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## NATIONAL QUALITY FORUM

Moderator: Reva Winkler September 02, 2011 3:00 pm CT

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

Reva Winkler: Welcome everyone; this is Reva Winkler from the National Quality Forum. Thank you all for joining us today on our conference call of the Cardiovascular Endorsement Maintenance Steering Committee.

Our primary goal today is for the committee to review the comments submitted on the draft report and recommendations made earlier in the year. And so I'm going to turn it over to our co-chairs, Mary George and Ray Gibbons.

Raymond Gibbons: Hi, this is Ray Gibbons. Welcome everybody. Reva, do we want to take a quick roll call of who we have so everybody knows who else is on the call?

Reva Winkler: I have a list, but - I have a list.

Raymond Gibbons: Okay, why don't you read the list?

Reva Winkler: I will. Ray, Mary George, Leslie Cho, Dianne Jewell, Dana King, Tom Kottke, George Philipedes, Mark Sanz, Christine Stearns, Kathy Szumanski and Suma Thomas. Is there anybody I didn't get?

Roger Snow: Roger Snow.

Reva Winkler: Hi, Roger, welcome.

Roger Snow: Thank you.

Raymond Gibbons: Good. Well thank you, everybody, for taking time out of Friday afternoon before Labor Day weekend for this task. We do have a formidable task that will be a challenge, which is to give adequate attention to the whole range of comments that were received on our draft report.

I think that it is highly unlikely that time is going to permit us to get to the three new measures, which are the second part of the official agenda. And it is very likely that we will require the other call that we have scheduled on September 12 for that purpose.

Please note that in - when the staff prepared this agenda, at that point I think we had something in the 60-odd comment realm. Within the last 24 hours before the deadline, a great number of additional comments came in so that we now have 200-plus comments. So that is why I think it's unlikely we will complete the agenda as originally outlined.

The materials that you need as committee members to participate in this call were all sent around again today in an email that was timed at 13:38 from Kathryn Streeter.

In addition to the agenda there is a memo that was prepared by the staff which summarizes the main categories of the comments, an actual spreadsheet, which is the Excel document of all the

comments, a separate letter from the ACCF, AHA, AMA, PCPI group, and then the documents required for the three new measures, number 229, 230, and 330.

Now those of you who have just plenty of room on your desk may also find it useful if you have it available to refer to our earlier draft document which is 90-plus pages. But the staff are going to help us as needed to refer back to that draft document in response to the comments and to the actual submissions if we need to.

So those are what you need to participate. The order in which we're going to do things are to start out with the document that says, (MMSC) Comments. And as needed we are going to refer to the spreadsheet, particularly for replies from the measure developers and then get to the ACCF, AHA, AMA document.

For those who are listening from the Yale Group we apologize that we're unlikely to get to measure 229, 230 and 330, but we want those of you who are here to help us respond to the comments came in on the other members - on the other measures that involve the Yale Group.

And we want to make sure that when we do finally get to 229, 230 and 330, that we give them adequate time since they are obviously very important and in response to one of the concerns expressed in the very first meeting of this committee.

The timeline for this call is going to be quite firm. So for those of you who are worried about getting away for the weekend, you are going to get away. We're not going to keep you all evening on this call.

At 5:45 Eastern, 4:45 Central, we're going to open up to public comments and then sum up in the last five minutes before we adjourn at 6:00 pm Eastern, 5:00 pm Central, and oh yes, for Mark, 4:00 pm Mountain Time.

Are there questions from anybody regarding the materials or the timeline of what we're doing today, before we start? Have I put everybody to sleep already?

Reva Winkler: No, you were very clear.

Raymond Gibbons: Okay. Well and just to reassure everybody you will not have to listen to me drone on for two hours. Mary and I are going to tag-team this a bit in terms of the various comments and sort of categories of comments that were received.

So we're going to begin with that (MMSC) Comments document dated August 24, where Reva has attempted to summarize for us, with Kathryn's help, the different categories of comments, all 215 of them that were received regarding our draft report.

And the first category we're going to start out with is the heading on Page 1, Assessment Measures.

And just to make sure everybody's in the right place, this is the paragraph that says, "Several commenters have identified the following measures as check-the-box measures that are inadequate to advance patient care because they merely ask whether something has been assessed and don't consider appropriate care and desired results."

And the first comment is regarding Measure 1524, which was Assessment of Thromboembolic Risk Factors CHADS2. This was a measure we overwhelming approved and you may recall it's one of the measures where we said the title was misleading and urged them to get CHADS2 in the title.

So the comment came back, "The measure should report the patient's actual CHADS2 score. This would allow tracking of stroke risk over time as well as promote accountability. The committee states this measure meets the usability test because it improves physician documentation. This is a basic competency of care and is insufficient to merit endorsement in this area."

Thoughts about this comment?

Tom Kottke: Tom Kottke here. I mean, I would agree that, you know, assessing stroke risk is a basic competency, but there are lacks of competency out there. And I think actually, you know, documenting that there was an assessment is an advance. I disagree with the commenter that this doesn't do anything to drive the quality of care.

Mark Sanz: It's Mark Sanz, can I make a comment?

Raymond Gibbons: Yes absolutely, Mark.

Mark Sanz: The commenter who said this, the last line is pertinent to a lot of what we discussed. I mean New York Heart Association class somebody wanted - I remember there was some study in Australia in a family practice group that was simply documentation of some part of clinical care that we didn't think was all that important.

I guess - are we supposed to separate measures that don't do something to a patient by procedure or drug or something else, from measures that are simply documenting what otherwise should be part of a basic history and physical for a given diagnosis?

So, you know, anybody who has A-fib should get a CHADS score. I mean that's pretty obvious. Does that have to be a measure or not? If not, there are a lot of things we discuss that probably don't deserve becoming a measure.

Reva Winkler: Mark, this is Reva. You know, this is a kind of conversation that goes on throughout all of NQF's projects, not just to this one. I think a couple of things.

These comments are again what we see. Folks are looking - a lot of our stakeholders are looking for very robust measures that really get into and touch the patient.

I think from what is NQF looking for, I always want to go back to measure evaluation criteria and I suppose for this one the best thing to ask yourself is, "Is there evidence that doing that assessment without regard to what may happen afterward, is related to patient outcome?"

Raymond Gibbons: Yes, and I would just chime in and point out that when we went through this measure in detail, we voted unanimously that it was important from a scientific acceptability standpoint we voted pretty strongly, 12 completely, 6 partially. Similar vote for usability.

We were a little bit more mixed on feasibility, but in the end in terms of voting for endorsement, you know, we voted 17 to 3 that this was worth doing.

And I think, reflecting what Tom said at the outset, we felt that there was sufficient link to evidence to guidelines and that this isn't being consistently done.

Roger Snow: And that's an important fact, that last one, because one of the reasons for having a measure is to call attention to a facet of care and, you know, this is something that is important. We all agree on that.

And it's not being - if it were, you know, at the 90% level only time would be able to tell us whether it was worth going for the other 10%. But it's not and it's inconsistent presently and so I think that that justifies having a measure.

Raymond Gibbons: Are there any contrary opinions from the committee members regarding this one?

Christine Stearns: This is Christine, I just have a question which is that ((inaudible)).

Raymond Gibbons: Sorry, I can't hear you. Can you speak more directly into the phone or whatever you're using?

Christine Stearns: This is sort of the best you're going to get.

Raymond Gibbons: Okay.

Christine Stearns: My question is, I think the suggestion from one of the commenter was to record the score. Is that possible? Is that being done? Is that feasible? Could someone comment on that?

Raymond Gibbons: Well that's more, I think, a question for the measure developer. It's - the measure is specifically looking to see whether the five components of the score are recorded.

Reva Winkler: Which would imply that the score is there.

Raymond Gibbons: Right.

Mary George: This is Mary and I just pulled up the performance rates on this measure that the developer submitted. Two thousand nine it was 70%. Two thousand ten, 58%. Clearly there's room for improvement.

- Tom Kottke: This is Tom Kottke. But does this mean that CHADS2 is the only language that can be, you know, since the language that can be spoken? And if they use some other, you know, CHA2DS2-VASc or, you know, does that mean that they don't meet this criteria? Are we being overly narrow with this, what is acceptable as a assessment of thromboembolic risk?
- Raymond Gibbons: All this measure actually specifies is that they consider those five things in the CHADS score, prior stroke, advanced stage, hypertension, diabetes and heart failure or impaired LV systolic function. That's the measure.
- Tom Kottke: Then I would support it as it is. I think to force people to calculate a score is too constraining.
- Raymond Gibbons: Okay, I think we're going to have to move on in the interest of time. But, you know, the next two are in the same spirit.

