NATIONAL QUALITY FORUM

Moderator: Reva Winkler
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2:00 pm CT

Reva Winkler: Hello, everyone. This is Reva Winkler at the National Quality Forum. Thank you very much for joining us today for this conference call of the Cardiovascular Endorsement Maintenance Steering Committee. To the steering committee members, thank you very much for taking time to join us today.

I just wanted to do a quick logistics review. We will be using the agenda that was sent to you 2 days ago on May 9th. It is revised with a couple of new additional measures to be discussed. At the same time, with that e-mail we sent you the same version of the call materials. It's a PDF document that's bookmarked with three memos in it. We'll be working off of those. Those materials are also posted on our Web site.

In addition, a week ago, we had sent you the first set of meeting materials. And in that group was a letter from the ACCF, AHA, and PCPI that we will be referring to. And as we are discussing the measures, we will be expecting the committee to make some decisions, but we will not be voting on the call. We will use the SurveyMonkey tool that we'll send to you after the call for you to register your votes, and that'll be logistically easier.

So with those basic logistics, I'm going to turn it over to Ray and Mary. Ray?

Ray Gibbons: Hi, this is Ray. Welcome. Thank you for taking the time out of your busy schedules. Just to let you know I am doing this call in Washington Reagan Airport, and it is beyond my capabilities to mute and un-mute rapidly enough, so you will hear security announcements periodically and you'll also hear time announcements every 30 minutes. That actually might keep us on schedule.

So our task today is pretty ambitious. We will do what we can to get through the agenda. I want to allow adequate time – I think the – for the discussion of the important issues. I do think that one of the challenges will be to make sure that everyone is literally on the same page and finding the correct document to refer to as we've discussed them. Unfortunately, in terms of the first segment of the agenda, none of the original discussions, primary discussions for these three measures are available for the call, so we will have to make do with the notes and summary of our previous meeting.

So the first item is 0073. And that is included in the PDF that went out that's labeled "Update Measures." So I want to make sure that everybody finds the right PDF and is with us as we start to tackle that one. It was vascular disease, blood pressure management, 0073. I'll give everybody a minute to make sure that they've got the right item.

So this was the item where we deferred action because of several concerns dealing with the measure. One was the blood pressure level of 140/80. Another was the absence of any age limitation. And a third was the fact that at one point in the document there was an exclusion listed for end-stage renal disease, but that was inconsistent in the document.

So all of those issues were referred back to the actual developer who came back with responses. And those responses are actually in a separate document that is entitled "Deferred Inactive Competing Measures," a separate PDF. So if you want to open both PDFs, that might be

advisable, but the original is in, as I indicated, one PDF, and the actual responses from the developer are in the other PDF.

And the responses appear beginning on page 2 of the second PDF that starts deferred inactive measures. So this is in the deferred measure bookmark. I'll give everybody a minute to find that. And basically, then we'll go through what the developer said.

Okay, so I hope everybody can find that. So the developer basically said in response to our questions, what's the evidence for the less than 140/80 target? They withdrew it and will continue with the target of less than 140/90, with the intention of reviewing or revising when JNC8 is released in 2012. And they went into various and sundry other comments about that, but I think the important thing is they switched to 140/90.

We also raised concern about the absence of an upper age limit. And they basically said there's no simple rule, pointed out that these things should be harmonized, but only after sort of evaluation with multiple other developers. So they didn't propose one.

The other question we raised was home blood pressure values, the fact that they weren't accepted and they basically indicated that their advisory group was – thought there was a significant problem with respect to standardization, how to correlate these measurements to those obtained in randomized trials in the office, and were willing to open again for consideration, only after full testing of feasibility and reliability, including blood pressure monitoring and home blood pressure measurement.

And then lastly, I think the important thing where we raised some concern about the exclusions, regarding end-stage renal disease, they corrected that and added exclusions for end-stage renal disease, pregnancy, and admission to a non-acute inpatient facility.

So those were their responses. Comments or discussion about their responses?

(Snow): Well, my initial response to their response is that they seem to have, for the most part, accepted our observations. And you know I think that that was what we were looking for, pretty much. I guess the big question is whether the area in which they said, well, they didn't think so, whether that should be enough for us to withhold…

Ray Gibbons: Yes, approval.

(Snow): … approval.

Ray Gibbons: Other comments? I should say, in terms of – although I think I can recognize voices pretty well, as you comment, please identify yourself.

(Snow): I'm sorry. This is (Snow) in Boston.

Ray Gibbons: Yes, I knew. Appreciate that, thanks.

(Snow): Is that because I just spilled some coffee?

Ray Gibbons: Right. Other thoughts about this? And in particular, I'd welcome any thoughts about the age cutoff question.

Mary George: This is Mary. And I just had a question in regard to the age cutoff, whether the 2011 consensus document on hypertension and the elderly gives us any guidance on that.

Ray Gibbons: Well, I think there's been a literature review published that (Sid Smith) pointed out at the meeting. I think there – you know there has been a recognition that the randomized trials in the

elderly often started way above 140/90 in terms of pre-treatment, and then the treatment groups didn't get – did not get to 140/90.

I think the other issue that everybody should be aware of is we did approve the optimal vascular care measure from Minnesota that has an upper age limit of 75 to avoid the controversy.

(Tom Kotke): This is (Tom Kotke). I think you know the individualization of care after 75 becomes much more important. And I think that's – I think what we did with Minnesota Community Measurement is pretty reasonable.

Ray Gibbons: So one possibility would be go back to the developer and say, "We've approved the measure." They've indicated their desire to harmonize, open to harmonizing the measure with 0076. All they said was most specifications must be carried out in a careful and deliberate manner since changes can affect both trendability, as well as completeness, accuracy, and reliability of data collection.

I think if we asked them to harmonize with 0076 and then said age 75, that would be one approach, realizing that JNC8 may then come out early next year and clarify the age issue.

(Dionne Jule): This is (Dionne Jule). From an implementation standpoint, given that the guidelines we think are going to be out early next year, if the measure is endorsed now, with 75 as the cutoff, what happens practically? Does it wait for review again to see whether they've adopted the new guideline, if there is a new threshold? Or do they have to implement that new threshold immediately?

Reva Winkler: This is Reva. Once the new guidelines come out, depending on what they say, will impact what measure developers may or may not do. All measure developers are expected to provide

us with annual updates, and we would certainly – since we have raised this as an issue – except as part of that update to be responsive to the new JNC8 guidelines.

Ray Gibbons: And both of these developers, both Minnesota Community Measurement and NCQA have indicated that they're going to be.

(Dionne Jule): Right. I just didn't know from an actual practical application standpoint how the measure would – if the measure would itself be altered for reporting purposes in order to do that adoption even if they wanted to or if they'd have to wait.

Female: We can certainly address that in an expeditious manner, particularly since we're waiting for it and expecting it.

(Dionne Jule): Okay. Well, I'd be inclined to go along with the prior recommendation that we suggest to them that 75 be the cutoff until we see the guideline.

Ray Gibbons: Other thoughts about that? Are there major objections to that? Everybody's going to get a chance to vote, but not on the call. Can I – are there other thoughts about this that we should subsequently vote on?

(Bruce): Hi, this is (Bruce). So just so I understand, the main – it seems like they've addressed everything except for that one issue where they said we don't agree or something like that.

Ray Gibbons: The ambulatory, yes. They've just flat-out disagreed on that. And they did not – they have no age cutoff. And when we raised it, they said, yes, it's important, everybody should discuss it, but they also said they're willing to harmonize with 0076, which has an age cutoff of 75.

Male: Of the three issues, I think the ambulatory is the one where their position is most defensible, because at clinical level, getting ambulatory measurements I always have found to be very valuable. I don't (dis it) at all.

But from the standpoint of having a measure and things that a measure needs, comparability of the data becomes kind of important. And with an individual person, the internal consistency of how some guy measures his blood pressure, even though it may not be accurate exactly, is kind of – drops out of the equation.

So if there were a place to give, that's the one where I would go along with them and accept their position, from the standpoint that this is the measure, because I don't think it's – as clinical as it is, I don't think that that's the entire story.

Ray Gibbons: Okay. Are there any other thoughts? Otherwise I'm going to propose that we simply vote on approval without ambulatory blood pressures and with an age cutoff of 75, realizing that we expect JNC8 will have something to say about that issue early next year.

Male: Okay.

Ray Gibbons: Is that acceptable? Are there concerns about that?

(Tom Kotke): Sounds good to me. This is (Tom Kotke).

Female: Me, as well.

Ray Gibbons: Okay. Let's move ahead, then, to the next two. And these are both – I think it's important. These are both addressed in the letter from ACCF, AHA and PCPI that is one of the other – was

one of the other attachments that Reva mentioned. The letter was dated May 3rd. It was addressed to me in my capacity as chair. And I want to make sure everybody gets that letter out.

