Karen, can you hear me OK?

Karen Johnson: Yes, I can, thank you.

Kyle Campbell: All right, great, just want to make sure I had an open line too. Good afternoon, my name is Kyle Campbell and I'm a pharmacist and the executive director at FMQAI for the CMS medication measure, special innovation project. As Karen mentioned at the steering committee on February 21st, we received very constructive feedback regarding improving measure validity for NQF 2468, by revising the measure to account for patients that might switch from oral therapy to an insulin-only regimen.

In addition in the interim period we did receive a comment during the public comment period that we also addressed the use of incretin mimetic therapy which is indicated, it's an injectable, they are injectable medications and they are indicated for treatment of diabetes alone. So we also evaluated that as part of this measure revision.

So I don't know, Karen, is it possible to open up the memo that we provided to the steering committee?

Karen Johnson: Yes, exactly.

Female: Give us a second.

Kyle Campbell: OK. I think the easiest thing to do, because we did re-specify the measure and we conducted additional analysis. I think the best thing to do is just walk through that memo. And that they're doing with that, we just recognized that the committee considered this measure to be very important and we really appreciate the opportunity to revise the specification to improve validity. So thank you for your consideration of the measure today.

So the first question we asked ourselves in revision of the measure was what proportion of patients and the dominator use insulin and incretin mimetics? And so in the 10-state 100 percent sample that we have of the Medicare administrative data, we've had about 24 percent of those patients had at least one claim for insulin. And a little less than 3 percent has a claim for one of the incretin mimetic drugs.

So then further to evaluate this issue of switching, we looked at the proportion of individuals who switch from an oral diabetes agent to insulin or the incretin mimetic only therapy during the measurement period. So again looking at that over all 10 state sample of data that we had, we looked among those who had at least one claim for insulin and found that about 13 percent switched from an oral diabetes agent to insulin-only therapy.

And then among those who had at least one claim for an incretin mimetic, little less than 9 percent switched from an ODA to an incretin mimetic only therapy. And so that suggested to us as the committee brought to our attention that this potentially was, you know, large enough to require re-specification of the measure to address in terms of validity.

So at number three, how are individuals who switch from ODAs to insulin or these incretin mimetic drugs identified? We identify them by looking whether

they have at least one claim for any type of insulin or incretin mimetic after the end of the day supply from the last oral diabetes agent.

So let's say at the six-month mark, you had a patient that was on metformin and that they supply, you know, ran out during the six-month period. If that patient have at least one claim after that period, they were considered to be switching to an insulin-only regimen or if it was an incretin mimetic, an incretin mimetic regimen.

So then, we thought, how would we operationalize adherence to ODAs for these individuals who switch to insulin? And I now originally the committee has thought perhaps we should exclude, you know, these patients that receive insulin that sends such a large proportion of the denominator.

We thought the best way to do it was to potentially create an algorithm that would account for a fair measurement of their oral medication regimen. So basically the individuals that have their ODA measurement period is set to the end of the day supply of the last ODA prescription during the measurement year.

So for that patient on metformin, let's say they started, you know, January 1, they continued for six months, their adherence to the metformin would be calculated for that period …

(Off-mike)

Kyle Campbell: … just one to six. And the same thing could be said for, you know, any patient that was switching to or on any other oral regimen I should say. Now, the other thing in review, we took to our team, endocrinologist, was, should the measure specification also address potential switching between ODAs, so that we don't underrepresent adherence if patients are switching from, let's say, you know, metformin to a sulfonylurea.

And there's, you know, switching between the oral medication classes. And it was so – but since there's so many different types of complexity in terms of the way that these drugs could be switched between each other, that we would just calculate the adherence across the entire class of oral diabetes agents. So

if the patient was on, again on our metformin example, if the patient was on metformin, you know, month one through six but they switched over to a sulfonylurea at month five, you know, then the adherence would be calculated across, you know, their adherence to those drugs across the whole drug class.

So there would be no penalty or disincentive for switching, you know, switching patient therapy. And I think you can go to the next page, if you scroll down. So then, what are the proposed impacts of these specification changes that we're recommending to you? So we basically reran all of the measure results, including the reliability and validity.

And the measure rates increased approximately 1 to 3 percent across each level measured in the overall mean. We still identify the substantial gap and performance with the mean rate of 76 percent overall. And variation and performance generally remained between, you know, 10 to 14 percent when comparing the 10th and 90th percentile at each level.

And we provided a full, you know, result for you in the appendix to this memo, and the reliability which was originally high remained adequate, you know, across all levels of measurement. And the convergent validity for the measure when we looked at correlation with other adherence, another adherence metric that is endorsed, actually improved somewhat. And those results are in appendix B.

So to summarize, the final recommendations and conclusions that we have for the steering committee is to revise the specifications to account for individual switching to either insulin or incretin mimetic only therapy and to also calculate adherence across all oral diabetic agent drug classes collectively rather than by individual class. And the proposed revision to those specifications are shown in red.