Zero zero seven nine, Heart Failure, LV Ejection Fraction Assessment in the Outpatient Setting. This measure won't improve patient care. The goal of the measure should report the patient's health status so the clinicians and others can determine whether the patient is improving over time.

Same spirit, that is, do we feel that measuring the ejection fraction in somebody with heart failure is important enough and is not being done consistently enough that it's worth the measure?

Andrea Russo: Yes, this is Andrea Russo. I'm sorry I joined late, but I think it's an important measure because it has ramifications not just in terms of treatment of heart failure, but in terms of risks for setting cardiac arrest and assessment for that. So if we don't measure it we can't get to the next step. So it, you know, could it be, you know, it's obviously an important measure but should it be, you know, a separate measure or only be used as a combined, you know, composite measure that, you know, that would be, you know, something obviously for discussion?

Roger Snow: The other thing is there's several other measures that require this.

Tom Kottke: Tom again. The - and I don't know about other organizations, but when I talk to people about this, it's amazing the number of organizations that even have an electronic record that can not report ejection fraction in their patients.

And they - so I think this measure ought to be in there so that they can assess. Then further on, are they implementing ICD implantations appropriately? Are they, you know, ACE inhibitors, et cetera, et cetera. So I think the measure has value as written.

Raymond Gibbons: Yes.

Mary George: I'd agree.

Raymond Gibbons: Are there other, you know, other thoughts from committee members with respect to this concern that was expressed?

Roger Snow: I just want to say the concern is almost not appropriate in that the objector, I don't know who, it was the same person, although that rings like being the same person, he is saying look I want a different measure. Well that other measure may be a fine measure to have, but that doesn't exclude the validity of these.

Raymond Gibbons: Good point. I think that's - yes, and that's what this is about, is this valid? And let's move on to the next one in the same category.

Evaluating - Evaluation of LV Systolic Function. This is the - one of the ones we put in reserve status. We don't agree with the committee's decision to maintain endorsement and place in reserve status. The measure should be removed altogether.

Now I want to remind everybody that when we discuss these and had this whole philosophic discussion about reserve status, we were trying to balance the notion of maintaining measures with the concern over if we took them away completely then things might get worse over time.

So that was the - this was a compromise between not having too many active measures and losing sight of important things that could potentially deteriorate.

So, this comment seems to be saying, well just take it off the list. And I think we as a group, came to a sort of consensus that we weren't comfortable just taking it off the list.

So I think we vetted this pretty well in our discussions, but I'm open to any additional thoughts about this comment.

Dianne Jewell: I agree.

Mark Sanz: I agree

Roger Snow: I agree.

Tom Kottke: Agree.

Mary George: Agree.

Dana King: Agree.

George Philipedes: Agree.

Leslie Cho: Yes.

Andrea Russo: Agree.

Raymond Gibbons: All right. I think we have a good sense on that one, because we did spend a lot of time on it and I think had a good meeting of the minds about it.

So now to move on to the final sort of action item for this category, considering these comments does the committee wish to reconsider the recommendation of these three measures?

Dianne Jewell: And this is Dianne and I would vote no, but I would also just want to offer maybe one more comment about the CHADS2 measure.

Raymond Gibbons: Yes.

Dianne Jewell: And that is that I think it would be helpful for external viewers, readers, whatever, to understand that this is also a measure that has five components to it. And so, you know, this notion of it's a checkbox versus it's a score or it's an outcome, we're going to wrestle with that in perpetuity I think.

But it's important to recognize that the more complex checkbox measures are worth thinking about in their own right because of the number of steps or components required. Raymond Gibbons: Yes, I think that's an excellent point. Staff, can we in responding on this one, incorporate that somehow?

Reva Winkler: Yes. I'm trying to capture all of your thoughts so that we can provide a complete response to the comments.

Raymond Gibbons: All right. So we've had one person say that we don't want to reconsider. Is - any other thoughts or people want to express their opinions to - let's put it this way. Is there anyone who feels we should reconsider our recommendation of these three measures?

Okay. Hearing none I'm going to assume that everybody else feels they're comfortable with what we decided on these three and the whole notion of having measures that actually just record whether things were documented in the record or measured, rather than outcomes, and that we will convey that in our response to this series of comments.

Staff, do we need anything else in this section?

Reva Winkler: We're good.

Raymond Gibbons: All right. Let's move on to the next one which we're - is a - the section labeled Broad Exclusions. And I think people need to read this a little bit. Several - so I'm going to read it to you.

"Several commenters object to the overly broad exclusions for patient reasons, system reasons and medical reasons in a variety of measures." All of which are the PCPI measures listed in bold. And they say, "Exclusions should always be evidence-based, highly specific and explicitly defined. This ensures that removal of a patient is appropriate and the exact nature of the removal will be clear in an audit. Having rigorous parameters will also result in more informative data."

And, you know, at least I for one think that we looked at these exclusions carefully. The data had already been very well vetted in the AMA PCPI process before they came forward.

I think for me they reflect the clinical reality of the complexity of, you know, patient reasons and medical reasons that do exist and it strikes me that this comment is purely from a measurement perspective without enough of the clinical reality component.

But I want everybody else to chime in and see what they think.

Roger Snow: Ray, I agree with you. I think what - they're basically turning things around and measures have come from the perspective that people are only included when there's evidence that the measure affects their outcome.

And here they're saying you need to include everybody unless there's evidence that you ought to exclude them. And I think this is just too broad and it doesn't reflect the clinical realities that is out there and that the measure process risks really losing its validity if you start throwing everybody in without consideration of the clinical context.

Mary George: This is Mary and I really agree with that. And I think, you know, one thing about these measures that we have to realize that they are at clinicians at all the patient levels and this data comes largely from registries and a different situation.

Reva Winkler: Yes, no. I would agree too. And I think if you start to - you know, say you can't use those exclusions, perhaps the sicker patients sometimes will - people with renal insufficiency may have some, you know, patient reasons why they can't get (a central).

So you start to do that you may even, you know, it would affect, you know, it may bias the results. So I think, you know, they have to have good reasons and they're good. They were well written from the ones - the details I recall on a couple, three of them at least. So I would agree totally what you said.

Roger Snow: I think we spent as much time talking about exclusions generally as any other facet and kept coming back to the recognition that these things have to work in the real world.

And remembering that different people use measures in different ways for different purposes. And some people who take a very narrow view of it do so because they want that measure to work for them for what they're doing and we're not going to please everybody.

- Raymond Gibbons: Well I hope you were recording that one from Roger. That's almost perfect from my standpoint. Anybody else want to chime in on this? I do think we paid a fair bit of attention to exclusions and at least for the these this set of measures, I think we felt strongly they were well done. And somehow or other I think we'll have to reflect that back in our comments.
- Reva Winkler: Just so everybody knows, we're comments will be put into the spreadsheet, but they also will be included in the next iteration of the report where we include the comments and your responses.
- Raymond Gibbons: So I think the themes that people all struck their we discussed this, they reflect the clinical reality. We recognize that they might, you know, that people using measures for different purposes might object.

But we're comfortable when we talk about doing physician and patient-level measures that they have to have flexibility in the exclusions. And I'll depend on the staff to put that in more articulate language

Reva Winkler: I'll do my best.

- Raymond Gibbons: Okay. I think we're getting in the flow of things here and I encourage everybody to continue to participate as you're doing. I think we're doing well and Mary's going to come take over the competing measures block.
- Mary George: All right. And the first comment under competing measures, the commenter asked whether the draft guidance on best-in-class was used to assist the committee as several measures in the project appear to be competing. And I know we had a great deal of discussion about competing as well as individual and composite measures and that issue that we reviewed.

The first set of competing measures 67 and 68, 67 is at the coronary artery disease antiplatelet therapy at the provider level and 68, the NCQA measure for antiplatelet therapy with ischemic vascular disease.

So these two measures represent a broad population and a narrow population. One is at the provider level. One is at the healthcare level.

Reva Winkler: Actually, Mary, let me just correct you. The NCQA measure is a clinician-level measure.

Mary George: Oh okay. All right.

Reva Winkler: This is not their health plan measure.

Mary George: Okay. So we do have a difference in the patient population. First comment as the Steering Committee notes, the measure overlaps with NCQA's measure of the use which is in wide use in the private sector to promote alignment with the private sector.

We recommend instead endorsing 67 to broaden the application. Sixty-eight is actually the broader measure. The committee want to react to that comment?