So the pertinent part of the letter begins with a subheading at the bottom of page one that says, considerations regarding measures for hypertension, where PCPI basically attempts to justify their use of a target blood pressure or at least two anti-hypertensive medications, something that we were concerned about, may include an article or attached an article and quoted from that article, and I think the quote is actually – I think you can look at the quote both ways.

It says many blacks, 28%, and whites, 34%, with blood pressure above goal had fewer than two hypertensive drug classes prescribed. So that's the data they cite. But I would point out that from that same data, presumably that means that 72% of the blacks and 66% of the whites with blood pressure above goal had, in fact, two or more anti-hypertensive drug classes prescribed. So this measure as they proposed it would presumably therefore only identify a minority of those with blood pressure above goal.

So I think the gist of this – and everybody can read it – but the gist of it that they want – felt their measure needed to avoid adverse consequences and be feasible, and they were concerned that their – the feasibility of the measure that required three or more hypertensives.

As I recall our discussion and what I saw in that paragraph, one point that was explicitly raised in our discussion is the way this measure was framed. Somebody could have a blood pressure of 220/120 on very minimal doses of two anti-hypertensives and that would be okay. And they don't address that in their response.

Female: Ray, did you want to see if anyone is on the line from PCPI to comment?

Ray Gibbons: Yes, please. PCPI?

(John Curtis): Yes, this is (John Curtis). Can you hear me?

Ray Gibbons: (John), yes, sure, go.

(John Curtis): So you know you clearly hold out sort of an extreme example of somebody with a blood pressure of 220/140 on small doses of two anti-hypertensive medicines. And our concern – and we spent a tremendous amount of time discussing how to feasibly collect this – was that you know if somebody is at that level you know some patients are very hard to control their blood pressures for intolerance to certain classes of agents or for other reasons.

And you know we ended up selecting two medicines as opposed to three or more anti-hypertensive medicines because it would signal that there was a significant intent to try and control the blood pressure. And we didn't want to have patients with poorly controlled blood pressure, somebody who you know was at 150/100 and couldn't tolerate more medicines, to be, quote, unquote, dinged for not you know getting good, quality care.

And the converse was to try and figure out from a data collection sheet or an EMR and second-guess the clinician who was in the room to – you know whether or not they had used the right technique or really pushed some of the medicines as much as they could have. We thought that would be very difficult, because you couldn't tell whether higher doses or additional medicines had been tried in the past and had been intolerable by the patient.

And so we really were concerned in striking a balance to find a threshold where it really suggested that there was an intent to try to control blood pressure without being in the position of second-guessing whether they couldn't have done better.

And so that's why anybody who's successful with one, two or more medicines and does have a blood pressure below 140/90, that patient would be considered having provided good, quality care for that patient's anti-hypertensive control.

If they did not (need that) but they had at least – you know were putting patients on multiple medications, we felt that at this point in time, given the current state of records, that that was the best, most fair way to balance a significant effort to control the blood pressure, while also not being in a position to perhaps inappropriately judge whether other efforts had been tried, and they currently were on only two medicines. So that was the logic behind that.

And it extends where previous measures had been, which is just, was there a plan of action? Which was very vague and amorphous and you know could have – we felt was inadequate to start to get at the need to be emphasizing attaining blood pressure control or making even a stronger effort to control it.

Ray Gibbons: Other comments or questions from the committee for (John)?

(Tom Kotke): (Tom Kotke) here. I'm a little torn between the – you know the expertise of my clinical – my colleagues and the debate which I want to respect, but – and my feeling that – I mean two drugs is (like 12.5 of hydrochlorothiazide and you know a little bit (of ACE) and a little bit – or a little bit of beta blocker.

And you know I think that my typical patients are on four drugs. They're on some diuretic. They're on (some ACE), some beta blocker, and probably some amlodipine. I guess I would say, okay, the ACC, their intention you know the ACCF, that they thought this through, their intentions are right, they had a very hefty discussion about it. They are pushing the science forward by saying, hey; you don't need just a plan. You need to actually prescribe some drugs.

And so I guess I would vote to endorse the measure, recognizing that as this is thought out, though, they'll probably keep pushing for the science and the measurement forward.

Male: And I would say we definitely intend to do that, (Tom). And you know I do – I mean a lot of patients are on you know much higher doses of these medicines. I mean they could be on you know 200 a day of beta blockers and you know a high dose of (ACE) or – and they could have more medicines. I mean this would credit anybody who had somebody on three or four medicines.

What it would really ding is somebody – we just felt there were enough medication options for the control of blood pressure that if you were on only one medicine and you were not controlled, that was inadequate. And you know there's no limit to how much, and I don't think that we should presume that doctors are going to try and just meet the measure by giving homeopathic doses of two different classes or two different agents.

You know they're really trying to get the blood pressure under control. And they haven't just stopped at one medicine. They've prescribed more.

Ray Gibbons: So I think it's just – in terms of getting everybody to look at all the right documents, since we didn't have the primary reviewer available, the NQF staff on Tuesday morning, I believe, at 10:20 am sent an e-mail which has the summary of our votes the last time on this measure, which was 0013, where – just to remind everybody, importance was 19 to 1 yes. Scientific acceptability was three completes, five partial, eight minimal, five no. Usable was five complete, nine partial, six minimal, one no. Feasibility, complete nine, partial six, minimal five, no zero. And the vote for endorsement was 6 yes's and 15 no.

So if you've found that e-mail, I've tried to just highlight it in case you haven't, because we have a lot of different documents. So, basically, the ACCF, AHA and PCPI are asking us to revisit this

earlier vote and have given this response. And (John) has just addressed some of the issues. So are there other questions for (John) or discussion, realizing that then we'll have a subsequent mail ballot re-voting on this?

Mary George: This is Mary. And this, I guess, is to the developers. What data do you have to show that this change to this type of measure will have an impact on the control among treated hypertensive patients?

Male: Well, it's difficult to know you know what this – I mean there's – you know we can go back and do cross-sectional analyses or actually longitudinal analyses comparing those on multiple meds versus one and provide that data to you separately from you know about 500,000 patients from PINNACLE.

But you know the challenge is that you're asking, if you raise the bar, because that's just going to be an association, and it's going to be compounded by the fact that some patients are not going to have great control, and that's why they're on the multiple medications.

And if you want to know what the impact of you know sort of increased accountability for more aggressive anti-hypertensive control on subsequent blood pressure control, that's never been tested. I mean that's never – we've never had a performance measure. A lot of this is to develop those performance measures and then to study whether that drives better blood pressure control over time.

And as we enter an age of increasing accountability and increasingly titrate the scrutiny of the quality of care for blood pressure management, I think we'll have that data. But right now, it hasn't existed. And if we do the analysis within PINNACLE, I just am concerned by confounding that patients will have higher blood pressure controls who are on more medicines, and they're on

the more medicines because they have tougher-to-control blood pressures, not that you know looking – having more medicines is associated with worse blood pressure control.

We do feel that this is advancing what we had before, which was just an amorphous plan of action that was previously endorsed, and we feel that's too low a bar.

(Andrea Russo): This is (Andrea Russo). I'm sorry. I was very late getting on the call. But I guess, were there any thoughts – I guess the two or more to me, was there any thought of having three or more anti-hypertensive medications? Because a lot of people – I'm just thinking of specific scenarios where I've seen patients, particularly – and they might have heart failure and they might have coronary disease, but they might be on a little bit of an ACE inhibitor or a little bit of a beta blocker, and people aren't paying as much attention to the blood pressure as they should be.

How did you decide on the two or more drugs? To me, if you had three in there, it would be you know a no-brainer. That would be, you're really trying. But I wonder, with two, a lot of people are on two and thinking of an ACE inhibitor plus beta blocker combination. So was that based on anything in particular or just arbitrary?

Male: It was based on, as you increase the number of medicines you know patients will be and have been tried on other classes of medicines in the past and might be intolerant. And you know this was the best judgment of a consensus of experts who – you know I mean this was a very hotly debated issue. I mean there were people as fervent about (primary prevention) as (Tom Cochran), including (David Gough) and others that were on this measure – this group – I may have the wrong committee.

But in any event you know this was a heated discussion over multiple – I think it was (Don Casey) that was advocating very strongly for higher levels. And you know we ultimately you know felt that this was the best first step. And we would like to – you know if we learned this is not

adequate and need to increase it further and keep raising the bar, that's good, but this was significantly raising the bar over where it had been, and we thought that it did indicate a real effort. And if they have other comorbidities that you know get prescribed the same class of medicines, that even further underscores the importance of controlling blood pressure and ((inaudible)) just only you know hope that the doctors would be trying to do it.

You're really trying to capture here people who are not giving adequate attention to blood pressure control. And I think there are a lot of patients – and it differs a little bit by race – that you know are not (well controlled) and are not even on two medicines. I mean if we just got those third of the patients – of blacks and a quarter of whites who have poor blood pressure control and are on less than two medicines, to be on two or more medicines, you would probably make a huge impact.