So what we provided here for you is the original specifications and then the items in red are either where we clarify the language or we added information that discusses, you know, how we operationalize this identification of switching for patients. And if you …

Female: Thanks, Kyle.

Kyle Campbell: Yes.

Female: Oh sorry, go ahead.

Kyle Campbell: I was just going to say if you scroll on down then, you know, the results for both reliability and validity are presented in full. And I would be happy to, you know, take any questions or, if there are any questions about the results or what's been presented so far.

Female: So let's go ahead and open it up to the committee for the final changes, so what do you think?

Sue Kirkman: So this is Sue Kirkman. I just had a question, I wasn't clear, are you going to try the measure adherence to insulin therapy if they switch, because …

Kyle Campbell: Yes.

Sue Kirkman: … that's fairly difficult to do.

Kyle Campbell: Yes, no, we are not, we're truncating the – the measure is still to measure adherence to oral diabetic agents only.

Sue Kirkman: OK. So you will just …

Kyle Campbell: We're just truncating the measurement period. Yes, for those patients.

Sue Kirkman: OK, so you'll just take them out of – they won't subsequently be part of the measure?

Kyle Campbell: Correct, yes. That period of time won't be part of the adherence calculation. So if the patient, in my example again, if the patient had 12 months of therapy, six months in metformin, six months insulin, that follow up period, the six months with insulin only won't be included in the calculation.

Bill Golden: So this is Bill Golden. This is a measure, it was one where a socioeconomic adjustment might be indicated, when you did your validity checking and you're looking at the different groups, were you able to look at the

socioeconomic characteristics of the patient populations about FQHCs and Medicaid populations, health literacy issues. This one I think, if you're comparing providers, create a huge impact in a normative way.

Kyle Campbell: Yes. So we did look in our original measure submission, not in the revised measure submission. We did look at the differences between the dual eligible population as well as the non-dual eligible population. And we did we did do, I mean in terms of the socioeconomic analysis that's pretty much all that we look at.

And I just have to get to that section of the form because it's part of the original submissions.

Bill Taylor: For our process, do some of us jump in while others are asking questions, do we wait out turn, how do we do this? I'm Bill Taylor, wondering.

Karen Johnson: Yes, go ahead Bill.

Bill Taylor: So Bill Golden, thank you for that question but for those of us who don't receive the connection, why is this a measure of any as one where socioeconomic status should be adjusted for?

Bill Golden: Just because the co-pays management of multiple medications, I have a number – I have a couple of patients in my practice that they're on five or six drugs and they end up taking three or four. It's a variety of factors that limit their ability to regularly get their medicines, so.

Bill Taylor: Thanks.

Karen Johnson: Kyle do you want to define your data from duals and non-duals for your original analysis?

Kyle Campbell: Yes, this was able to pull that up. And it is true when age groups greater than or equal to 65 years of age, non-dual eligible individuals did have higher rates of adherence than those who were dual eligible. The difference, and again, we did not compare this across, you know, the various provider levels, we compared it across the 10 state sample.

But the dual eligible population had a mean adherence rate for this measure of 69.4 percent and the non-dual eligible population had a mean of 74.6 percent.

These measures because – I will say these measures because they are profits like all of the other NQF adherence measures have not generally been risk adjusted at all.

Karen Johnson: And this is Karen. I will say that most of you probably know that NQF is in the middle of some work thinking about SES adjustments for outcome measures or other types of measures. And that work has not been completed. The initial recommendations of that panel was that outcome measures should be adjusted for SES and even some process measures perhaps should be. But again, those are draft recommendations. They have not yet been considered by our governing bodies. So, what we're asking committees to do is to think about being in our current regime which is SES adjustments is not something that we wouldn't necessarily expect.

Any other comments from the committee? Everybody understand the changes that Kyle made and the effects on the measures?

Kyle Campbell: Well I guess the question is, if there is a measure that might have a socioeconomic impact, what would NQF have to do about it when it gets released? Was there something – you know because the implication here was the performance gaps and is this – that means, it's not necessarily the performance gap of the provider necessarily or maybe even the health system it's just generally they were the disparity but it may not be a performance gap per se.

Karen Johnson: Right. So I think, one of the things that the SES group is struggling with now is just realizing that looking at performance measurement and quality improvement is kind of a different question than thinking about disparities. So, I think where they're leaning although this is not – they are still very much in their voting on recommendations and stuff, there is still the opportunity to stratify by different groups so that, you know, internally, you can do your internal QI and you can see if there are disparities in your own shop if you will.

So, and that would be the case. Anyway, you know, even without some kind of a risk adjustment. So, it's – I think where they're learning right now is that it's the stratification that we give you information about the disparities.

Any other questions or discussion on this measure?

Bill Taylor: This is Bill Taylor. This is confusing, right? I mean this is a complex area where there's an additional level of complexity now introduced where you figure out when somebody stopped their oral agent and switched to insulin and how it's computed. It seems to me, there's opportunity for unintended consequences that we might not be seeing and you know, to read a measure now and hear about it and vote on it. So, is there an opportunity to have it considered more, you know, more public comment as to think about it and so on, or is there a rush to decide right now whether this is efficiently addresses the concern that was raised?