Roger Snow: Mary could you review why we chose one over the other?

- Reva Winkler: You actually didn't choose one over the other. We went this was the first group that I think really had to struggle. And in fact, you were the first ones to look at the guidance on best-inclass. And it's not a simple thing to do. And you struggled with this and ultimately did not choose between them.
- Mary George: We agreed to maintain endorsement for both. On Measure 67 the overall recommendation was 12 to 3 and for 68 it was 11 to 4. So they were very, very close, but we did recommend endorsing both of them.
- Female: Excuse refresh reply for specific so we did it for a reason. It was the specific groups that this is more general vascular disease on 68. Is that correct? Or what were the other differences? I don't remember.
- Reva Winkler: The difference is in population. Sixty-eight is broader. The IVD includes coronary artery disease, peripheral artery disease and carotid artery disease.

Female: Okay.

Raymond Gibbons: And I - correct me, Reva, if I'm wrong, but I think these are, you know, they're already in use and they're used in different data sets and data collection systems. Isn't that right?

Reva Winkler: I believe you're right.

Mary George: Yes.

- Female: And they included the same drugs? Any antiplatelet agent was for both of them? Or were there different agents...?
- Reva Winkler: There are different agents. NCQA measure was about six different agents and the PCPI measure actually only lists aspirin and clopidogrel.
- Female: So that alone is a pretty big difference because some of the other agents that may be listed may not be proven or evidence-based in 67. So it sounds to me like we still need both as what we decided initially.
- Mary George: And I think the second comment gets to the point of harmonization and, Reva, I think you have some information on the major developers working to harmonize.
- Reva Winkler: Well, yes. I mean, harmonization, when we've got so many measures is very challenging. And at this point, when the measures are already developed and in use, is really difficult and so we've been having conversations sort of building.

My first effort of harmonization was to talk yesterday actually with the folks from NCQA and the folks from Minnesota Community Measurement because they have the similar denominator population with very minor differences in the codes and very minor differences in the numerator.

So we're starting there and then we'll keep branching out. But this is not an easy process in any way.

Dianne Jewell: And this is Dianne. I remember that there were some measures that we were evaluating as competing measures that were also different in terms of settings in which the data were collected. I don't remember if these two - if that issue applied to these two.

Reva Winkler: These two are clinician-level managers.

Dianne Jewell: Right, but the settings, were they outpatient ...?

Reva Winkler: Outpatient.

- Dianne Jewell: They both were outpatient. Okay. So I remember there were some that were I thought nursing home or institutional.
- Reva Winkler: I think you're right. I think that some of them do include explicitly, you know, long-term care settings.

Dianne Jewell: Right. Okay.

Mary George: Okay. And the other - any other comments on the antiplatelet measures?

Mark Sanz: Well this is Mark Sanz. As someone who uses a lot of antiplatelet drugs, I just find this frustrating that we have multiple measures that we have to report to.

And while there may be historical difficulties with changing the inclusion/exclusion criteria for something that's been around a while, medicine advances, things change and I just don't think it's

fair to ask private institutions to have to respond to multiple measures asking for 95% of the same thing.

I think we need to pick one and ask them to - or ask them both to come back and say we want one only that deals with antiplatelet measures.

Female: Can I ask a question? To the other drugs, other than aspirin and clopidogrel, so is it just that the data - there may be different data with peripheral vascular disease that other drugs may be - they're different - potentially different evidence-based medicine recommendations.

So maybe for vascular disease, I don't know whatever drugs were included there, may not be appropriate to include in patients who have coronary disease.

So there may be, since the drugs themselves are different, I think before we decide to make it all one, we have to make sure we're treating the disease that's, you know, evidence that's in the appropriate disease category.

Roger Snow: I don't disagree, but that could be done in an appropriately designed measure. And already Ticagrelor's going to be available within months. You know, we have Effient, we have Plavix.

The number of drugs is going to change. It's just designing the measure to allow for FDAapproved drugs in this category.

Mary George: I guess the question would be how would we - so what is the process to design a new measure that incorporates both? Do the two developers...?

- Reva Winkler: From a Steering Committee perspective, what you can do is make recommendations back to the measure developers. They will, you know, either do it or not, but the Steering Committee itself is not a measure developer.
- Mary George: So they would just contact each other to do it, or how would you said they would have to come up with one measure from...
- Reva Winkler: Depending on what your recommendation is we would try to facilitate it as much as possible.

Raymond Gibbons: So - but, Reva, help me, am I correct that NCQA it's an administrative database?

Reva Winkler: Not necessarily, because these are the clinician-level measures. These measures actually have been re-tooled for EHRs and these are the measures they use in their physician recognition program.

Raymond Gibbons: Okay, can they - but they don't generally permit accounting for exclusions very well.

- Reva Winkler: They, you know, just as any they have exclusions or not, but they don't tend to have they don't have those same exclusion categories. Let me go up and I'll pull up scrolling. No, there are no denominator exclusions.
- Raymond Gibbons: So for example, 67 allows for exclusion such as Coumadin use and 68 does not and I think that's one of the differences when you're asking about drugs that you see 68 includes Coumadin as therapy because they don't have a way to exclude patients on Coumadin from a denominator being considered for antiplatelet therapy.

I remember when we discussed this it's really dependent on the data set and the methodology as to how these have both evolved in different ways.

Dianne Jewell: So this is Dianne and I, you know, as someone who isn't - as a professional who's not responsible for reporting these measures, I don't have a sense enough of the pain of reporting versus the current recognition that these measures are different.

And so it, you know, on its face to me it seems that because they're different enough they both they're not competing enough. But having said that I'm mindful of what Mark said a minute ago.

So I would need a little more help understanding what the tradeoff is there. I'm inclined to stick with our original decision otherwise.

Mary George: Well let's move on to 75 and 74. Again these are two lipid profile measures, one NCQA, one PCPI. The NCQA - the comment here is that it includes a complete lipid profile, while the PCPI measure does not, it only looks at LDL I believe.

And it's unclear whether the commenter wonders whether that complete lipid profile is necessary. And the second comment again dealing with the broad exclusions that we've already discussed for some of the other measures. Any comments on this? We did recommend both of these measures.

Christine Stearns: This is Christine. You know, I keep coming back to some of the perspective of the consumer that two measures that are so close, I mean depending on how these are pulled out and used, it would be great if we could be able to make - to narrow it down to just one.

They would to me seem like they're so similar, you know, from a consumer trying to look for quality information. If there was some way that we could get the measure developers to harmonize.

- Reva Winkler: Again we have the issue of a narrower population with CAD and a broader population with IVD.
- Christine Stearns: I hear what you're and I I hear what you're saying. I think I've got consumer I don't
  I respect what you're saying. I don't think I entirely understand. You know, I think that from a consumer's perspective having just one.
- Mark Sanz: Let me give you, this is Mark Sanz, let me give you an example of what how this causes issues. So I'm part of the Providence Healthcare System in Northwestern U.S. and we're trying to create best practice alerts in a new epic implementation for 30 hospitals and some of these alerts I'm trying to get harmonized to NQF measures.

How do you do this with these two lipid measures? Are we going to have to create separate alerts for each measure? So as a example for 75 we have to create an alert where we look for all forms of ischemic vascular disease that only a full lipid profile instead of an LDL, and then another alert for the other one?

And what happens when they cross over, because we do a full lipid profile for one but only an LDL necessarily for the other. I mean this is a nightmare.

Leslie Cho: It's Leslie Cho. Does anyone really order just LDL alone? I mean I feel like when people order a lipid panel it's a full panel and I'm not so sure about, you know, I think the whole point of this measure is to make sure that patients with coronary artery disease or peripheral vascular disease have their LDLs be less than 100.

The secondary goal is non-HDL, but I mean I think the primary goal of this measure is kind of quality that you get those patients who are at high risk less than 100, at least.

Female: Yes. I don't agree. This seems like one that could be more easily - harmonized or become a single measure if the goals are the same and it's, you know, the disease processes, I assume that, again the evidence-based part of this for other vascular diseases other than coronary disease, I'm assuming it's, you know, or somewhat equally as strong.

If - and why can't we make that one one measure? And you're right. Everyone orders the panel. I don't think we order individual HDL LDL all the time, you know, frequently. I think that's rare.