(Andrea Russo): And I guess I'm just trying to – you know I see your point. And I just wonder if maybe the frequency of follow-up visits – because it you know most or the majority, I guess, of patients, you might bring them back sooner, increase their medicines, and then you might get to a third pretty quickly you know if you only have two visits…

Male: If they can tolerate it, that's absolutely right. And this is to hopefully draw attention to the issue and incentivize exactly that kind of behavior.

(Rochelle): This is (Rochelle). And I was just wondering, what's the downside of actually using the blood pressure target, like you know the goal, say, for example, 140/90, as opposed to doing it in this sort of – sort of little step towards…

Male: So, we were very concerned – for example, nephrologists see very refractory – patients with very refractory hypertension. And a nephrologist who had a patient on five anti-hypertensives medicines and still could not ((inaudible)) blood pressure below 140/90 would look like they were

delivering bad care, even though it's humanly the best care possible that that patient could receive, and we didn't want to create that adverse consequence such that you know patients with really tough to control hypertension couldn't get care because nobody wanted to look so terrible and they're just really tough to handle.

And so we created a double-barreled success for the numerator, attaining good blood pressure control, whether that was you know just with diet or exercise or you know minimal pharmacokinetic interventions, or that there was an (evidence) of a substantial commitment to trying to use pharmacotherapy to control the blood pressure. And that's why we came out – we didn't leave it as just blood pressure.

(Crosstalk)

Female: Well, then I think that what you're trying to accomplish there then, it seems like the types of (physicians) that you're trying to help with this would be those specialists that are really trying many different anti-hypertensives and probably have maxed out on many of them. And so if that's your goal, maybe you should raise the bar on that part of the measure, in terms of not only the number of drugs, but also the doses that they're pushing the drugs to, like you know what percentage of the maximum dose.

Male: Right. Well, we – so we thought about maximum doses. And we felt that there – it can be very difficult to know whether you know a patient ((inaudible)) intolerant of higher doses or not, that the burden of that kind of – that detailed data collection exceeded the feasibility of the measure, and that's why we didn't look at actual doses or percent of maximal doses, because there's a lot of (interpatient) variability that would be very hard to capture and to capture validly. I mean how do you even know that they are really intolerant or not? What somebody might consider intolerant, another would not feel that way. And so we felt that was a very difficult variable to capture.

The – I forgot what the other part of your question was. I'm sorry. That's why we didn't do maximal doses. Oh…

Female: Right.

Male: … and you know two or three – I mean look, if the committee came back and uniformly said, you had to pick three, that's you know fine. We could revisit that with our committee. But you know ultimately, we're all just you know guessing and we're putting forth you know one threshold versus another. And there were people who argued just as articulately as you that we should have raised the bar, and there were others who you know felt that this was indicating a significant effort of the clinician to try to control blood pressure using at least two medicines.

They could certainly use three or four and get credit for it, but if they used just two, was that bad care? And you know we ultimately came down at two as the threshold, but you know I think that our opinion is similar to your opinion, and a different task force on this committee might think two was fine. Another might think four was needed.

And I just you know think we should recognize the limits of creating these measures and at this point you know we felt that there was – you know two was reasonable and there is good evidence that you know 28% of blacks and 34% of whites who are ((inaudible)) 140/90 are not on even two medicines. And so you know all those patients would be considered to be getting bad care by this measure.

(Tom Kotke): (Tom Kotke). And I think you know we have to remember that distribution of blood pressure, if we can get patients on two medications, we're going to probably get the majority of patients. And I think it behooves us to resist the urge to try to get the outlier patient in under the tent.

I think we ought to support the ACCF recommendation, and knowing full well that they're going to push the bar forward anyway. They're a bunch of aggressive people.

Ray Gibbons: Are there other questions or comments on this one? Because I think we've given it plenty of time, but we must move forward, in terms of the agenda.

(Snow): Yes, I'll go along with what (Tom) said. (Snow) here.

Ray Gibbons: Okay. So we will…

Female: We'll include it in the ballot for a revote.

Ray Gibbons: Yes, we will be re-voting on the this measure. Now, we've got move on to the other request from PCPI, which dealt with the two different measures, 0065 and 0077. And there's a separate section in the paragraph – I mean in the letter about them, consideration regarding patient-centric outcome measures for CAD and heart failure.

And these were basically dealing with symptoms. So, (John), do you want to comment on them?

(John Curtis): Sorry. I was on mute.

You know so this measure failed on importance. And you know we were a little struck sort of understanding that, but the – you know the NQF launched you know your first face-to-face meeting with a very strong ((inaudible)) to outcomes and in understanding disparities. And there is a lot of evidence that the symptom control of blacks is worse than whites and that quality of life you know symptom control is one of the two primary outcomes of treating anybody with cardiovascular disease.

They come to us for care to either live longer or feel better. And a lot of these patients are symptomatic, and those that are symptomatic want alleviation of their symptoms by whatever mechanism, medicines, lifestyle changes, revascularization, et cetera. And so it is really, we think you know moving the bar forward to start to include outcomes, particularly patient-centered outcomes.

And so we feel this is a very, very important measure. And if you agree that understanding that this is important, then there's – we sort of view two levels. Originally, the NQF had endorsed the clear, explicit documentation in a reproducible way of symptoms and activity levels for patients with coronary disease and heart failure.

And we had two measures that we brought forth originally. One was that same measure that had been originally endorsed, and the second was then to look at the results of that measure in order to be able to look at the control across time.

We ultimately withdrew the last one, because we had not done all of the preliminary testing on that, although there is lots of evidence in the literature that there's enormous variability in symptom control, and I think we included a paper from over 200 clinics in Australia that documented extraordinary variability in the presence of weekly angina in primary care clinics' offices and that the clinician assessment of that did not correlate with it.

And that there – you know our feeling is that they're – that if this first measure, just that it's systematically documented were accepted by the committee, that we would then be able to go to the next step and bring forth data showing that there is variability and lots of opportunity for improvement by holding physicians accountable for the health status of this patients, their symptoms and their function, and create a way for this very sort of relevant patient-centered outcome to start being quantified and also used as a tool for eradicating disparities.

And so you know this measure never got the full voter consideration because it wasn't considered important. And you know I feel that if you – you know that – I can't remember right now ((inaudible)) from the (Jack article), but almost 32% of encounters in the PINNACLE registry did not have accurate documentation of symptoms and function. And you know there's enormous (gain to) be made by having that go up to 100%. And that will then lay the foundation for really looking at the results of those assessments in a systematic way.

And I guess the one last thing is that the – that you want to eventually get to efficiency and appropriateness, and this will be again a very important application of symptom control, is looking at appropriateness, and this will be a very good foundation for supporting those goals of the NQF, as well.

Reva Winkler: Ray, this is Reva. I'd just like to remind the committee that, in terms of the measure evaluation criteria, there really is a distinction between things that are important and NQF's importance to measure and report.

And I just want to remind the committee that the importance criteria focuses on three parts. One is the impact. Two is the opportunity for improvement. And three is the evidence of relationship of the process of care being measured to outcomes. And that is what we need the committee to evaluate the measure against.

(John Curtis): And can I just address those? So you know the opportunity for – I forgot what the first one was. The second one was opportunity for improvement. And we've provided an article showing in a survey of consecutive patients' tremendous variability and opportunity for improvement.

And you know to say relationship to outcome; I mean this is the outcome. I mean the outcome is controlling patient symptoms. That's what they come to the doctor to get treated for. They want their angina controlled, their shortness of breath controlled.

So I think it – and what was the first one, Reva?

Reva Winkler: Impact.

(John Curtis): You know and impact, how ((inaudible)).

Reva Winkler: Number of patients, (intent of morbidity). It can be defined any number of ways.

(John Curtis): So you know 100% of patients with coronary disease are at risk for angina. After a myocardial infarction, about 20 to 25% at 1, 6 and 12 months after an MI still have residual angina. You know it skewed you know the – the other 75% are asymptomatic, but at risk for developing recurrent angina.

In heart failure, the patients are more symptomatic, and it's even – there's even greater impact, as that's you know not asymptomatic, sort of just (LB dysfunction). But once they get a diagnosis of heart failure, the heart failure syndrome, that's a much greater burden of their lifestyle. I think it's very impactful. I mean and, again, it's sort of why they come to get care, is because it's having a big impact on their lives.

(Karen Pace): And this is (Karen Pace). Just for clarification, but the measure is the process of administering the tool, right, not the actual scores on symptoms?

(John Curtis): Right, so I tried to clarify that. So there's currently a real gap in the systematic documentation of symptoms and activity in outpatient charts of patients with coronary disease and heart failure. It's very common to say symptoms stable or not even to you know address it at all. And so this is ((inaudible)) come up with applying the Canadian Cardiovascular Society

classification or New York Heart, or even for those practices ((inaudible)) a more standardized assessment of symptoms and function, and that that be reproducibly documented in the chart.