Karen Johnson: Well, what we would do now is I just need a nod from the committee as to whether the changes that Kyle has made makes you at least want to reconsider your re-vote. So, just to remind you, this measure failed initially on validity. So, if you decided that you want to revote, we would ask you to revote on validity and the new analysis that Kyle provided would be what you would be looking at there. But then, we would go on and have you discuss feasibility and then usability and use, and it is – there is potential on the kind of consequence that would come up under the usability and use sub-criterion. So you would have a chance to discuss that just like you did in the in-person meeting.

Bill Taylor: Thank you.

Female: And I'll just tie it on to Karen's comment. In the draft's report, it was clear that the reason the committee voted this measure down was because there was no exclusion for patients who are switched to insulin during the measurement period and the comments that we received were very much inline with, in agreement that there needed to be an exclusion for insulin patients. We didn't receive comments on the other aspects of the measure.

Female: And even though I'm getting ahead of myself a little bit, in the usability and use discussion, where you're thinking about potential unintended consequences. The intent is not to think about you know, theoretical ones that may happen but they really that discussion is supposed to really focus on consequences where there are some evidence that it really is happening. You know, (inaudible) with that.

Male: Real quick – process questions online for the committee. We are now a standing committee, so we can make a decision today and then go through this process or we could table it to our next group meeting. When do we meet again to consider measures again?

Karen Johnson: Well, what we have going on right now with the endocrine project is we are actually in a pilot. So, unlike most of our other projects, we are going to have another cycle of measurements and I think our meetings for those measures are the second week of July I believe.

Female: Yes.

Karen Johnson: So, we could potentially – and I'll let Lindsey kick in on this because she's a lot more in our process. I will tell you that that's not something that other projects would be allowed to do. If we did something like that, it would be only because we are piloting this more frequent submission. So Lindsey, what do you think?

Lindsey Tighe: I was just to add a kind of comment I would say. Unless there is a specific input that you are looking for, a specific question that you won't answer and really, we would not want to push it off any further because certainly at this point in time, we've gotten inputs from the public both prior to the in-person meeting and after the in-person meetings. The developers have done an additional analysis at this point. And so, unless there is a different input that you're looking for, we really don't want to push it any further.

Kyle Campbell: OK. Now, the only reason we had stopped – I was, you know, it's weighing in the socioeconomic impact and the validity code of that now would be a different discussion.

Lindsey Tighe: Let's just speak to that process. Certainly although these are draft recommendations right now, they'll go through NQF governance and they won't be required of the measures until they're due back for maintenance which will be in three years from now. So, we have to give the developers' time to do run the analysis to understand which potential sociodemographic factors that they may need to include within a risk adjustment model. So given that, it would take time. It wouldn't be until three years that we would start to look for measures to have that information included.

Karen Johnson: OK. Anybody else from the committee want to weigh in? I'm really looking for a signal from you as to whether you want to revote on this measure or if you want to stay with your original recommendation not to endorse the measure?

Anne Kearns: This is Anne Kearns. Can I ask a question?

Karen Johnson: Sure.

Anne Kearns: So if we revote on the validity, then we still have to go through the other steps to assess this measure, correct?

Karen Johnson: Right. So if you revote validity and it passes then we would …

Anne Kearns: Right, then we still have all the other steps?

Karen Johnson: Well, we would have feasibility and then usability and use because you guys have already discussed importance and priority and gap and reliabilities.

Anne Kearns: Right.

Karen Johnson: So those are off the table. So what's on the table right now is the one that voted all if so you would be voting on validity and then on feasibility, on usability and use and then one final up or down recommendation for endorsement. So, it would be four votes.

Sue Kirkman: This is Sue Kirkman. I think we should vote.

Jim Dudl: Jim Dudl, I agree.

Karen Johnson: OK. Is there any discussion about Kyle's new validity results? So again, we provided those in the memo that you provided.

Anne Leddy: This is Anne Leddy speaking. I also would like to vote I think the developer has done a very good job at adjusting their concerns. And also listed out the public comments and the comments that are attached to our document. I'm ready to vote.

Lindsey Tighe: Sure. If there are no other comments on validity, we can move towards the vote. OK. (Sean), do you want to walk through briefly how the committee members should vote?

(Sean): Absolutely. You should see right now some options to vote on your screen next to the A, B, C and D option, you'll see a box. Voting members which are voting roster members only. You'd use your personalized link or you have your voting privileges assigned to enter the meeting today. If you simply click in that box next to the answer of your choice, your vote will be registered and we will be able to pull a report on the back end to see who voted what.

And it looks like I believe we have 14 voting members on right now.

Karen Johnson: OK. Hold on a minute. We were thinking we had 16 Sean. Let's make sure we've got our counts right.

(Sean): Yes ma'am, you do. Actually ahead, I had to scroll down a little further. I apologize.

Karen Johnson: OK. Do we have 17?

Lindsey Tighe: If all committee members could please select the vote?

Female: Here. OK so we have one high, 13 moderate, one low, zero insufficient, and we'll move forward. OK.