- Suma Thomas: This is Suma. I also agree that we should consider making this one measure and seeing if the developers could combine it because I agree with all the comments, including Mark's, that the difficulty to clinicians would be great and that we can't have all these measures, we're...
- Reva Winkler: Okay. I need to have a better understanding what you mean by combine because the denominator of 74 is already a subset of 75 and the numerators are both lipid LDL less than 100. What part of is it I'm not quite understanding combined.
- Suma Thomas: Well I think, as other people have pointed out, that we should have most of us do order a complete lipid profile and not just LDL.
- Mary George: And the important thing being, you know, lipid control is the important thing for both, no matter what type of effort, and so to combine all vascular disease including chronic stable coronary disease with an LDL control of, you know, less than 100 as one measure.

Reva Winkler: Well, isn't that what 75 is?

Female: You know, the exclusion, you know, I don't have all the specifics under - was there a reason why wouldn't we have just recommended that initially? That's what I would - there must have been something else that's different in there. Exclusions, or...?

Reva Winkler: Exclusions are the same differences. Meaning that there were no exclusions in the NCQA.

Mary George: Let me - I'll...

Raymond Gibbons: Right. This is Ray. As I recall, again, this is one of the bigger differences between these two, was for example, statin and tolerance is not an allowable exclusion under the NCQA.

Mary George: So that would be, you know, clinically that's a really important thing. And was that an administrative or they both were clinical measures?

Reva Winkler: They're both clinical - they're all clinician-level managers.

Christine Stearns: So if we were to chose that as the measure, can we still go back to the - make a recommendation to the developer that those exclusions need to be refined?

Reva Winkler: We certainly can make that recommendation. You bet.

Female: Or the other way, if you could - what if - and again I'd have to look at the details in there, but if you just took 74, because do we really care - well maybe we care that they ordered a complete lipid panel, I'm not sure.

But it's just expanding the population from chronic stable coronary disease to all, you know, vascular disease. So maybe that's the easier one if it has the exclusions in it, because Mark's right.

You know, it's a good way to look at it. It must be a nightmare. Can you imagine all these pop-ups on your screen and...

Mary George: (Production) item really directs us to choose between the competing measures to provide a compelling rationale for endorsing two similar measures and we do have the option, as Reva said, to go back to the developers and recommend harmonization.

Christine Stearns: So if I understand, and here's my layperson's language, the two measures are identical but for the exclusion.

Reva Winkler: No. They are different in terms of the patient population. Seventy-five includes more patients.

Raymond Gibbons: Right.

Christine Stearns: In which - I would think we would prefer. So that what we would need to do is choose and then go back to one of the developers and either suggest the expansion of the patient population or suggest an adjustment to the exclusion.

Reva Winkler: Yes.

Christine Stearns: If we were to feel that that was important for this criteria. That we would - the developer might or might not opt to accept our recommendation. So ultimately our choice is the

population being included or whether or not these exclusions exist is the choice that we're having to make.

Mary George: I think one of the issues with the broad exclusions, again, is I think one dataset is not able to collect those exclusions. Is that correct?

Reva Winkler: I'm not sure that that's true when you're looking at clinician-level measures. NCQA's data system for that in the measure are medical record EHR.

Mary George: Okay.

Reva Winkler: Paper medical record, flow sheet, electronic clinical data, electronic record, you know.

Dianne Jewell: So it's possible they've just chosen not to specify the measure with exclusion as opposed to we can't identify exclusions, right? I mean, theoretically at least, they could change the specification to include exclusions.

Tom Kottke: Tom Kottke here. I think, at least for me, some of the problem is that it's, you know, would really like to see IVD from 75 but say okay, you know, just an LDL is fine. I mean the - if you want to get a direct LDL in a non-fasting patient, you know, fine.

And so it's, you know, some of one measure is attractive, while some of the other measure is more attractive than - and so that's - I think that's one stumbling point that we're having is that neither measure is clearly superior to the other.

Both have shortcomings and they - each has parts that are somewhat more attractive than the other measure.

Mary George: So I think one thing that we should probably take our pulse-check on is whether or we want to choose between the competing measures.

Roger Snow: Well aren't we supposed to?

Mary George: We - I think we also have - we can provide a rationale for not doing that and we've heard a lot of comments about going back to the major developers and requesting harmonization.

Raymond Gibbons: You know, to me these measures don't really compete, they overlap, but they don't really compete. A competing measure would be one says in patients with coronary disease LDL goal ought to be 70, and the other one says no it ought to be 100.

Those would be truly competing measures. These really meet the criteria of overlapping measures and I think we could ask them to go back and, you know, clean them up and choose the best from each one and come up with a single measure

Christine Stearns: I would say, my two cents ((inaudible)) in the end we just end up with one measure in this area. So I guess that means I would say we need to choose.

Mark Sanz: Reva, this is Mark Sanz. We are not measure developers. Are we still allowed to say what an optimal measure would contain?

Reva Winkler: Sure. You can make recommendations, suggestions, whatever. Things that you feel would make the measure better.

Mary George: If we go back to the antiplatelet measure is there a sense that most of you would prefer to go back and ask the developers to harmonize these into a single measure or rather chose between the two existing?

- Roger Snow: I mean what I'd like to see basically IVD and LDL less than 100. That's it, simple. Then maybe you throw in some exclusions like statin and tolerance.
- Dianne Jewell: This is Dianne. I guess I have a question for staff. If we were to do if we were to select say we're going to endorse Measure 75 and we want - we'll make our recommendations about harmonization, could we also put in reserve status Measure 74 so that we're not tossing it all together, but...

Reva Winkler: Remember reserve status is for topped-out measures.

Dianne Jewell: Oh, for topped-out measures. Okay. That I did not remember. Okay thank you.

Female: It's almost hard without seeing the specifics. I mean they're, again, I thought we had, you know, I'm sure we went through a lot of detail, so I'm wondering is there anyway to just pull that up? I was just trying to look on the Web site but, is there anyway to pull up...?

Reva Winkler: What is it you want to pull up?

Female: Well there - it's not only the difference, it's the difference in other - on the specifications of the measure. Is it - there's got to be - there was some reason - we reviewed these, right?

So there - if we're going to make recommendations is there one that's closer the ideal right now? So the population should be the overall, so they both have to make it more inclusive to the populations, that's pretty clear.

But in the absence of exclusions that doesn't sound good. But I don't know how many exclusions are in each of them. But I guess one doesn't have exclusion for intolerance to drug. Is that right?

Reva Winkler: NCQA's measure doesn't have any exclusion in its current form.

- Female: But how could you have no exclusions? So it seems to me that that's not real life. It's either or there's always exclusions to I mean what about allergy to the drug? Obviously that's a little unusual for this particular situation. Or patient refusal to take the medicine, you know, or...?
- Tom Kottke: That just lowers the bar. I mean for example in Heath Partners, our corporate goal for perfect vascular care at 60%. I mean it's not 100%, it's 60%. That allows for these kind of things without having to specify them.
- Female: But I have concerns about that because you may have certain areas of the country that they're going to get a lot more of that unless you correct for that later.

So there's, you know, you have an indigent population may not be able to afford it or may - so I'm not sure - I don't know, you know, that that's necessarily a good way, unless you're going to look at that after the fact and control for that.

But you don't want any consequences where people are going to not take care of people who are not going to take their medicines.

Raymond Gibbons: So, let me see if I can sort of synthesize things in a way that makes sense to people, because we are going to have to move ahead. We're at the one hour mark already and we have a number of other issues to go through.

And I think we had lengthy discussions about these competing measures or perceived competing measures. We're all I think a little rusty on all the details of those discussions.

But I think as Tom tried to summarize earlier, I recall that in some cases we thought there were good components of this one, good components of this one. Neither one of them was perfect and therefore clearly superior and that's why we chose to preserve both of them.

I think this discussion has made us all, my sense is, a bit uncomfortable that we're unable to recall all of those details and it was a difficult discussion as it was originally.

So if the committee wants to - we have to decide whether we're going to keep endorsing both of these, which is what we've done thus far in the draft report, whether we're comfortable with that.

If we're not comfortable with that and want to revisit the idea of choosing one or the other then I would suggest we do it on the next call, assigning the original reviewers et cetera to actually come back with all those details as part of the discussion.

Mary George: That sounds like a good ...

- Raymond Gibbons: So can I get a, if that's a reasonable sort of outcome, one way or the other, can I get a sense of everybody as to where they fall? Shall we come back to this on the September 12 call with more preparation for this two - these two pairings? Or are we comfortable with our current endorsement of both?
- Dianne Jewell: So this is Dianne. I would I guess reiterate my previous comment, unless it's clearer to me that the burden on the consumer or the provider is greater by having the presence of both, I'm inclined to keep both because they're still different enough and to make recommendations to the measure developers about the things we would like to see harmonized.
- Mark Sands: This is Mark Sands, I'd like to see us come back and try to give a optimal single measure to the developers.