And then the second measure that we withdrew, because we didn't have enough data to support it, was what the actual results of that assessment were.

(Bob Bonno): Ray, this is (Bob Bonno). I've been listening in to (John Curtis), and he's been carrying the ball so well that I felt no reason to say anything other than I think he's made the point very, very clearly that – how important this would be for the heart failure measure, as well as the CAD measure.

Ray Gibbons: So since we don't have the primary discussions, I want to refer everybody back to the e-mail again from Tuesday morning, at least in terms of 0065. The original discussant was – is summarized in that e-mail with four bullet points from the staff, reflecting our earlier discussion. We do not have the primary discussant available for the call.

(Dionne Jule): So, this is (Dionne Jule). I think, if my memory is on target at least to where my head was when we discussed this back in February, the challenge for me in the measure specification is that – I appreciate the need to prompt providers to assess and to document what the assessment is.

But the lack of a link even to action of some kind, regardless of what the results of that assessment might be, is a place where I struggle, because we also – there are plenty of data out there, for instance, about the lack of referral to cardiac rehab for quite eligible individuals, and there are lots of reasons why that lack of referral happened, but some piece of that is documented to be you know in the hands of the clinician or the provider who could make the referral.

So I guess I would feel better about the measure (as specified) if it at least had a statement that identified a link to some form of action in response to the assessment. So I think that's where my head was when we spoke in February, and I would say it's still there.

Ray Gibbons: Can I ask other committee members if you have comments?

(Snow): (Snow) here. That's a problem for me, too. I would agree that – it really looks more like a process measure than an outcome measure. There are so (many switch) between the (cup and the lip) there that – I'd like to see it linked better to outcomes somehow.

(John Curtis): So, again, I would just reiterate that it is an outcome, that patients' symptom control is the outcome of the care you've given for that underlying disease, and…

(Crosstalk)

(Snow): But you're not indicating anything we've suggested to control…

(Crosstalk)

(Snow): … what they are.

(John Curtis): … that a cardiologist or a family practitioner or internist would have at their disposal, whether it's titrating medications, whether it's referral to a specialist for further evaluation, whether it's coronary revascularization in the case of heart failure, consideration of intracardiac devices, such as biventricular pacers. There are a range of ((inaudible)) that come from significant symptoms that ((inaudible)) you know but to ((inaudible)) each of those, that has to be very much individualized to each of the patients.

But it is so – such bread and butter to the practicing cardiologists and to the internists who deals with a lot of these patients, they do, when they do, in fact, identify that patients have significant symptom burdens, that we didn't link it to it. And you know again, our ultimate goal is to be able to report out the actual control so that you could look at best practices and compare how those practices are linking – are doing compared to practices that aren't doing as well.

And ultimately there could be lots of algorithms, automatic referrals every year to a cardiologist in a big multi-specialty practice with an (EMR) ((inaudible)) found that patients had class III angina or greater or class III heart failure or greater, just to make sure they have adequate access to specialty care.

(Dionne Jule): So this is (Dionne Jule) again. I agree with you that it's – it would be unwieldy to try to identify all the possible permutations on a response to the assessment. My point was simply to say that if the measure specification indicated that a response was in the note or whatever it has to be to be indicative, when we have other measures that are like that now, where a standardized assessment was completed and a plan of care was developed you know to me, that at least gets us on the road toward outcomes beyond just, did the provider take the assessment, yes or no?

So that was really my point, not to make it such a cumbersome measure that nobody could reasonably do it, but just to really link it more to something beyond the provider, that they actually did something that might impact the patient beyond just collecting the data.

(Andrea Russo): I guess I feel – this is (Andrea) – actually, I don't have a problem with this particular measure. I think you know – I do think and, in fact, in PINNACLE – I can't believe that's not 100%, because that's a motivated group. You know maybe people are just not documenting it. But I could see people go in the room and say, "Do you have chest pain?", but not really asking, "What's your level of activity? How far can you you know walk?"

I hate to say it, but I wonder if there really is a gap here and how much people are – you know you hate to think that this is pretty basic, but if it's not and if we measure it for one year and – or you know we measure it for 3 years or whatever it is, then it's 100% you know then it goes away or it gets – I think coupling it with – whether you consider a process or outcome, if you couple it with another type of outcome or plan part of the measure, it's great, but is it bad the way it is? And you know I don't really have problems with this one.

I think it would be interesting, actually. It would be – if it's not close to 100%, why isn't it?

Female: But isn't that part of the pre-measure evaluation that is in the hands of the developers in the first place?

(Andrea Russo): But why…

Female: ((Inaudible)).

(Andrea Russo): But they wrote down here PINNACLE – is this right – is a general perception of the clinicians not doing as well. PINNACLE data is only 85%, and PINNACLE you know participants are really motivated, I think, to be able to – and they're only 85? I wonder if the rest of the country is more like 50%.

Female: I see your point. Thank you.

(Andrea Russo): So I actually think, if we're not asking, maybe we're not all asking that. We're running in and out, maybe asking half of the question.

(Tom Kotke): I think this – (Tom Kotke) again – one of the questions that's not asked here is level of satisfaction with current physical work capacity and with symptoms. I mean it doesn't say – you

know did the patient want to do something about this? I have a lot of patients who have some chest pain from time to time or who have some shortness of breath, probably mostly because they're obese, but who don't – you know are pretty satisfied with where they are and do not choose to pursue further diagnostics or interventions. And I guess I don't understand how that's taken in account by this measure.

Female: I think we're going…

(Crosstalk)

(John Curtis): You know the measure actually – you know would give credit, for example, in coronary disease for the (CCS class), which does not address that, or the use of Seattle Angina Questionnaire, which does get much more detailed in their satisfaction with care, their quality of life, their perception of their quality of life, et cetera.

The same thing with heart failure. We had the NYHA, which is ubiquitous simple to administer scale that does not (get at) those issues and ((inaudible)) (KCCQ), which explicitly has domains to capture those issues.

So you know our hope was to ask for a standardized assessment, but that seemed very impractical to do. And the assignment of CCS class or New York Heart class seems to be something that (can) be much more feasible. So it's, again, accepting good, but feeling that you know perfect would be the enemy of getting anything done.

And so that's why it's – that was the logic behind accepting both of those. But you raise a very good point, and we would like to see those kinds of standardized assessments used much more often.

Female: And I think it would be interesting to – just a very – we all think this is so basic and you know why isn't everyone doing it all the time? But I wonder – I really question you know maybe some of the basics aren't being done. And then you know people need to ask before they can go the next step.

(John Curtis): I mean an anecdotal story is that's exactly right. And (Joe Messer), who's a very experienced clinician who is one of the co-chairs of the group when we first proposed this back in ((inaudible)) I think went back to his charts and looked at his own charts and found that he had not documented this adequately and started documenting it much more after sort of being privy to this discussion, in that it does – it just isn't documented or documented well.

So that what happens is that, if one doctor is out of town and another doctor picks up the chart, and it's not documented, this patient's always been in class III angina and all that's been documented is angina stable, et cetera, we ended up feeling that you know they would admit that patient in the hospital for doing much worse all of a sudden.

And so there really was felt to be a need in clinical practice to clearly document the symptoms and activity of our patients.

(Tom Kotke): (John), wouldn't they ask the patient if things had changed?

(John Curtis): Well you know I mean…

(Tom Kotke): I mean I wouldn't admit that patient. I'd ask him, has anything changed…

(Crosstalk)

Ray Gibbons: Let (Tom) finish, please, (John), all right? (Tom), you were going to say something. Have we lost (Tom)?

(Tom Kotke): What? No, I'm there.

Ray Gibbons: Okay, you were starting – you were – just complete your thought.

(Tom Kotke): Yes, no, it's just that – I mean I don't think it necessarily – I mean that the argument can be – you know that if I saw one of my colleague's patients and the patient says, "I have chest pain when I walk to the mailbox," I mean my next question would be you know "Is this new?", not, "Gee, when can we give you the cath lab?" I mean maybe he asked for the cath lab if it's new, but, I mean – you know so I think the argument that you know the Canadian – you know putting down the Canadian classification would sold the problem, I don't – I just don't buy that argument.

(John Curtis): I'm not trying to overstate it. You know I'm just – you know the feeling was that it was not accurately documented in a clear fashion and it made it difficult to be able to eventually look at the control of symptoms, which is our long-term goal, because it's a relevant outcome.

And so if we could systematically have this documented in all patients, then the measure that we will withdrew will start to have greater opportunity to impact care by looking at the actual success in controlling patient symptoms.

Ray Gibbons: Okay. Are there other comments from the committee? All right. So we're going to – I would suggest at this point, we can – we've had a very lengthy discussion about this, and that we will simply re-ballot everybody on 0065.

Now, Reva, I see a process issue that the letter actually also dealt with 0077.