So next we will discuss feasibility of the measure. So let's see, Kyle, remind me this is all based on claims data if I recall correctly.

Kyle Campbell: Yes, that is correct.

Bill Taylor: And this is Bill Taylor. Does the feasibility change now that you've modified the criteria? I mean I know all the comments were consistent with the committees concerned about you know, what about people have switched to insulin but do all the rest of these things now get influenced by the changes that are made? Nobody would comment on these, right? Because you know, they changed way to identify patients and keep them in for a certain period is different now.

Kyle Campbell: Right. I think the general feasibility criteria remains unchanged and that you know, the data are collected in the same way. These are administrative data that are provided to CMS and we were able to fully operationalize the committees' recommendations using the claims data and we didn't have any – we didn't identify any feasibility concerns with operationalizing the data in that way. And we did have an expert in endocrinology as well as our full team, and have reviewed those results.

Karen Johnson: OK. Any other questions about feasibility? Any discussion the committee wants to have on that? OK if not …

Bill Taylor: Bill Taylor again. In your example about metformin, if somebody were on metformin, they had to finish the period during which the metformin was prescribed in order to then be counted as switching to insulin. I mean if somebody's got on to insulin before the period was over in which their metformin prescriptions run out, does that make problems in terms of your ability to collect who they are. I'm sorry. But you know, it's tricky to understand all of this in the short time and incorporate it and that we're supposed to consider these different facets.

Kyle Campbell: Sure now – no, I think that's a good question. Know, the date are based on you know, prescription drug claim data that's turned into Part D. So if the patient actually filled the prescription, let's say for that last 30-day periods for the metformin, they would get full credit for the 30 days for which they filled the prescription before, you know, the measurement period was truncated. And then, once they didn't have a claim, an overlapping claim for insulin, you

know, with metformin after that period ended, they wouldn't – there wouldn't be any follow up period at all. So we don't think there's a danger of misclassifying the patient.

You know, I think there's a little bit of grace you know, built in there automatically just by the way the measure is calculated.

Bill Taylor: Great. Thank you.

Karen Johnson: Right. My understanding is you just wouldn't refill at the end of that period and it doesn't really matter whether you dropped it, you know, a month into the period or two and a half months into the period, right?

Kyle Campbell: Correct.

Bill Curry: This is Bill Curry. So if the patient continue the metformin and the insulin, they're still truncated from the denominators, is that correct?

Kyle Campbell: Right. Now, they're only – as long as they can take insulin and an oral medication at the same time and they are, you know, their follow up period is followed up however, at this point in time, if they stop, meaning that we see prior to the end of the measurement period, that there's not coverage of the metformin and they remain on insulin and no other oral diabetes agent, then the follow up period is truncated. Otherwise, let's say, you know, if they were not adherent to metformin and insulin, then that, you know, that non-adherence would be captured by the – the insulin adherence wouldn't be captured but the non-adherence, the metformin would be captured by the algorithm.

Male: And we have to be clear for the members of the committee. I think the question here of feasibility is, do the data exist and I think some of the questions being asked right now is a reflection of how you program the analysis of the existing data. But clearly, I think depending on how you program it, the data that's in existence could be changed to accommodate some of the questions that have been asked. So I think the feasibility is cannot be done because those data exists, and then can you do the analysis on the data?

Kyle Campbell: And we believe the answer to that question is yes on those account. Yes, the data are readily available. There aren't any issues with missing day supply related to the oral diabetes agents. It's very similar to the way we operationalize, calculating adherence rather chronic medications like statins. And you know, we think that this method to identify those that switch will effectively you know, ensure that providers are not, you know, their adherence isn't underestimated.

Male: I would like to suggest that maybe the committee should consider voting at this time on feasibility unless someone has a learning concern or confusion.

Jim Dudl: Yes, Jim, vote.

(Crosstalk)

Karen Johnson: Ready? Yes.

Jim Dudl: OK.

Karen Johnson: OK, voting is open.

Male: I think we only have 15 – 16, there it is.

Female: We have 17 but (inaudible) click somebody is (lacking).

Male: They are not adherent.

Karen Johnson: Last chance to vote?

Female: Hi, I'm sorry. I'm having a little bit of difficulty. When I select the item, am I supposed to push the enter or?

Female: No, just click the box next to the answer.

Female: Maybe that's (inaudible).

Kyle Campbell: And you hit your registration bottom when you came online?

Female: Yes. OK, thanks.

Female: OK, so our final vote is eight high, eight moderate, zero low, zero insufficient and we'll move on to usability.

Karen Johnson: OK. So, criterion for usability and use basically we're interested in whether or not the measure has been in use and in just a second put on them. It's going to switch us over to our staff review on workgroup summaries because you know, at least the work has been discussed this. The developer decides plan to use for the measure but it is currently my understanding and it's not in use at this point. The other two sub criteria under usability needs have to do with improvement. So, is there any indication that with use of this measure that performance has gotten better? And then finally, we can talk about potential unintended consequences. So let me open it up there and see if the committee wants to discuss either of these items under usability needs.