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Raymond Gibbons: Okay, so revisit in the next call, other?

Thomas Kottke: Yes Tom here. I'm nearly the same as Mark, but I think after, you know, two hours of beating this around and two different - we're going to end up in the same place and I guess I would just encourage NCQA and PCPI and probably PCPI, you know, calling up NCQA and saying can we have a conference call and get together and come up with a single measure?

I don't think we're going to get any further, I'm happy to listen in for another hour, but I think we're going to be in exactly the same spot.

Raymond Gibbons: So you would stick with our decision and just encourage these two groups to work together?

Thomas Kottke: Yes.

Raymond Gibbons: Okay.

Thomas Kottke: And like Mark says, it's a real problem.

Raymond Gibbons: Others?

- Female: Yes, I guess I would agree with Mark for the first, the anti-platelet one, I think that they were very much - I think we covered some of the significant differences, but for the lipid one, I wonder if we can really create one? So I would go with, you know, revisiting at least the lipid one.
- Roger Snow: Yes, this is Roger Snow; I think that if I were going to pick one I'd probably pick 75. I'm content to have both and suggest to the developers that they try to harmonize.

Female: Yes, I mean, I think at the end of the day, even if we - I'm not opposed to revisiting at the next call, but even if we come up with criteria that we would identify as the optimal measure, we actually can't create the measure.

So we're still going to have decide, keep both or only pick one while we're waiting for the measure developers to decide what they want to do with our recommendations. So I'm kind of also thinking we're going to end up in the same place we are now.

- Reva Winkler: This is Reva; the one thing I can add is, given your conversation, I will see if, you know, our measure developer colleagues, be sure that they hear these things from you and recommendations. And I'll have a conversation with both to see where we might, you know, what our options might be and I'll be able to add that on the next call.
- Raymond Gibbons: Are there other thoughts about this? Let's see, I think there's been a modest majority in favor of standing with what we have and telling the developers to keep working on harmonizing.

But, Mark, that may not satisfy your desire to have a single measure come out of this process. And Andrea's concern about lipids in particular, that we might be able to do a better job with that one.

Mark Sands: I'll go along with the group, I can just tell you from somebody who's trying to do patient care, which is, I think, the highest goal of this group, all these different measures that dramatically overlap make it more difficult not less difficult to do optimal patient care at the frontline, but it's a group decision.

Raymond Gibbons: I haven't heard from some people, there's some thinkers still here, Suma?

Suma Thomas: Yes, I actually see what everyone's saying in terms of the possibility of revisiting, but then somebody made the point that if we revisit it we probably will come up with the same thing, that we probably need to have them just work together on a measure that would basically cover everything.

And so, I mean, I'm happy to agree to the bid, but I think we all agree that it would be nice to have one measure. And I don't know if we'll get much further, but if they need guidance, we can ask (Chloe) to provide it.

Raymond Gibbons: George, are you with us?

George Philippides: I got called away by a couple of pages, I'm actually with Mark on this one. I think that we could help a lot of people who are struggling to have a good quality metric for lipids by sitting it down and coming up with one good metric that can be used easily.

And I don't think that we're there yet and I don't know that we're that close, so I sort of would be in favor of putting this one aside and focusing just on it for a few minutes in the future. So I'm with Mark on this.

Raymond Gibbons: Okay, my sense of this is everybody recognizes how hard this is. I think Mark's made the most compelling argument that it's worth at least revisiting in light of these comments.

And, you know, unless there's objection I think we should try to do this as part of our September 12 call in a bit more detail and we'll have to constrain the time obviously, lest we, as Tom said, spend another hour discussing it.

But I do think it's a serious enough issue and remains something that we're all struggling with. I mean, the first few blocks here we just blew through and then we ran into this one and obviously are all struggling. So I think we should revisit, staff, if we can.

Female: Sure, we will. And we'll try and pull in all the input from the developers as well.

Raymond Gibbons: Okay, let's move on to the next block, composite measures, under optimal vascular care, several comments talk about all or none. As a measurement at a clinical/provider level, there's no apparent exclusion for patients and despite excellent clinical care, choose not to follow the best provider best practice recommendations.

I guess I would say that's true, but it's true for every provider. Importantly, includes in its components whether a patient achieves tobacco-free status, we agree. Currently the measure is identified for use at the level of the group or practice.

We urge the Steering Committee and measure developer to specify this measure at the level of the individual physician. Consumers choose individual physicians to be part of their care team. Existing NCQA measures that reflect many of the elements of the composite are specified at the individual clinician level.

Thoughts about this? Tom, I'm going to put you on the spot. You've heard all this discussion previously in the state of Minnesota.

Thomas Kottke: Yes, I mean, this generally works. I mean, sure I have patients that don't do what, you know, ((inaudible)) in, I mean they are...

Raymond Gibbons: Remember, Tom, this is being recorded for the public.

- Thomas Kottke: And yes, like I mentioned earlier in the conversation, we don't set the bar at 100% and measures have to be simple enough to be measurable. But on the other hand I think the composites are worth having because it really does outline, I mean, it does draw attention to the fact that a lot of our patients simply don't get that complete care that they deserve to get.
- Raymond Gibbons: Other comments on this one? I guess I would just offer the perspective that in terms of the group practice level versus the individual physician level, the last time I looked no one works 24/7. So whenever they're taking care of somebody there are other members of their group who are involved on an ongoing basis.

And by having it specified this way I think it actually encourages coordinated care within the group, which I think should be a quality goal. And it seems to have worked that way in the ten years of experience in the state of Minnesota where, you know, it's no longer individual physicians trying to figure out why one he or she is better or worse than their group, it's how does the group improve?

Male: Yes.

Female: I agree 100% with that.

- Male: So do I and I think these optimal care approaches are trying to approach the process of care totally, rather than single small elements. And it fits, I think, the medical home model and things like that.
- Raymond Gibbons: Okay, let's see, are there other comments in the committee about this one? And then there's another block of comments. One comment, a reporter recommended the composite measure 0076 only, while others supported recommending the individual components. Current

measure set may require harmonization as a number of questions have been raised by the Steering Committee requiring measure harmonization and best-in-class measures.

I mean, I think we voted, you know, where we could in support of the composite, but in some cases felt that it was worth preserving the individuals, and we did. And boy we vetted this, I think, pretty carefully. Does anybody think we need to revisit our discussion or change our recommendations of the composite measure?

Female: No.

Male: No.

Male: No.

Female: No.

Female: No.

Male: No.

Male: No.

Raymond Gibbons: Staff, do you need anything else?

Female: No, you're good.

Raymond Gibbons: All right, Mary, you want to take over topped out measures?
- Mary George: Topped out measures, a commenter supported our decision to place 142 and 160 in reserve status. Two other measures that the commenters identified as topped out and recommended that we place in reserve status as well. Their specific comments on those were that CMS is suspending data collection on both of those measures. And, I think, Reva, you've not...
- Reva Winkler: I'm trying to get CMS to verify it, but too many patients are a little bit limited. They also didn't respond to the comments as a measure developer as we'd ask the others, apparently there are some issues with the - we're between contracts with the contractor who manages these measures.

So I will keep trying to verify that, though certainly if you look at the final rule for value-based purchasing, CMS has indicated they aren't using these measures because they are topped out and they describe their way of determining that.

I would like to verify it with CMS that they are suspending data collection.

Andrea Russo: Do we know what the topped out measurements are for those? I mean, 132 I would definitely think is topped out and with the ACE-ARB, like over 98%? I mean I guess it was there, it must be really high obviously, but I wonder - and I'm a little surprised that that one's totally topped out, based on even some of the clinical trials don't get up real high.

Reva Winker: I don't ...

Thomas Kottke: Tom here, I would, I guess, make a subjunctive motion that if CMS indeed has topped them out that we top them out in the NQF.

Reva Winkler: Ray, you might...

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Dana King: This is Dana, I agree.

Mark Sands: I agree, Mark Sands.

Mary George: Was there any question on either of these in terms of disparities that we discussed?

- Reva Winkler: I've got the data for the 137 and 96% was the first quarter of 2010 national performance rate. I can't quickly get to that breakdown that they sent us, but although we do have the disparities ranged 94% for Native Americans, 94% for Hispanic, 94% for Asians, 95% for Whites, 95%...
- Andrea Russo: And that does have exclusions so shouldn't it be higher? I don't know, I mean, I guess we can make the global decision to follow CMS, but I don't know if that's good enough.
- Raymond Gibbons: This is Ray; I think we at least should recognize that some of what they're dealing with here is the payment issue rather than the quality issue. That is, they don't want all these to be very high because then they can't distinguish payment.