Reva Winkler: Yes. And the question I guess I would say to the committee – you're right. I didn't differentiate the two. It sounds like the issues were very similar and were talked about together. Do you want to re-vote both of those measures?

Ray Gibbons: I think if we do that, we should at least distribute to the committee the summary of the votes on 0077…

Reva Winkler: Will do.

Ray Gibbons: … in a subsequent e-mail. Are there other comments that – we've had the discussion about angina, and the letter deals with both angina and heart failure? So are there other comments – are there members of the committee who feel that we should have a more extended discussion on another occasion about 0077 before re-voting on that? Let me ask it that way. Let me get a sense from everybody.

Male: … 0077 is heart failure?

Ray Gibbons: Yes.

Male: Yes. As distinguished from angina.

Male: I think we've had the discussion.

Male: Right.

(Crosstalk)

Male: … thank (John) and that group for their hard work, no matter what the income is, but implore them to keep on pushing.

Ray Gibbons: Are there others who feel that we need to have a separate discussion on 0077? Okay, Reva, I would suggest therefore we distribute to the committee members in a subsequent e-mail the actual summary of the original discussion on 0077 and we re-ballot that one at the same time.

Reva Winkler: Okay. Will do.

Ray Gibbons: All right. Thank you, (John) and (Bob). We're going to have to move on now to the topic of competing and related measures. And I would point out to everybody, in terms of finding the right document, to open up that these are – the key summaries and tables are in the PDF that's labeled "Deferred Inactive Competing Measures."

So if you go to the bookmark on competing measures, you will be where you need to be. And we discussed the competing measures in Phase I, which included 0076, which is the optimal vascular care from the Minnesota Community Measurement Project, 0073, which was the blood pressure management issue from NCQA, which has already been discussed today, and then we also discussed the anti-platelet and lipid control measures.

And we asked the committee to – I'm sorry. We asked the NQF to prepare a list of pros and cons. And that actually appears on the – at that bookmark that I mentioned on competing measures. So the pros, which largely reflected our discussion, about having a single composite measure, focuses on several factors that are important and an individual patient more challenging, but important (and patient focused).

Second pro is it reduces the number of measures and eliminates redundancy. The third is that it eliminates the need for harmonization of multiple measures. The fourth is that it conserves what

we call the opportunity costs. And we also talked about the need to consolidate measures across conditions, which is also listed there. And the (CSAC) has been pushing for more challenging broad patient-focused measures, which this certainly is. And a significant harmonization is needed if we preserve individual measures.

The cons are summarized, as well. And for those who might not have found the right document, the individual measures such as blood pressure control or aspirin use are important for end users as standalones. The individual components of the (community) measurement project haven't been evaluated really as standalone measures. The lack of uniform availability of electronic platforms, at this point in time, necessitates maintenance of measures that depend on different data sources.

The individual measures have endorsed for several years and are in use in many large programs, such as CMS's PQRS and the NCQA HEDIS. And those current uses are listed in a table, and some of them have already been retooled for – (as e-measures) for the meaningful use program.

Reva, do you want to comment at all on the pros and cons analysis?

Reva Winkler: No. I think that, to paraphrase a discussion we had with (Helen Burstein) the other day, I mean I think that NQF's ultimate goal, if we could have exactly what we want, is we would like to see a composite measure with individual components that could be used as standalones all specified for EHR.

We're not there yet, but we would really like to see our portfolio of measures move in that direction, and so all of these pros and cons kind of play into that to a greater or lesser degree.

Ray Gibbons: Are there questions or comments about the pros and cons of having a single composite or individual – a single composite and not endorsing the individual measures versus a composite and endorsing the individual measures, which is really the first issue here?

(Tom Kotke): Ray, (Tom). As point of information, if the – in the composite, each of the individual measures would undergo the same scrutiny as they would as if they were individual measures. Is that not correct?

Reva Winkler: Yes, (Tom). To be individual measures as opposed to the component, they would end up having separate submissions and separate evaluations. As it is now, Minnesota does report out the individual measure component values along with the composite, and that's fine, but the bundle goes together and isn't broken apart.

(Tom Kotke): What I was just sort of asking was the diligence of – with which each of the – I think we had a little bit of anxiety about the validity or the diligence with which some of the individual components of a component measure were documented.

Reva Winkler: Okay.

(Tom Kotke): And I was just wondering basically if the – if we had a composite measure, would we require that all of the components be able to stand on their own.

Reva Winkler: No, we don't require that, nor do we require them to be individually endorsed. We expect that as part of your evaluation you will evaluate the individual components.

(Tom Kotke): Okay.

Female: I'm sorry. With the composite measures – and I think you said this, but let me just make sure I heard it correctly – they would be reported – each of the individual results of individual measures would still be reported to the site as – regarding the results of that particular component of the measure. So if you're doing poorly on one of the components, you'll know that where you need to work and improve. Is that correct?

Reva Winkler: That's correct. That's correct.

Female: Okay, but you won't necessarily – I'm just trying to think, is there any other sort of negative – so if they're being looked at in terms of disparities, if there's disparities in one of the components would it be apparent, because it may not be a disparity overall in the composite measure. Would we be able to get at that kind of information or not?

Reva Winkler: I think that will depend on how it's implemented. That's really getting into significant implementation reporting details.

(Bruce): This is (Bruce). I have a quick question. I just want to make sure I understand that – someone briefly mentioned that you don't – if you have a composite measure, that each of the components do not necessarily need to be able to stand on their own. Is that correct?

Reva Winkler: That's correct.

(Bruce): Okay. Yes, I thought we had had some discussion in the past about wanting the individual measures, but maybe I misunderstood. For instance, there was some discussion when we met in person about the tobacco status issue and that there were some shortcomings of that or something like that.

But that – you could have a component – composite measure that incorporated that, even though there were problems with it?

Reva Winkler: Well, I think you're confusing it with the smoking cessation measure that was part of the hospital measure set for (AMI), pneumonia and heart failure, which are very problematic and were – the endorsement on those was removed. But this particular measure actually in the composite – the smoking component is whether the patient is a non-smoker or not, and actually NQF does not have an individual measure of that particular type for smoking.

Ray Gibbons: (Bruce), does that help?

(Bruce): Yes, I guess it helps.

(Crosstalk)

(Bruce): Maybe I used the wrong example, but what if we had a component where there was no gap really involved and that component of the measure, it was very close to 100%? You could still have a composite. Everyone would feel comfortable having a composite that incorporated such a component.

Reva Winkler: I mean that's one of the decisions the steering committee makes, but it is not a requirement that the components are independently endorsed.

Ray Gibbons: Right. I think it's worth pointing out, (Bruce), that that's one of the arguments for composite measures.

(Cathy): Reva, this is (Cathy) with a question. There would be no weighting of the individual measures within the composite?

Reva Winkler: These are – this is an all-or-none composite…

(Crosstalk)

(Cathy): All or none, okay.

Ray Gibbons: There's no weighting.

(Cathy): No weighting. Okay, thank you.

Female: Hi ((inaudible)) from a public reporting point of view, I think to the consumer it's – in some ways, it would be – the composite is very nice. It's one number. But it'd also be interesting to know, well, okay, they're doing – they're not doing that well. Where are they falling short? So I guess I would be interested in seeing for the composite if it could be reported that – the breakdown you know kind of behind-the-scenes for people who are interested.

Reva Winkler: That's the intention. And we asked Minnesota to clarify that in a revision of their submission form, because that is, indeed, the way they implemented it.

Female: So that's how we would do it?

Reva Winkler: Yes.

Female: Okay, thanks.

Ray Gibbons: So have we had enough discussion that we're going to be able to – is everybody comfortable that they're going to be able to vote on the issue for this set of whether we want a single composite or whether we want a composite plus individual measures?

Female: I think so. Let me ask one more question. As if – so in terms of the workload, as time goes on, with reviewing each of the individual measures, I guess that would be one advantage of just having the composite – is it possible to say if the composite is looked at and endorsed again that that means automatically that the individual components would be re-endorsed, if one were to vote for both?

Reva Winkler: Well, at that point, that's really not something that the steering committee can deal with at this point in time. NQF has guidance on evaluation composite measures, which is actually going to undergo review in the near future, and that's where that kind of an issue can be dealt with. Right now, the requirement is that the parts are evaluated.

(Dionne Jule): So this is (Dionne) again. So right now, we're talking about just the anti-platelet agents group, not the others that are on the list? Is that right?

Ray Gibbons: Correct.

(Dionne Jule): And so would the – you ((inaudible)) just lost track of it.

Ray Gibbons: Yes, it's easy. Don't worry. It's easy to lose track.

(Dionne Jule): So if – when we talk about a composite, are we talking about only the three 067, 068 and 0631? Or are we also talking about the related measures?

Reva Winkler: Okay. The only composite we're talking about is Minnesota Community Measurement. They're 076. It's an all-or-none composite measure that has four components.

(Dionne Jule): Got it. I'm sorry. Okay.