Bill Taylor: And this is Bill Taylor again. Help me please how we think about usability when it has not been in use?

Karen Johnson: Yes, so for a brand new measure, you pretty much only have to think about does it seem reasonable that it could be in use. This measure isn't new and Kyle, you may have to help me here. Just a second, I'm going back. This is not a new measure, correct Kyle? This is an older measure that was initially endorsed.

Kyle Campbell: It was but it is new in a sense that due to the complexity, NQF staff recommended that the measure be separated into its component parts. So, for example, the other two measures that have different NQF numbers 545 and 2467 that look at statins and ACE ARBS. All of those are originally combined in one measure. And so, this is the first time that the measure that looks at oral diabetic agents would stand alone.

So from that perspective, it is new and we did submit it to the NQF to map for the measures under consideration process for ACO Shared Savings Program.

Karen Johnson: And Kyle, do you know when your original measure was endorsed?

Kyle Campbell: I believe it was approximately three years ago. I think it was – we're on a three year cycle with this one.

Karen Johnson: OK. OK and I'm pulling in.

Male: The main unintended consequences I could see is we will get a zillion letters from the managed care plans telling us the patient has to pick up a prescription. I've already hit many of the (methods) …

Female: Any other comments on usability and use?

Karen Johnson: And just to put this in a little bit more perspective. The unintended consequences were really interested in with the unintended consequences of the patient.

Male: True, but it has an – it has an increased expense to the health system when we get all these things.

Female: Right. Ready to vote.

Male: Yes.

Female: OK voting is open. OK, so we have two high, 13 moderate, one low, zero insufficient and we'll go on to the final vote. Any other overall considerations before we move to a final vote. Hearing none. We'll go ahead and move to the final vote. OK, voting is open. OK, so we have 15 yes, one no, and this measure will be recommended for it. OK, thank you.

So, we're going to move on now to measure 2418 and this was another one of the measures that you as a committee did not recommend for endorsement in the in-person meeting. And, just to remind you, that measure was set up where either provision of discharge instructions or referral to a fraction – fracture liaison service. Either of those things would have met the measure and the committee did not choose to recommend this measure for endorsement because of lack of evidence showing that discharge instruction could actually impact outcomes in a positive way. So, we did receive four comments in the post evaluation period and all four comments were non-

supportive of your recommendation not to endorse. However, none of the comments are – while they noted their non-support of your decision, they did not offer any additional evidence that would potentially make a difference I would think in your recommendations.

So, the question that I would like you guys to consider was with any new evidence presented, either in the comments or you know, since the meeting , have you found anything new that would make you reconsider your decision not to recommend this measure for endorsement?

Male: And to just clarify process issue here. The question on the table would be vote for reconsideration. I would assume by NQF processes, we consider by a majority vote of the committee or let's take a two-thirds vote.

Female: Basically, for this one I think, it's more just – if there is a gestalt from the committee that you feel like you want to – we vote, you could do that. This measure, they go down on evidence, so, if you decide to re-vote, you would have to go through the entire voting process.

Male: You know, but as a general rule, if we have made a decision, obviously we wouldn't do a reconsideration here. If it wasn't at least the majority, and I didn't know if it was a process where there had to be a majority or two-thirds vote to be re-consider. I'm taking from your comments, it's the same majority vote.

Female: Yes, a simple majority vote.

Sue Kirkman: This is Sue Kirkman. I would move that we not revote on this measure. I went they went down on evidence. There's no new evidence presented and just because people aren't happy doesn't mean we should revote.

Male: Well I will (agree) on that.

Tracy Breen: This is Tracy Breen. I agree that …

Female: I agree.

Male: Agree.

Ann Watts: Karen in committee, excuse me. This is Ann Watts from the Joint Commission. I just did want to point out that in one of the public comments to NQF, there was an additional citation provided. And my colleague, Kathy Domzalski is here and perhaps she could just briefly, because I know that you're on time constraints, you know, describe this to you. You know, there are changes – your minds are not. I don't know but …

Kathy Domzalski: Hi, this is Kathy. Hi everyone. In the comments submitted by Amgen and others, there was a study appearing in Osteoporosis International which was a meta-analysis conducted by Ganda et al. And I've looked at four models to reduce the risk of further fractures amongst fragility fractures in patients. And the four models ranged in intensity from type A which was full intensity identification assessment and treatment, type B without treatment, C is physician alerts and D, patient education. And the findings were that the more intense interventions of type A, identification assessment and treatment is part of the service would cover fracture liaison service. But type B similar to A without initiating treatment was also more effective.

And I would also – would like to just recap some of the evidence that was submitted. There was a Cochrane collaboration?

Male: OK, well I think we have that evidence so …

Kathy Domzalski: Thank you.

Kyle Campbell: I would like to suggest to the NQF staff that we put to the committee a vote with some of the discussion about whether we want to reconsider as a yes or no vote that we can vote on this call if that's OK. Can we do that?

Female: OK.