So they have to have a spread, as it were, for value-based purchasing. So it's a different priority in some cases then you might have from the standpoint of quality.

(Katie): This is (Katie), I also wanted to update you all, we did receive responses late last night and I did update that in the spreadsheet today, but it's probably hard to notice, it's just in two of the cells. And they said CMS is suspending data collection beginning with January 1, 2012 discharges.

Raymond Gibbons: For both of these.

(Katie): Yes.

Mary George: This is Mary; I'm just looking at the racial/ethnic breakdown on 132 and really does not appear to have any disparities in 132. Rates were in the 97% to 98% range.

Thomas Kottke: Tom here, you know, like with ACE, you know, at 95%, the organizations are going to tumble to the fact that they have to try different rather than try harder. That is, they institutionalize things like staining orders and alerts, and, you know, I think that we're not going to get much better by just having them measure this unless, you know, and so I think we ought to put them as topped out measures.

Mary George: Others agree, disagree with that?

Male: I agree.

Reva Winkler: Is there anybody who disagrees?

Andrea Russo: I guess I still have it - I'm wondering if the non - so right now a lot of the data collection's been voluntary. And I'm just thinking, because I'm out in practice and seeing patients coming in not on ACEs and ARBs, I'm wondering if we still have a little bit of bias in the sample that we're seeing. And if really the whole country in terms of people who have not been, you know, maybe the early highly-motivated groups for measurement, if we might see something.

So I guess I would - I don't totally disagree because I think 96 is pretty high, but overall I have to wonder - I would almost say, you know, give it another year when things are, you know, more people are measuring this and I just don't think...

Female: Andrea, this is the hospital discharge measure...

Andrea Russo: Oh it's hospital discharge, so there is a lot of that, so everyone is kind of measuring, most of the people are know, so we know that. So I don't know what the percentage is, if it includes all, shouldn't it be 98 if it's including - and I'm picking out a number out of hat, or if we say 95, or maybe we should be consistent, what is a topped out measure and is it really different for different measures or not?

If you have exclusions in it, maybe it shouldn't be, maybe over 95% is topped out. I'm not sure.

Male: This will be reserve, right? Not just no longer used.

Mary George: Correct, it would be placing them in reserve status.

- Thomas Kottke: And there are a lot of mechanisms that drive change in practice other than measurement. And I think that unless hospitals adopt systems to make sure that their patients get on these, making them measure it isn't going to improve care because there are going to be patients who slip through the cracks.
- Andrea Russo: And, you know, as I think of it now, maybe I'll change my opinion and say yes I agree or whatever, because it is acute MI, it is in the hospital measure and not cardiomyopathy measure. So I would be fine with that.

Reva Winkler: Is there agreement among the committee or do we need to do an offline vote?

Raymond Gibbons: Maybe we should ask it this way, is there any disagreement with regarding 132 and 137, because they've been topped out by CMS, going to reserve status? Does anybody object to that?

Female: No.

Male: No.

Female: No.

Female: No.

Male: No.

Reva Winkler: So I can say it was a unanimous of the people on the call? Okay, that's important.

Raymond Gibbons: All right, moving on, mortality measures are on Page 5 in the memo. Several comments were submitted regarding mortality measures. Two, two, nine, that's all-cause risk standardized mortality following heart failure. The first comment is quite difficult to understand, an all-cause mortality rate does not correlate well with AMI mortality.

I for one don't quite understand what that comment has to do with mortality after a heart failure hospitalization. I presume it was just pasted from somewhere and is not applicable. Agree with the mortality measure, but have two concerns.

First, the validity of the risk standardization adjustment. I think we went through in some detail the very careful methodology from the folks at Yale regarding this issue.

And second, whether it should be all-cause mortality or cardiovascular mortality. As a clinician I would strongly favor all-cause mortality because we can put people on drugs and make them hypotensive and they fall down the stairs, hit their head, and die.

And you're not going to capture that if you stick to cardiovascular mortality, particularly in heart failure, all sorts of things go wrong as a result of treatment or absence of treatment, it's got to be all-cause mortality.

And the third comment, given the advanced age and an increasing proportion of whom are in palliative care programs, many deaths cannot be considered a result of substandard care. This comment comes from somebody who didn't read the measure because patients who are on hospice programs on admission are excluded, they're not in the measure.

Male: Ray, I second your, you know, for hundreds of years cardiologists have figured out how to kill patients. You know, quinidine, lidocaine, you know, ya, ya, ya. And, you know, just look at ACCORD where, you know, overaggressive treatment of diabetes results in the death of patients and we need to all-cause mortality.

Reva Winkler: I agree on all the comments you made, Ray.

Thomas Kottke: I agree, but not for all those comments you made.

Male: I agree with Tom's comment.

Raymond Gibbons: All right, so on the next set is about 230. All-cause readmission loses its meaning as it does not provide information that could lead to performance improvement. But this is a comment about mortality rate, again, seems to have been entered in the wrong block.

And then the last sets are dealing with PCI mortality. We have concerns about the inclusion of measures that include a post-PCI mortality component. States which have a history of data collection have had to deal with cherry-picking. The measure as described, although risk

adjusted, would not adequately distinguish between urgent rescue procedure and the elective planned procedure.

And then there's a plea for waiting for changes in the CathPCI data set. Mark, you're the one interventionalist on this group, what do you think?

Mark Sands: Well, I'm not sure what changes they're talking about and unfortunately I can't remember the risk adjustment. You know, NCDR, if I remember right - and that's the ACC risk adjustment model that's now the national standard, so it is risk adjusted.

And in the NCDR is about six different, well eight different checks that you - well you have to pick one of eight different reasons for PCI, including STEMI, STEMI rescue, non-STEMI, high-risk unstable angina, I mean, it's all in there. So I'm not sure what they're getting at.

Raymond Gibbons: Okay, good, I wasn't either, and I thought maybe there was some subtlety here I was missing. You know, it's not perfect, but boy it's pretty good. And in terms of trying to, you know, improve care, I think it's the best we've got.

And then the last comment expresses concern about using registries, well, they're the best we've got.

Mark Sands: And I would say to this person, whoever it was, that when one state has a registry and the other one does not, such as when New York started theirs and then, you know, some of the really high-risk people went out of state, that's not really very true anymore. Almost every state in the country now uses NCDR, so certainly almost the big states.

So now that it's really truly a national database and repository, I think that's much, much less of an issue, this cherry-picking.

- Female: Yes, Mark, I think the other part of the comment was about the cost and data collection burden using registries also.
- Andrea Russo: And it's hard to argue that that's true, but, you know, that's the way it is and there's no other way to get the data unless we have people who can collect it. So I think most hospitals have, you know, hopefully resigned themselves to the fact that we need to have someone to do that who's a well-qualified person to get the right data. And that's the key, is to pay for the right person to get the accurate data.

Male: I don't know what to say about cost, every single measure here has cost.

- Mark Sands: Yes, and hospitals that have cathlabs are going to participate and they're not going to shutdown. And then the last sentence, NAHQ recommends measures of open sources. There are no data on these issues other than the NCDR, I mean, that's it.
- Raymond Gibbons: Okay, I really couldn't get excited about any of these comments. Does anybody feel that there is much we need to respond to here? And do we need to change any of our recommendations around these measures?

Male: No.

Female: No.

Male: No.

Raymond Gibbons: I think we have, you know, consistently our shortest discussion about these measures because they were very well-done.

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Male: Right.

Raymond Gibbons: And then contrast the comments, they're not well-done. Okay, do we need anything else, staff?

Female: No, that's fine.

Raymond Gibbons: All right, medication measures, you know, I for one wish we had (John) with us because a lot of the points and concerns that were raised in here were points that he raised in our discussions of these medication measures. Pairing prescription written with prescription filled, work with the developer to expand the measure...

Reva Winkler: This one the developer responded that because the data is collected in the registry, they don't collect and have no access to the data on what is dispensed.

Raymond Gibbons: Yes and then there's one about good evidence about regular blood pressure monitoring with regular interaction would help patients stay compliant. Regular visits to a medication management pharmacist may be helpful. I don't, you know, I don't see - there's nothing to disagree with there, but that's not relevant to our task here.

I mean, we would agree, I would agree with most of the comments, but they don't really require any change in what we've done about these measures.

Reva Winkler: Those messages are important enough to say something in the general body of the report?