Reva Winkler: Okay. So that's the only composite there is. The committee at our meeting identified that as a competing measure with five other measures, which addressed blood pressure, anti-thrombotics, and lipids.

(Dionne Jule): Okay.

Ray Gibbons: So…

(Crosstalk)

Ray Gibbons: Yes, and, Dionne, it's very confusing. But, I mean I think we want to try to separate this into two separate issues. One is are you going to improve the composite, as well as individual measures? And then the second step is, then you've got to look at the individual measures and say, okay, they're all competing. You approve all of them.

Female: Right.

Ray Gibbons: Or do you choose one or whatever? Okay.

Female: Correct.

Ray Gibbons: So I think if people are comfortable that we've had enough discussion about the composite versus individuals, now we should proceed to the second stage, which is the individual competing

measure for anti-platelet agents. And if you have the right document opened in front of you, it's 0067, 0068, and 0631, although 0631 – is that the one that's not up for review right now?

Female: That's not up, right.

Ray Gibbons: That's the one that's not up for review right now, but in the – we can still provide guidance regarding that issue. So let me just lead off by pointing out that 0067 is about coronary artery disease. So from the standpoint of the evidence base, it's extremely strong. This is, in essence, secondary prevention, what most people would label secondary prevention.

Ischemic vascular disease is a broader population, so, for example, it includes stroke as a condition, for which Mary can comment, but I think the evidence is also strong. But it also includes, for example, peripheral vascular disease, for which most people would say I think currently the evidence is not so strong.

Mary George: This is Mary. And in you know reviewing the PAD guidelines, it's really – aspirin is in there mentioned in the context of preventing coronary disease and stroke, basically because you have a population with atherosclerotic disease.

Ray Gibbons: So, Mary, do you want to comment on the strength of the data for cerebrovascular disease?

Mary George: Well, the updated guidelines, both primary prevention and secondary prevention – well, I'll just stick with secondary prevention. Certainly, the guidelines have been recently revised and continue to support that, both intracranial ischemic disease and carotid ischemic disease.

Ray Gibbons: So are there other comments from the committee regarding these competing measures? And I think at this point, it's very important for the committee to consider the lengthy comments

from ACCF, AHA and PCPI in their letter, the same letter we talked about earlier. The most lengthy comments are reserved for the issue of competing measures. And they express, I think, a number of important concerns about how competing measures should be evaluated, and they've very concerned that the breadth of the population is getting too much weight in the guidance with respect to how to evaluate competing measures and that there's no place in the guidance where the process used to develop the measures is factored in.

Male: This is a philosophic issue to a certain extent. The question is do you use a rifle or a howitzer you know?

Ray Gibbons: I like that one.

Male: And the benefit of having a rifle is that you can identify a narrow problem and do something about it. But the – as I think others know as well or better than I, the benefit of the composite is that it looks more towards overall care and the episode of care, because you can do absolutely wonderfully with anti-platelet therapy and still have everybody dying of hypertension.

So that unless you're trying to juggle six or seven different measures all at the same time, that can be hard to do. And if – I think that the philosophic part is that the folks who wrote the letter may be more concerned with individual action items. And I think both have a place, myself.

(Karen Pace): And this is (Karen Pace). I just wanted to mention that these comments were also submitted in response to the public comment period we had on the competing measures guidance, and the (CSAC) is reviewing this.

But just in terms of clarifying the position about preferring broad-based measures you know the caveat to that is if it's supported by the evidence. So I think there's some mention in here about the evidence being different, and that's a perfect example of why you would need different

measures, if the evidence is really different for different patient populations, so just to kind of keep that in the forefront, as well.

And in terms of the – looking at the measure developers' process, it's really not part of our evaluation criteria. I guess our criteria are based on the assumption that developers that follow best practices in measure development will be able to demonstrate that they meet the various criteria, but we don't specifically look at the process of their development separately.

Ray Gibbons: And that's the concern they're raising, in essence. They're saying we should or…

(Karen Pace): That's right. That's right.

Ray Gibbons: … NQF should.

(Karen Pace): But that is – and it's something that the (CSAC) will respond to.

Ray Gibbons: Okay. So we're struggling with this, I sense, in the absence of any comments. And that's, I think, expected because they were the first group to really deal with this competing measures question. I would point out, in addition to the points we've outlined already, that the two measures that are under our you know purview right now, 0067 and 0068, also differ in the sense that 0067 allows for a variety of exclusions, which are really not feasible under 0068.

Female: And one other question, although it's not one of the ones that I guess is up for review. When they refer to – obviously, there's administrative data, but with clinical – with some clinical data, that's – it's a third one over the 0631. I know that's up for review right now. I guess it's not. It's endorsed. But what is that referring to?

So there's some pharmacy data? Is that what it is? Or…

Female: Yes. Well, it can include encounter data, pharmacy data, and also actually, the way this is implemented, you can include elements from EHRs or PHRs.

Female: So it's not (only was it prescribed is was it filled)? Or – the pharmacy part of it? So are they…

Female: If they're using pharmacy, which is not typical for aspirin, it will be filled, but if it's just aspirin usage, it may just be reflected in the EHR or PHR.

Female: So it's kind of a different kind of thing than the other measures?

Ray Gibbons: Well, yes. And that's one of the challenges, as we – as you know people look at and say, oh, there are too many measures. They're all a little bit different. If they were a virtual – I mean if they were totally identical, then hopefully they wouldn't exist as different measures, but the challenge for us is to decide whether we're going to continue to endorse all of them.

Mary George: Yes, this is Mary. And you know when I look at these, one from PINNACLE, one from you know administrative data, one from pharmacy data, it's having similar measures that are tailored to a specific data collection system which is really problematic in trying to really evaluate what we want to measure.

Reva Winkler: Mary, this is Reva. I think that the committee is echoing comments we hear from a lot of the membership. And we've got several competing issues. It's well known that different data platforms do generate somewhat slightly different measures. And given where we are, perhaps it's okay in the interim, until we reach a common data platform.

On the other hand, it just adds to a huge list of measures that's confusing and redundant to a lot of audiences. So those two tensions are very real.

Mary George: Yes.

Ray Gibbons: And you know I think, for example, to go back to the exclusion question, my favorite example these days, which I cite whenever I can, because I think it demonstrates the problem, is we've got millions of Americans with coronary disease and we've got millions of Americans with atrial fibrillation and the need for chronic warfarin therapy.

Now, we therefore have millions of Americans who happen to have both. And do you just willy-nilly put, say, well, everybody needs warfarin and aspirin? There is no – the evidence on that point is incredibly skim, yet there are millions of Americans. And so, in this case, one of these measures excludes all the people on warfarin, and the other does not.

(Dionne Jule): So – this is (Dionne) again – so – maybe this is backtracking, but relative to the composite versus individual measures conversation, the measures are different enough – well, the numerator statements are different enough that they don't feel competing to me, in that sense, because the composite measure has as a numerator statement achievement of targets by the patient, whereas the individual measures look at the performance of the clinician, right, as I read the…

Female: Right. And ((inaudible)) just to point out to you all that, throughout both meetings, there were numerous comments about how many measures that were all about the same topic. So this was sort of a theme that the steering committee brought up.

But in terms of the guidance that NQF provides in terms of determining whether there are competing measures, that's defined as measures that address the same concept for the measure focus – that would be the numerator – for the same target population.

Female: Well, so maybe I'm being too strict in my interpretation, but to me – to me, the composite measure numerator is not the same as…

(Crosstalk)

Female: … broad content area, but it's – the focus is different. So for me, it boils down to more of this individual idea of – if we care about clinician behavior, if we think there's some value in endorsing measures that are more focused on the clinicians' behavior as the end product of the measure, rather than how the patient ends up, then it's more for me a discussion about, is it 0600 – I'm sorry, I've lost the numbers – 0067 and 0068, are they competing?

Ray Gibbons: No, I'm sorry if I didn't make that clear. That's where we are right now.

Female: No, I know that's where you are, but I just – I'm really responding to the guidance, the letter from the…

(Crosstalk)

Ray Gibbons: Yes. Oh, okay, right.

Female: That's why ((inaudible)) you know to look at them, that it's not just you know composite or not, which is I think part of what they talk about. It's also this other piece about, what is the intent? What is the focus in the first place?

Female: And which patients are we – you know I don't know you know that coronary disease alone you know would really – or does ischemic vascular disease you know drugs may not be identical, right ((inaudible)) those two columns. So how do we – we can't necessarily say they should be – and

maybe the target groups are not identical and one is more diffuse vascular disease or other – other than coronary disease can be included.

So the data – and you know again, I'm not the one to know all the data for peripheral vascular disease. I don't claim to be. But I would imagine that you know there may be some differences in data there.