Female: Hold on just a minute, we're …

Female: So we'll do the revote. If you could

Female: It's not a revote. We're just asking if anybody is interested in …

Female: If you're interested in reconsidering.

Female: Yes.

Female: If you could use the raise your hand function on – I believe it's the upper left hand side of your screen. Just raise you hand if you are interested in reconsidering.

Kyle Campbell: Right. But we're not ready to vote quite yet so make sure anybody else from the committee has any further comment before we vote. So just to …

Karen Johnson: Well I'm sorry. We had a previous motion not to vote. So, but we're not voting on that. We're voting the opposite way?

Male: No, OK, the question on the table was, do we want to reconsider the measure and I gather there was (hot) testimony to say we should not reconsider the measure so.

Karen Johnson: Right. But it sounded like the instruction was to raise your hand if you wanted to reconsider the measure. That's not how the motion was made.

Kyle Campbell: That is correct. And we can at least clarify the intent of how you're voting. So …

Male: So raise your hand if you want to reconsider.

Female: Please.

Karen Johnson: Right.

Kyle Campbell: We will, you know, restate the measure in a minute. But does anybody else have any comments about desiring to reconsider? I mean …

Anne: This is Anne. I did not have the chance to read the referenced article in the Osteoporosis International. Has anybody on the committee done that or did anybody do that when we had our in-person meetings?

Bill Curry: So, this is Bill Curry. Actually, during our discussion, I did reference again the article in Osteoporosis International. It was part of the discussion in the evidence from the meta analysis shows that when an intervention such as giving discharge instructions asking a patient to follow up with their provider because of a fragility fracture, it made no impact in their follow on care. It's a class D, or model D of the four models in the Ganda article and it was not cost effective nor was there any efficacy in the improving fracture care.

So we had talked about our committee meeting at the in-person meeting.

Female: Thank you.

Female: OK any …

Kyle Campbell: Other comments from the committee? So if we want to vote, if you want to reconsider correct, we get to raise your hand.

Female: Correct.

Anne Kearns: We're – Anne again.

Female: I'm sorry I'm not being able to raise my hand.

Kyle Campbell: (Inaudible) meeting info in the upper left corner.

Karen Johnson: You do. Thank you.

Kyle Campbell: Right there.

Karen Johnson: And all you need to do is simply click that one time and the little hand should show up for you.

Kyle Campbell: So this – so raise your hand if you want to reconsider the measures.

Jessie Sullivan: This is Jessie. I don't want to reconsider the measure but raising my hand isn't working so just, I'd prefer we didn't use that.

Female: OK, we have no hands raised anyway to reconsider the measure. So it is blank.

Kyle Campbell: I see one.

Female: There is one now.

Female: All right, so there is one that's kind of coming and going. But at this point we just have – well, just coming and going. One or none hand has been raised so it's OK. So, move forward.

Female: OK thank you for …

Female: That was me, I'm so sorry.

Female: It's all right.

Karen Johnson: OK, our next point of discussion is about measure 0555, comprehensive diabetes care eye exam performed and there were seven comments that came in regarding this measure. Four of them were supportive of the measure and your decision to recommend for endorsement.

Two of the comments, just one clarification from the developer as to why women with polycystic ovarian syndrome are excluded and the developer did respond to that. And let me just keep going. Another comments were – was concerned about a couple of CPT codes particular 9227 and 9228. Both of those are related to remote imaging. So there was a concern about those CPT codes being included in the measure.

And then finally, there was a comment suggesting that the measure be aligned with the new age specifications that NCQA agreed to for their foot measure. And just to remind you on that one, initially, both of those measures were specified for patients ages 18 to 75 for the foot measure. NCQA did agree to drop the age limitation dropped to 75 limits. So the commenter was curious about whether that should also be done for the eye exams measure.

So, let me open it up – well I guess – first of all I guess, do we have anybody from NCQA on the phone?

Mary Barton: Yes, we have a room full of people from NCQA. This is Mary Barton, vice-president for performance measurement.

Kyle Campbell: Why don't we split the question also for sake of simplicity? So we have two separate issues on the table. So the first issue would be the remote imaging and the second would be the harmonization of age.

So why don't we start – and we have to consider both of these commentaries. So, why don't we discuss the remote imaging issue first.

Mary Barton: This is Mary Barton from NCQA. Can you hear me?

Female: Yes.

Kyle Campbell: A little bit, but you're OK.

Mary Barton: OK, so let's see. With regard to remote imaging, we have been trying to track down these questions since we heard this and that maybe not coincidentally. It had also come in through our own policy clarification system that I think I had described to the steering committee as our own continuous feedback when we hear from the focus, we use our measures about questions they ask.

We are – because this is a claims-based measure and it relies on claims that Medicare assigns to appropriate or imaging – I won't say appropriate but I'll say, CMS assigns the code to imaging they pay for. And as long as there are decisions that are made by CMS about what they will take for, we are – it's a little hard for us to parse the questions of whether this new technology is what's being done or not (for one). And two, I think that my contact within the diabetes expert world and I would certainly be interested to hear any thoughts this (inaudible) has, would suggest to me that the diabetes expert world is reluctant to say that they would endorse the use of this particular technology. But they have – they've actually not gone so far in their guideline as to say that right out.