Raymond Gibbons: Yes, well, and as I say, I wish - you could even email (John) because I'm sure he would specifically comment on what he thinks we should say because he was very, very articulate throughout our discussions about the limitations of some of what we were approving, but they were the best we had.

Reva Winkler: Okay, I can do that. I can run that through him.

Raymond Gibbons: Anybody else want to comment on these?

- Thomas Kottke: Well like that second bullet, I mean, they're absolutely right, but that's not part of the measure as proposed and, you know, it goes well-beyond and we don't make the measures, we just evaluate them.
- Mark Sands: This is Mark, the one thing that I think hits home here, and I remember us discussing, were FDA-approved drugs for these measures where the measure only comes up every three years, but drugs are constantly coming online. There was one I remember, the EP Group, we had this big argument about...

Andrea Russo: Dabigatran.

Mark Sands: Yes, whether Pradaxa should be allowed and it wasn't in the measure, but it was approved by the FDA. And I would think that we should add something. Our group seemed to feel, I remember at the time, that if the drug is FDA-approved for a given indication, it should automatically be added to the measure.

Raymond Gibbons: Sure, why not.

Andrea Russo: Again, Mark, that's a really good point, and in particular for the drug, the dabigatran that was - because there's going to be a lot more agents in that particular A-fib measure, so I think that's something to consider. And so I'm not sure how it went up, if it was measured - we're talking about the numerator, the denominator, or where it wound up, but it somehow needs to be incorporated in the measure.

Reva Winkler: Yes, and it has been.

Raymond Gibbons: It has been, but as, Andrea, as you point out, there's another one coming.

Male: Well there's one ...

Raymond Gibbons: Panel recommended approval, hasn't been approved yet, rivaroxaban.

Male: Right.

Female: Yes.

Reva Winkler: This is Reva, let me just - two things, it sounds like the committee supports including sort of a general comment recommendation about this two measures in general that address medications.

Raymond Gibbons: Right.

Reva Winkler: Okay, and then secondly, Mark, even though the measures only come up for intensive review every three years, they do come in to us for annual updates yearly, and we would expect to see that in the annual update.

Mark Sands: Great, thanks for that.

Raymond Gibbons: Okay, any other thoughts on that one? ICD measures, very narrow patient focus, it would be helpful for the developer to clarify the importance of so many exclusions. Basically, you know, these are all about the ICD patient group and I just think we felt they were important given the high-stakes in that group and the existing database to do it. Andrea, your thoughts?

- Andrea Russo: Yes, I would agree with that, you know, it's a select population, but it's a database, it's a robust database, and a way to collect it relatively easily. So I thought it was fine then I think it's fine now.
- Raymond Gibbons: Yes, and I think if we had the famous (cocky) calculation here it would be pretty impressive. I mean, these are, you know, these are sick folks.
- Reva Winkler: Just in terms of the comment from the measure developer on the denominator exclusions, basically it says, the exclusion that is measured at discharge status of deceased and contraindicated or blinded for the medication. These exclusions follow specifications used by PCPI and AHA for similar discharge medication measures.
- Male: So you don't have to put the medications in with the send them down to the morgue with the patient?

Raymond Gibbons: All right, staff, do we need any more on these?

Reva Winkler: That's fine.

Raymond Gibbons: Okay, measures not recommended, 282, angina without procedure. We ask the Steering Committee to re-evaluate, this measure helps to assess overuse of invasive procedures.

If you recall, we had, as the staff have noted here, quite a discussion about this one where we actually thought this would have unattended consequences, the reverse of what they were trying to do.

Roger Snow: Right, moreover, there was a very thoughtful paper written about this because a fairly precipitous change decrease in angina without procedure was shown to be due, not to any change in care quality, but due to the fact that people stopped using angina as a diagnosis and use coronary artery disease instead.

So the measure's ability to, I mean, we just had a big flaw in the measure, its ability to do what it was supposed to do, it was very marginal.

Raymond Gibbons: Right, thanks for reminding us of that, Roger. Staff, can you make sure we get that in our response?

Reva Winkler: Yes.

Raymond Gibbons: And likewise on 276, I know somebody raised this, but, you know, we thought the measure was flawed because people came in, not with a primary diagnosis of hypertension, but with something else.

Roger Snow: Yes.

Reva Winkler: Yes, we had a long discussion about that.

Raymond Gibbons: Yes, so I didn't see that we should spend any more time on it. Okay, congestive heart failure admission rate, while ED admissions, per se, are not measured, pressure from

medical center administration to reduce admission of such patients will directly impact ED throughput.

If adopted, one of the unintended consequences will be an increased burden on ED observation units. On the other hand it'll place pressure on hospitals to support outpatient CHF clinics where EDs can send patients. So one of those is a bad thing and one of those is a good thing.

Male: Ray, it sounds like they're worried about the pressures on them because people won't want a high heart failure admission rate. And so they'll just say we'll keep them in the ED forever, but really, I mean, I think that's stretching it.

Thomas Kottke: I would agree, don't you think this is kind of theoretical?

Raymond Gibbons: Yes, I don't think that consequence outweighs the benefit of the measure.

Andrea Russo: Right and I would hope it would be the latter part of the comment...

Raymond Gibbons: Right, the good consequence.

Andrea Russo: ...is that it would increase outpatient heart failure clinics and ways to treat these patients and have appropriate follow-up timing.

Male: I agree with Andrea.

Raymond Gibbons: Okay, I think we've settled that one. All right, Mary, do you want to get people to comment on the - we've got eight minutes on the ACCF, AHA, PCPI letter.

Mary George: Are we setting aside the 330?

- Reva Winkler: Yes, in fact, Mary, frankly these are comments that speak to the Yale CMS three measures that we're actually going to be discussing next time, the revised specifications, so it might be best to combine those conversations.
- Mary George: Okay, I hope all of you have had an opportunity to carefully read the letter that we received from the ACCF, AHA, PCPI group regarding their measures. And they wanted us to reconsider several of the measures that we previously discussed, and I think some of these we actually reconsidered a second time.

So I don't know if any of you have general comments or specific comments regarding any of the measures that they've specifically asked us to look at again.

- Male: You know, one expert in our group was (Syd Smith), has he commented on this to you, Ray, or anybody?
- Raymond Gibbons: We don't have (Syd) on the call. I can't remember whether he was on the earlier call when we reconsidered certainly the high blood pressure measure in some detail. We had a lengthy discussion about that one.
- Thomas Kottke: Tom Kottke here, we've been looking at harmonizing the PINNACLE Registry with (EPIC) and, I mean, there are things that our docs simply don't do. They don't do the Seattle Angina Questionnaire, they don't do a six-minute walk on every heart failure patient every time, and they aren't going to.

I think basically demanding that docs use a particular language in recording how their patients are doing does not necessarily mean that they patients are going to do better and it's also burdensome, can be burdensome on the patient, and also patients don't understand what, you know, stage C Class III heart failure is.

And for example, I send my notes right to the patient, I put it in English so they understand what I'm talking about. And so I think we were right in rejecting the heart failure measure that says we have to use the ACC, AHA classification.

Mary George: Just to refresh your memory on 77 and 65, our previous discussions on those we struggled with the importance test for both of those.

Andrea Russo: Is whether or not - and I actually think I'm pretty sure I voted to keep it, I don't remember the specifics between the two measures, 65 and 77, but I think we all are assuming that everyone's asking the specific questions, whether you call it New York Heart Association functional class or, you know, you ask someone how far can you walk before you get shortness of breath and specific symptoms?

And I think we're overestimating how good people are doing in that regard having, you know, been very much involved in a recognition program and having seen some of the data. So I think -I don't remember what data they presented about a gap in care, but I really believe there is this gap and I would not assume, unless someone shows us data that there's no gap, that we should just, you know, blow it off right now saying well everyone does it of course.

Again, not recalling the very specifics of the two measures, but I do recall that I had actually supported that. Now it may be more difficult to retrieve electronically from charts, it's a little bit - but if you're working on, you know, whether it be PINNACLE, (EPIC), or a specific EHR-based system you could, you know, obviously put that in as a standardized symptom assessment.

Female: Reva, can I just ask what was the vote on this particular measure because...

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Reva Winkler: I know, I'm trying to get to it.

Female: My recollection, I feel like the majority of the committee voted this measure down.

Mary George: On measure 77, the first vote on April 8 on the importance test was 8 to 12, and the revote on that was 6 to 9 in May.

Andrea Russo: So there was some controversy, obviously, within the group. And did they present any data regarding any gap measurement that's been done, I don't remember?