So I don't think they are the same target population. And the question would be you know I don't know that we could assume that we can just put all the coronaries under – there may be some very specific things for coronary disease that would apply. So between those two you know if we can't really evaluate all the other ones you know…

(Karen Pace): This is (Karen Pace) again. And just a couple points. But I think the reason the question is raised is, if they have the same numerator giving anti-platelet therapy – and I don't – and you're doing it for two different – the first question is do you need two separate measures if you're measuring the exact same thing in two different populations? So that's the question. Should they be combined? And if the evidence is different, then wouldn't the numerators be different or the exclusions different, which you've been talking about?

And we're not saying that they have to be the same, but it is the question before the steering committee, what your recommendation is.

Ray Gibbons: So I think part of our challenge here is whether there's any more discussion that's going to basically make people – Reva, help me. I think this part of the ballot is going to be, do we – have we made a decision composite versus composite plus individual?

Reva Winkler: Right.

Ray Gibbons: The second phase has got to be, do we continue to endorse both 0067 and 0068 or just 0067 or just 0068?

Reva Winkler: Right. And that's the way I've drafted the ballot right now, is there's a first question that is, do you – you know go for the composite-only, so you have that as a separate vote. But then, because we don't know the outcome of that vote, then these measures, the two anti-platelet and two lipid measures are there for you to vote whether you recommend or not.

Female: But I would still think that it's – and, again, I'm thinking about this out loud, but I don't – I almost think that maybe they should be (both there), because the data may be stronger, for example – if they're grouped together, then you know you're not going to know – the data may be stronger – I don't know if this is true – for coronary disease than it is for other types of peripheral vascular disease. And wouldn't you want to know them separately and then be able to have physicians know you know maybe where there is a gap in care in one or the other? I don't know.

The more I think about it is, since they're not the same – they're not – I know it's the same numerator, in terms of anti-thrombotic therapy, but if it's different diseases, I don't know that it makes sense to me to combine them.

Ray Gibbons: Well, we're not combining them. We're just picking one or the other.

Female: ((Inaudible)) I mean just eliminating…

(Crosstalk)

Ray Gibbons: We're just – we're just – you know because the push-back from primary care docs in particular is, "I don't understand this. Why are there so many different measures?"

Female: But then that would mean – by implying that you'd eliminated 0067, because it's more inclusive for ischemic vascular disease, which is what I think…

Ray Gibbons: Right, well, as I've tried to indicate, it's not that simple, because 0068 says if you're on Coumadin for atrial fibrillation, you're supposed to still be on anti-platelet therapy, because there's no exclusion.

Female: Right. So they'd have to modify – so it would have to be modified…

(Crosstalk)

Ray Gibbons: Well, again, we can't say that. I mean well, they can't do that. It's an administrative measure. They don't have the capacity to do that.

Female: Yes, good point.

Ray Gibbons: See, that's the…

(Crosstalk)

Female: And the administrative part of it you know isn't…

Ray Gibbons: All right. So I think we've discussed this one enough. I'm sure now we've got to move on to the next little area, which is lipid control. That's the next set of tables. And, again, we have the PCPI measure versus the NCQA measure that deal with, in one case, coronary artery disease, in the other case, again, broader population, including ischemic vascular disease. But they're both about lipid control.

And one basically – well, there are you know more differences here, right? I mean one has to be (at 100) during the most recent screening, whereas the other one basically takes into account potential problems, in terms of side effects and problems with (stents). You know so one considers allergies and tolerance, other medical reasons, patients' preference not to take them, but that's not in the administrative measure.

Has everybody found the right table?

Female: Is it all three that we consider, the first…

Ray Gibbons: It's, again, 0074 and 0075.

Female: Right.

Female: Okay, but 0076 isn't under – it's…

(Crosstalk)

Ray Gibbons: Well, it's the same question, remember? If we choose the composite, these first individual columns – if we say the composite only, these first two individual columns are dead. So we're saying, if we say both the composite and individual measures, then how do we choose or do we choose between 0074 and 0075?

Female: Well, on the same – not surprisingly, I guess, because it's the same group, the composite measure is about the achievement – the patient's achievement, right, of outcomes as opposed to the clinical behavior for the other two? Is that right?

Ray Gibbons: Well, 0075 is about the outcome.

(Crosstalk)

Ray Gibbons: This one – this one has another nuance. I mean 0075 has the outcome.

Female: Right.

Female: And the process and outcome for 0074…

Ray Gibbons: Right.

Female: Wow. And it's a different – subgroups of coronary disease patients. This isn't so easy.

Male: It's kind of noteworthy that (these committee) evaluations were substantially different for the much broader spread for 75.

Ray Gibbons: Comments? Questions? Because in essence, at this point, we want to make sure that everybody is reasonably comfortable balloting on this issue.

Female: So, to me, I mean the one – I don't know, the 75 having specific MI CABG PCI to me you know coronary disease obviously covers that, so it's kind of all-inclusive in the first one, and so that it doesn't have the administrative – this has an administrative component.

Ray Gibbons: I'm sorry. Somebody else was trying to say something. I heard a voice.

(Carol): Yes, this is (Carol).

Ray Gibbons: (Carol), you're very – it sounds like you're in Outer Mongolia, so we need you a little louder, if possible.

(Carol): ((Inaudible)) hotel room. Is that ((inaudible)) Outer Mongolia?

Ray Gibbons: Speak up if you can.

(Carol): Okay. I will. My question is – I'm confused. Do we have to choose between those two measures if we endorse the composite plus the individual?

Ray Gibbons: No. We can say – the ballot will have on it, presuming that we – if we choose just composite and not composite plus individuals, this is all moot.

(Carol): Okay.

Ray Gibbons: If we choose composite plus individuals, then the second part of the ballot becomes relevant, and it will say 0074 and 0075 or 0074 or 0075.

(Carol): Okay. I mean is this all moot when the new guidelines come out for composite measures?

Female: No. No.

(Carol): No? Okay. Thank you.

Female: It won't be that different.

Female: Hi, this is ((inaudible)) if we went with 74 instead of 75, what would we lose?

Ray Gibbons: The other patients who are part of the broader population, so it would – let's see if I can get this right. I have to go to the denominator statement. It's got to be, again, the vascular disease, but not coronary disease patients. I think that's correct.

Female: And I guess that, because the 74 is limited to a 12-month period and 75 is – I guess 75 is even shorter. I'm not sure.

Ray Gibbons: Seventy-five has a longer timeframe, so there is some difference there. But I think it's primarily in the patients…

Female: Right.

Male: Seventy-five includes patients with cerebrovascular and peripheral arterial disease.

Ray Gibbons: Right.

Female: Right.

Male: Which 74 does not.

Ray Gibbons: Right. And you know that – I'm trying to look down on the table. The table's pretty complicated. But, right, that's correct. So, for example, it specifically says ((inaudible)) or stenosis of pre-cerebral arteries, atherosclerosis of the renal artery, atherosclerosis of ((inaudible)) arteries of the extremities, chronic total occlusion of an artery of the extremities. And there's an entry that says cardiovascular disease, and I presume that's cerebrovascular disease, but maybe I've got it wrong.

Male: ((Inaudible)) shotgun.

Ray Gibbons: Right, the shotgun versus the rifle again.

Male: Or the howitzer.

Female: But 76 has already included the larger ischemic vascular disease population.

(Cathy): This is (Cathy). On 0074, it applies also in skilled nursing facilities, and 75 does not. And is that an important distinction?

Female: Seventy-six does not, either. Or does it? No, it does not.

Ray Gibbons: I presume that's by virtue of the data collection mechanism. Additional questions? Are people going to be comfortable – I know Reva and the staff have got to word all these ballots extraordinarily carefully so they're obvious?

Reva Winkler: Well, the one thing I would tell everybody is if, indeed, you decide that you cannot differentiate or cannot make a choice between them and you can explain why, that there are – is a need for both measures, that's fine, but please include those explanations, because we will need to present that information.

You will certainly – there will certainly be an opportunity for the public and NQF membership to comment on your decisions, and you'll get to see that feedback, and that may prompt another set of discussions.

(Dionne Jule): So just – this is (Dionne) again – just in my head, in terms of thinking about the ballot, it seems to me that what we've been discussing is side-to-side comparisons of who's included and

who's excluded, but that's one decision point that we might consider. Another is whether it's just process, just outcome, or some combination. That's another decision point we might consider.

And I'm asking. I'm just thinking out loud here, that where the patients are captured, so the setting question that was just brought up might be another point. Is that – that's what you mean, in terms of explanations, if we were to focus in, that you'd want us to explain those kinds of…

(Crosstalk)

Reva Winkler: … feel there's a benefit for having both, a value for having both, because we have to convey that explanation to the audience. So that will remind you that one of the common themes that this committee talked about during both of your meetings were, gee, this is – there are six measures for aspirin use. There are five measures for (EHR) use. That is something we hear a lot in various audiences.

So how do we resolve that? As you can see, it's difficult.

(Karen Kimitic): Reva, this is (Karen Kimitic). Are you open to comments?

Reva Winkler: Ray?

Ray Gibbons: Sure.