So, we as measure developers are just a little bit between a rock and hard plates here. So, I – as I said, well, I'm kind of curious what the (inaudible) would say.

Sue Kirkman: So this is Sue Kirkman and I – maybe I don't understand this comment but I disagree that this goes against the ADA guidelines. The ADA guidelines say that retinal photographs are acceptable.

Mary Barton: Sue, I think the questions that I – as I understood it was that the optomap technology which is a non-dilating retinal image. It's not precisely the same as a kind –as a retinal photograph that might have been imagined seven years ago when the CPT code was created. But I could be totally confused about this and I'm happy to be corrected.

Bill Golden: This is Bill Golden. When I – I sat on the PCPI committee that took – discussed a similar measure. This was about seven or – I mean six or seven years ago and there was extensive discussion about remote imaging such as in this measure. And there was a considerable evidence presented that it was acceptable technology. And the members of that committee which included people from the endocrine society were comfortable that this was an acceptable technology. So I'm a little bit surprised by the commentary.

We'll have the people on the committee have in terms of experience.

Female: And certainly, it's like the VA are doing you know, doing a lot of this.

Bill Taylor: This is Bill Taylor. Are there any studies, you know, comparing the photographs with assessment by the human being and, you know, validity …

(Crosstalk)

Female: I think there are a lot of studies and it actually pretty good. I mean it maybe be better than humans.

Bill Taylor: So that should not (inaudible).

Female: I mean you know again, it gets read by an expert. It's not just the photo itself.

Mary Burton: We're having a little trouble with our mute button, I'm not – can you hear me now. This is Mary Burton.

Bill Taylor: Yes.

Karen Johnson: Yes.

Mary Burton: OK. Well and so it sounds like, you know, the Steering Committee would not necessarily support the commenter's assertion and so therefore our response that we have not – that we would intend to make a change in our measure as it currently specified with (Vent).

Bill Taylor: In getting to the NQF staff, do we need to do anything else with this measure? There's nothing to vote on, it's just to frame your response?

Female: Exactly. And I think from the recommendation we've had we are right to move on to the next comment, so thank you.

Male: So now we go to the next comment which is the age issue.

Female: So I think …

Male: Mary do you want to make comments on the age?

Mary Burton: Thank you for asking. We are – this question, you know, would be a reasonable question if we only had two indicators and it was important to make them match. But instead we have a set of indicators as you heard on that day and this would not – a change in the age category would not be a no-brainer, it would be appropriate to seriously consider for – and I'll toss out, you know, the hemoglobin A1c less than eight measures, where I dare to say the Steering Committee would not be anonymous on the expansion of the age range.

So I'm reluctant to go sort of imposing a sort of unsubstantiated uniformity across the diabetes indicators without giving full due consideration to the issues related to the patients of that age group. So we would not want to make any on the slide changes.

Sue Kirkman: This is Sue Kirkman. I think there is a difference between talking about blood glucose goals versus screening for complication. So pretty much all the diabetes complications impacts older people disproportionately. So I think we

have to really think about why we would exclude older people from a measure that screening for a complication that's prevalent.

Male: Other comments? NQF staff, do you need additional framework here?

Female: No. I think what we're looking for here, we're certainly not expecting that NCQA would make a change anytime soon, but if the committee felt that was an important change that they need to seriously consider, now is the time to tell them that they, you know, you would like them to really consider that or perhaps you might say, you know, 75 is OK for this measure.

Jessie Sullivan: This is Jessie, I guess what I would say is that, you know, before the idea was to have a measure with one age. And with the first exam we got away from that, so now we have a measure with two different denominators. So it think it make sense to say to NCQA, "Now that you no longer have one denominator, you have to – can't you look at each of the other sections of this measure and make sure that the ones that are appropriate for an old of population fall into that older denominator, because we've already got two denominators."

Female: OK. Any other discussion?

Mary Burton: So this Mary Burton. We appreciate that input and we're glad to take all this back to our panels.

Female: OK? Right, thank you. OK, the next measures that came up in our comment where the two glucose control measures, hyperglycemia and hypoglycemia and for those, we received six comments. And the main concern was low reliability scores for one of the hospitals. So there was some testing done and the reliability scores were fine for most of the sites but except for the one hospital and one measure and I think two in the other measure. And then there was also a desire from these commenters that the measures be computed in a similar way.

And that actually came up in the in-person meeting. You guys questioned, you know, why they were computed in a different way. And that was an item of discussion. And then finally, a couple other commenters we're kind of

diametrically oppose, one even show if there was a need for the measures and another express support for the measures.

So in both cases, we ask the developers to respond to the question regarding reliability and the developer did do that in both cases the developer – I think its Kyle, right? Kyle? You know, or is it FMQAI? I'm sorry I'm getting my …

Kyle Campbell: Yes, it's Kyle Campbell from FMQAI, yes, yes.