Male: My problem isn't, I mean, I'm not saying there's a lack of gap, my problem is that it's like the proposals up here in Minnesota where they're, you know, making English the official language.

I mean, you know, they're basically saying there's one way to record functional status in heart failure and one way to record it, you know, coronary disease and that's it. And if you don't record it that way you don't get credit, and I object to that.

Andrea Russo: And the other side of that, and I agree with that in some ways, but should there be some standardization? I know there was a document out looking at terminology and some standardization for terminology in cardiology, and might there be some benefit to standardize, you know, some of these things so they can be measured and quantified and we can make sure that we are doing the right thing? So I could see both sides of that argument.

Mary George: Reva, just a point of information, I know we're approaching our time for public comment.

Reva Winkler: Yes.

Mary George: Should we table this discussion for the September 12 call?

Reva Winkler: Sure, we can do that.

Raymond Gibbons: Yes, I think that's a good idea, Mary, to make sure that we do due diligence here given some of the varied comments that have been made thus far, we'll come back to this I think.

Mary George: I think to carefully respond to ...

- Raymond Gibbons: Yes, to be fair to the measure developers who are, you know, put this detailed response back to us.
- Andrea Russo: Could I make, or I could just bring it, I didn't have my laptop because I wasn't in the office today, but what helps me too is if we had a link to just get to the specific measures so we could just refresh our memories about the details and to try to it just would help. We remember a lot of it, but not all of the details, there's a lot.

Raymond Gibbons: Okay, we will try to do that. Now I think we have to open for public comment, Reva.

Reva Winkler: Right, (Gwenn), could you please - we want to do QA now.

Operator: Thank you. If you do have a question or comment at this time, you may press star 1 on your touch-tone phone. If you're using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Once again, that is star 1 if you do have a question, we'll pause for just a moment.

And we'll go first to (Samantha Tury).

(Samantha Tury): Hi, thank you, Dr. Gibbons, and Steering Committee, for allowing us this opportunity to speak. I wanted to go back if I could to your discussion regarding the competing lipid control measures.

We recognize that, based on the discussion today, you plan to revisit them given that you didn't have the measure details in front of you. However, I just wanted to highlight that the numerators for these measures, 74 and 75, are more significantly different than was discussed.

Although both measures look to identify patients whose LDL is controlled, the ACC, AHA, PCPI measure also includes a focus on a plan to manage patients whose LDL is not controlled, including at a minimum, the prescription of a statin.

So we would ask that you carefully consider these differences when you revisit the issue on your next call. Thank you.

Raymond Gibbons: Thank you for that comment.

Operator: We'll go next to (Joseph Drasda).

(Joseph Drasda): Hi, I've been listening throughout and I appreciate the discussion, which I think was very thorough and, Ray, I think all of the appropriate questions were being asked and addressed.

I do have - and I was part of writing the ACC, AHA, PCPI letter so I would commend that to your careful consideration because we spent a considerable amount of time putting together what we thought were some fairly cogent arguments and I'm not going to reiterate those at this point, I'll let the letter stand on its own.

I would like though to clarify one point regarding the statement about the requirement for a single way of reporting symptoms being required by the CAD measurement set, in fact, I don't believe that to be true. The measure just requires that symptoms are assessed and reported.

We may have given some examples like using SAC or using a CCS classification, et cetera, of a way of doing that, of reporting symptoms and activity, but those are not required.

There has to be some documentation though that symptoms were assessed and a level of activity. Those are the only things that are required by that particular measure.

Raymond Gibbons: Okay, thank you, (Joe). I think Tom was actually probably making that comment more about the heart failure measure than the chronic stable angina measure, but that I think your clarification is correct. And we will come back to the letter at the next meeting to give it more time.

Operator: I apologize; we'll go next to (Robert Bono).

(Robert Bono): This is Bob Bono. And I realize, Dr. Gibbons, you'll be addressing the letter in greater detail next time, but as (Joe Drasda) spoke up on the patient-centered measure for CAD, I'd like to do the same for heart failure.

It's not one particular quantitative or semi-quantitative method, but it's a strong recommendation that we try to become more quantitative in our assessment of patient symptoms.

And therefore, several examples of quantitative measures were indicated in our measure set, which can include, you know, a Kansas City Quality of Life, or just New York Heart Association functional class, or something, that would allow one to determine whether patients are improving or not over the course of time and then to develop a plan of action to try to get to improvement. We thought these measures are important because they really are much more patient-centered and we think moving in that direction is going to be important.

Raymond Gibbons: Thank you, (Bob).

Operator: And once again, that is star 1. We'll go next to (Theresa Larson).

(Theresa Larson): Hi, thank you for this call and the ability to participate. We have a comment regarding measure 0229, which is the heart failure all-cause mortality.

In relation to the comment that was previously reviewed regarding the patients who are placed in palliative care, although we understand that the measure does not include Hospice patients who are in a Hospice state upon admission, it doesn't currently clarify for public recording, or for information, those patients who are appropriately placed in a palliative care Hospice relationship upon discharge, which also does not necessarily mean that there is substandard care.

Raymond Gibbons: Okay, I think in the actual submission the developers didn't refer to that issue because of the concern that if the patient's, regardless of the care, is it's an outcome of care is a bad result leading to Hospice placement that that should be included in the measure and not simply excluded.

(Theresa Larson): I'm sorry, could you clarify. Are you stating that placing a patient into Hospice care is considered substandard care?

Raymond Gibbons: No, I specifically said that that was not the case, ma'am. I pointed out that if a patient in the course of their care ends up having to go to a Hospice, and wasn't in Hospice care at the

start, that that somehow needs to be included rather than excluded because it might have resulted from the care, not definitely, not a reflection of substandard care, but might.

And having been involved in, myself, in several such patients over the last year, I think they belong in the measure rather than outside the measure.

(Theresa Larson): Well we respectfully disagree, but we appreciate your consideration.

- Operator: And as a final reminder, that is star 1 if you do have a question or comment at this time. And there are no other questions at this time.
- Raymond Gibbons: Okay, so I would remind everybody of what we've sort of decided because it's going to make our challenge for the next call considerable. We're going to have to review the new measures, 229, 230, and 330, which were assigned to David, Tom, and me as primary reviewers.

Today's email did include the final report of the Yale group's testing that included both AMI and heart failure. It is sort of what the sequel to the original document from June 3 that only included MI that was distributed to everybody. And so we will have to go through those three things.

We will have to revisit the two competing paired measures on platelets and lipids. And we will have to revisit the detailed letter from the ACCS, AHA, and AMA, PCPI consortium. So that's going to be a challenge for our two-hour timeframe, but I think as long as everybody spends some time looking over the materials in advance, I think we'll try to do it. And probably, as a preliminary suggestion, try to do it a 1/3, a 1/3, a 1/3 across those three items.

Reva Winkler: Ray, this is Reva. I just want to remind you that there were comments on the 330 measure on the readmission for heart failure from AHA. And so I think those comments can be addressed while we're discussing the measure... Raymond Gibbons: Okay.

Reva Winkler: ...in its revised form so that we'll be sure to consider those issues that were raised there. In terms of - we'll pull together all of this in sort of a summary of what was discussed. We'll try and pull together the information that will help you with the discussion of the specific measures so that it can be readily at-hand.

And we'll also have conversations with the measure developers based on the initial discussions you had about the competing measures and see what their responses are. So we should have that to you early next week because our call is scheduled for September 12.

Male: What time is that call?

Reva Winkler: (Katie)?

(Katie): The call is also 4:00 to 6:00, same time as this one.

Raymond Gibbons: Are there any other comments or questions from the committee? Thank you, Reva, and for reminding me about the 330 comments. I was trying to make sure we at least began the discussion of the letter and they were, just for the rest of the committee, they were Page 8 of the memo, detailed comments about the readmission rate after heart failure, which we skipped over today.

Any other comments or questions from the committee members? Hope everybody can try to join us on the next call on September 12. Thank you for everybody's participation today. I thought we had some excellent discussion about the very difficult issues posed by all of the comments. Reva Winkler: Yes, this is Reva, thank you all very much. Hope you have a wonderful holiday weekend and you'll definitely be hearing from us.

Raymond Gibbons: Drive safely everybody wherever you're going.

Male: Have a nice weekend.

Raymond Gibbons: Bye.

Male: Bye-bye.

Female: Bye.

Raymond Gibbons: Bye-bye.

Male: Bye.

Operator: Thanks, everyone, that does conclude today's conference. We thank you for your participation.

END