(Karen Kimitic): Hi, this is (Karen Kimitic). I'm with the PCPI. I just wanted to offer – regarding the communication aspect – and I certainly sympathize with what you just said, Reva – just to offer that you know we're also trying to communicate for providers whatever level of analysis we look at, the individual physician or the group or (the ACO). We're trying to encourage people to select a portfolio of measures that best address their patient population.

And so in communicating about these, instead of just listing, "Here are all the measures regarding anti-platelet therapy," you know to try to explain that, if you are primarily treating a patient population of CAD patients, then in your portfolio of measures that you manage for those patients, for which we're holding you accountable, we'd want to include anti-platelet therapy.

So I'm just offering that another way to kind of look about – if communication is the issue, is to remember that we want measures whereby we can advise those who we're holding accountable what measures should go into their portfolio of measures by which we will hold them accountable for a patient population that's relevant to them. Just wanted to offer that thought.

Female: And just a comment in return is the tension that – against the stakeholders that are looking for a focused, standardized set of measures so that there aren't redundancies within the portfolio, very definitely another tension.

Ray Gibbons: Okay. I think we've probably had enough discussion about this.

Female: Right.

Ray Gibbons: And I think, Reva, you can provide some guidance here, but I think we probably need to make sure we – at this point make sure there aren't additional public comments.

Reva Winkler: Right. I've got 15 minutes. And I'd like to perhaps, Ray, if at all possible, try and do the Phase II competing, mainly because I think I can shorten this one really quickly.

Ray Gibbons: All right.

Reva Winkler: Okay. On page 3 of the next page of the same memo, on competing related measures, we talk about three pairs of competing measures. Let these – the first measure of each of the pairs is a measure that you all have evaluated and recommended, although 1525 is a measure that there were some outstanding issues, most of which the measure developer has responded in accordance with the desires of the committee.

But the second measure, the 0624, 0610, and 0615 are very similar measures that are based on administrative or claims data. And in late-breaking news, the (CSAC) met 2 days ago and reviewed the guidance on competing measures, realizing the struggle you all are going through. And one of the things they wanted to emphasize was they fully support maintaining multiple measures that are similar, particularly if one of them is based on claims or administrative data. So you're not being asked to act on those measures, but the only question is, is it reasonable to have multiple measures addressing the same topic?

Female: I guess I would just ask a question to step back first. So it's based on – and you know what administrative data? And do we feel that that data is accurate? So…

Reva Winkler: Well, you're not evaluating those measures. They're based on basically encounters and pharmacy data.

Female: So, Reva, you're saying those measures are not up for review?

Reva Winkler: No, they're not. They're just provided for context because they are in the portfolio.

Female: No, I still think pharmacy data – I mean we're measuring – it's great. I mean it's the ultimate way to measure it, but you know it's measuring something different than you know what the doctor documented in a chart that they recommended. That's also getting into the patient compliance side of things.

Female: Correct.

Female: So, I mean that's great, but that's also – you know there's other factors there that would need to be you know assessed when we're looking at different – you know controlling for differences between groups there.

Reva Winkler: But the question before you is, I think, much more simple.

Ray Gibbons: So now, Reva, given that new guidance, I'm not actually sure in my mind what the question is.

Reva Winkler: Well, the question is simply – it almost makes this moot, but because these measures do address similar – they're essentially very similar, does the committee want to maintain their recommendations for the three that were evaluated, knowing the others do exist? Will we have to explain that we know that there are similar measures and the reason for recommending multiple measures is the differences in data platform? If the committee agrees with that, that's all we have to do.

(Karen Pace): So this is (Karen). And can – let me just give you a little more context about the (CSAC) discussion. And it's really in context of this move towards wanting clinical data – clinical measures to come from clinical data from electronic health records. And, obviously, we're not to that point of those being widely available.

And the idea is that, in this period of transition, which something will be longer than shorter, that there may be a rationale to have measures of the same thing that you can measure using different data platforms.

(Snow): Right. You know this is (Snow). You just said what I was going to say. Because I think that the time will come for these to go away, but we're not there yet.

(Karen Pace): Right. And so we don't want to – you know if choosing only one measure greatly diminishes how many entities you can have performance measurement for, we really haven't accomplished anything.

(Snow): In the bigger sense, we've lost something, yes.

(Karen Pace): Right.

(Snow): Yes. Right. And I agree with it. I mean…

(Crosstalk)

Ray Gibbons: Are there any members of the committee who feel that we should, in fact, do away with one of these or that there – is there an argument, given what Reva has told us about (CSAC) and the enunciated argument that we're in a transition time, is there an argument to take more drastic action at this time? I'm just asking whether somebody sees an argument.

Female: I have to ((inaudible)) 0624 measure and – do we have the second ones? Only because, does that also include you know with A-FIB, whether or not (debigratin) is in there. You know…

Ray Gibbons: That's been corrected. That's been corrected, the developer in response to our feedback. So, I mean the 1525, I don't know about 0624, because that's not up for review right now.

(Crosstalk)

Female: I guess I'm always a little hesitant, when – you know if it's administrative data only, and I have to look up that one. I don't even think we have it, probably, do we, or…

Female: No, because it's not…

Female: … because it's not up for review, so…

Female: It's in the side-by-sides, though, the…

(Crosstalk)

Female: … okay. So I guess I'm always a little hesitant with just – if it's just administrative data and how that's obtained. I guess that's from the pharmacy for prescription refill. Is that what it – what page is that on? Or how do we find that one?

Ray Gibbons: If you just keep going down the competing measures, it's bookmarked for competing measures, and then you've got to scroll through the anti-platelet, the lipid, and eventually you'll come to a narrower page, and the narrower page is 0624 versus 1525.

Female: We wouldn't be able to do anything with that anyway, so I guess…

Ray Gibbons: All we could do is say, we recommend, for example, that one of these be – we could recommend right now that we're not going to endorse 1525 because now we see that there's a previous competing measure or we could give the advice that we think 064 should go away, but we can't actually decide that. That's what we could do.

Female: Right.

Female: All right. So we still – we definitely need 1525.

Female: And our support for the ones that we did review was pretty substantial.

Female: Correct.

Female: Right.

Female: Could we not also recommend that in your criteria for evaluating competing measures that if it is based on claims data or different data platforms, it should be considered as important? That's not in your competing measure guidance.

Female: We're working on that now. As Reva said, the (CSAC) just discussed it the other day, and so we're…

Female: So you'll add that?

Female: Right.

Female: Okay.

Female: Right.

Female: So the numerator on the 0624, obviously, because it wasn't made when (debigratin) was available, does not include (debigratin), so, clearly, the 1525 would be superior in that…

Female: Well, I've checked with the developer. They're adding it.

Ray Gibbons: Okay. So the ballot is going to just basically – for these say, we reviewed – whatever, 1525. There's a separate administrative measure, 0624, on the same subject, and it's going to ask whether we should continue both.

Female: Correct.

Ray Gibbons: Are people comfortable with that? Do you have more questions about that? Or are you going to be comfortable voting on that?

(Roger): The short answer for me is yes, but I think that, in the preparation, it's kind of tricky, because anyone who wasn't on this call is at risk for not having an understanding that the reason for even thinking of having such apparent redundancy is the difference in the data platforms and the fact that there's a real benefit to supporting that for a while longer.

Female: (Roger). To take care of that, we're going to be pulling together a summary of this conversation to go out with that ballot.

(Roger): Fine. Fine.

Ray Gibbons: And I think we should, as part of that process – and you've identified a key point, I believe – is to point out to people is, because they weren't on the call, they're not comfortable, they don't vote. They can just abstain.

Female: Okay. We are getting close to time, so I do think we do need to do public comment.

Ray Gibbons: Okay. Public comment? Are there public comments?

Female: Not hearing any. Going once, going twice. Okay. Ray needs to sign off absolutely at 5:00, and I just wanted to wrap things up. Frankly, not knowing how the results of the ballot are going to turn out, I think we may need some follow-up based on that, but also of the measures for inactive endorsement, we have not acted on again. And so we will need to schedule another conference call, so we'll have a chance to go over some of these issues again, particularly if the votes we do now raise additional issues.

Ray Gibbons: Yes. And hopefully we can lump that together with any follow-up from this call, plus the inactive measures.

Female: Correct.

Ray Gibbons: All right. Well, I thank everybody for their perseverance. This is challenging. And the agenda was obviously challenging. We realized that from the start. So I don't think we view it as a failure that we didn't get to the inactive measures question. We made a decision to put that last in case we didn't.

So thank you, everybody, for their time and their perseverance. This is difficult enough, but doing it by phone, I think, is even more difficult. And we will rely on the staff to get the ballot out in due course.

Male: Have a nice flight.

Ray Gibbons: Thanks.

Male: Have a good flight, Ray.

Ray Gibbons: All right. Thank you.

(Crosstalk)

Male: Bye, guys.

Male: Bye-bye.

Female: Bye.

END