Female: OK. Sorry I am getting mix up here. So I think maybe you want to just give a very, very brief if only given us in your response written here and I've included that in the memo that maybe want to take, you know, a very quick one minute discussion of your response and then a question to the committee is from these comments. Was there any new information or anything question to make you want to reconsider your decision regarding the reliability, the measure. So Kyle, you want to just give us the quick version as your response?

Kyle Campbell: Absolutely yes. So I think it's important to know that there this commenter did support the steering committee's recommendation to endorse the two measures. With regards to the reliability, the lowest reliability that we found, we have one hospital with international tested that was a critical access hospital, which only have 25 beds and that particular hospital had an unreliable score for both the hyperglycemia and the hypoglycemia measure.

The only other hospital with an – approaching and I guess a reliable score was a hospital in the hypoglycemia measure where we had a 0.67. And that's really closely approaching, you know, reliability is not an absolute criterion. And when we start to see a signaled noise, you know, coefficient of approximately 0.7, it generally means that we can statistically differentiate the providers from the mean.

So in this case, we don't have any concerns here. We think that, you know, we wouldn't look at this concern in implementation in smaller facilities but that would be the case for any of the measures that would, you know, potentially be implemented in CMS reporting programs.

And so I think that really addresses the reliability issue overall and you did discuss specification of the measures. We really don't see an opportunity to do that because hyperglycemia and hypoglycemia are very different types of event. Hyperglycemia being sustained over a period of time or hypoglycemia being more of an isolated event and we don't think there's an opportunity to further align those measures in – for the measures to remain valid.

Male: I have a brief question. At the end of your comment, your comment is based on the same for both of these two measures. You made a comment where severe hypoglycemia, the rare event that occurs at the administrations, you know, there was a paper this week that said hypoglycemia now becoming more common as an admission than hyperglycemia. Do you want to continue with that statement in this discussion?

Kyle Campbell: I think the statement would be that it's a relatively rare event when we're talking about severe hypoglycemia less than 40 milligrams per deciliter being essentially, you know, we're finding measure rates, you know, approximately around the 1 percent, whereas with, you know, hyperglycemia measure rates are 20 to 30 percent. So I agree that hypoglycemia is – has been identified on the national action plan and is one of the most frequently-occurring (ADEs) but it still relatively rare compared to this sustained hyperglycemia that we see at least from our data sample, the data that we saw.

Male: Others comments from the committee?

Female: I don't see any reason to change the measure. I think it was very thoughtfully and logically developed.

Female: OK.

Male: Does NQF staff need additional input aside from our acceptance of the material from the developer?

Female: That's pretty it. We jus wanted to make sure that the comments are – was responded to. And then I'd agree with the comment, so that's great. We're at the end of our memo. We're almost at the end of our call. I would, you know,

obviously you saw that things that I pulled out for all of those comments that we had, but if there any other comments that came through that you guys would like to discuss we'd be happy to take those now.

And it's OK if there isn't.

Male: Why don't you go over next step also, just so we know what's coming up down the road?

Female: Actually, if we can just take a brief moment to do NQF member in public comment. Operator if you could open the lines, please.

Operator: Yes ma'am. And this time if you have a public comment, please press star one on your telephone keypad. We'll pause for just a moment to compile the comment roster.

We have no public comment at this time.

Female: OK. Thank you. And I'm going to hand it over to Katie now to tell us about the next steps.

Katie Streeter: Sure. So as for the next steps, NQF staff will update the comment table with responses to reflect discussion during today's call. We'll also be updating our draft report to include the comments and responses from developers and committee. The draft report will be posted on June 6, which is when all of the measures that we're recommended for endorsement will be available for NQF member voting at the 15 days voting period. After that, the measure, all of your recommendations will be reviewed during a CSAC meeting in July.

For cycle two which is surprisingly, rapidly approaching, the submission deadline is June 6. So we'll be sending new measures that come in for review cycle two by the last week of June. Then we will be reconvening with two conference call as Karen mentioned earlier, the second week of July and that's when will have you review all the new measure submission.

We would like to note that we will not be having workgroup calls because we anticipate in much lower number of measures that will be coming in for

review cycle two, so it will be important that you review each measure and submit your preliminary evaluation comments using the survey tool that would be available on SharePoint. And we'll make all of the comments available to the whole committee before we reconvene that second week in July.

Are there any questions about the next step? We'll send of all this out in an email, so every is clear on exactly what to be doing and what's going on in the timeline of everything.

Claudia Shwide-Slavin: This is Claudia. I don't have a question yet. I just have a comment that I really appreciated. The format that you submitted all of the comments to us and the overview, it really helped in thinking about them.

Katie Streeter: Thank you.

Claudia Shwide-Slavin: Thanks.

Katie Streeter: Any other questions, comments? Otherwise, we can end today's call a little bit earlier. Have some time back.

Male: Terrific.

Male: Great.

Katie Streeter: Great. OK. If you guys have any questions or anything, we're still at the same email address and phone numbers, so give us a call if you need to and we will be in touch.

Female: Thank you to the developers who joined us also.

Male: Thank you.

Male: Thank you.

Female: Bye.

END