NATIONAL QUALITY FORUM

Moderator: Cardiovascular Standing Committee
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OPERATOR: This is Conference #91115253.

Welcome, everyone. The webcast is about to begin. Please note today's call is being recorded. Please stand by.

Melissa Mariñelarena: Hi, everyone. Welcome. This is Melissa Mariñelarena, the Senior Director on the Cardiovascular Project Phase 4. I'd like to welcome everyone to our Post-Comment Call. I'd also like to welcome Tom Kottke, our Co-Chair, who's on the call today, who's going to co-facilitate.

(Crosstalk)

Melissa Mariñelarena: Mary George is unable to join us. So, at this moment, I'd like to turn this over to Tom so he can welcome the committee measure developers and anybody else who's joining us on the call.

Thomas Kottke: Thank you, Melissa. This is Tom Kottke. And welcome, everybody, and thank you for taking a brief period out of your Friday. And I hope that we have a very productive two hours. So I'll turn it back.

Melissa Mariñelarena: Thank you, Tom. So what – the purpose of the call today is to review and discuss the comments that we had. We only had six measures that went out for comments this time, and we only received four comments. So we're going to review the comments.

We have some proposed responses on behalf of the committee that staff proposed. So we'll ask the committee to approve those and then we'll move on to voting. If you recall, in the in-person meeting, we had two measures in which we didn't – one of them was Consensus Not Reached. So we will have to revote on that sub-criteria. And then we had another measure in which we deferred voting and asked the measure developer to provide some clarification on their measure. And we provided you with that information, and the measure developer is on the phone to provide any additional clarification if you need it as well.

So we are going to go ahead and get started with the -- go to the next slide -- with the comments. But before we do that, I'm going to turn it over to Wunmi, who all of you know, and she's going to do roll call. We're going to hopefully get quorum. There's 24 committee members. We don't have any conflicts on the two measures that we're going to be voting on, so we need a total of – a minimum of 16 members on the call today to obtain quorum.

So let me turn it over to Wunmi so she can take roll call.

Wunmi Isijola: And good afternoon, everyone. Again, we're trying to establish quorum. But before we get started, we just wanted to see who exactly is on the phone. So, when you hear your name, please let us know that you're on the phone.

Many of you or all of you should be dialed in to your personalized link. So if you have not received that, also do let us know. It is important that you are on the personalized link sent to you to ensure that you're able to vote. So I'll get started.

Brian Forrest?

Brian Forrest: I'm here. And Forrest is spelled with two Rs.

Wunmi Isijola: Perfect, OK. Thank you, Brian. Carol Allred?

Kurt Mahan?

Charles Mahan: I'm on the call.

Wunmi Isijola: Great. Thanks, Kurt. Daniel Waxman?

Daniel Waxman: Yes, I'm here.

Wunmi Isijola: Thank you. Liz DeLong?

Elizabeth DeLong: I'm here.

Wunmi Isijola: Great. Thank you. Ellen Hillegass?

Gary Puckrein?

Gary Puckrein: I'm here.

Wunmi Isijola: Thank you. Joel Marrs?

Kristi Mitchell?

Kumar Dharmarajan?

Kumar Dharmarajan: Here.

Wunmi Isijola: Thank you. Leslie Cho? And just if you're not speaking, could you please put your phone on mute. We're hearing some back noise.

Linda Baas?

Linda Baas: Here.

Wunmi Isijola: Thank you. Linda Briggs?

Michael Crouch?

Michael Crouch: Here.

Wunmi Isijola: Thank you.

Mladen Vidovich?

Linda Briggs: Linda is here.

Wunmi Isijola: I'm sorry, who was that?

Nicholas Ruggiero?

Sana Al-Khatib?

And, Linda Briggs, we see your hand there. Did you have a question?

Tom James?

Thomas James: I'm here.

Wunmi Isijola: Thank you, Tom. Tom Kottke, we have you. And William Downey?

William Downey: Here.

Wunmi Isijola: Thank you. Was there anyone that I missed during the roll call?

Leslie Cho: Oh, Leslie Cho.

Wunmi Isijola: Hi, Leslie. Thanks for joining.

Leslie Cholesterol: Hi.

Joseph Cleveland: And Joe Cleveland.

Wunmi Isijola: Thanks for joining, Joe. Was there anyone else?

OK. And I'll turn it back over to Melissa.

Melissa Mariñelarena: Thank you, Wunmi. OK. We're going to go ahead and start reviewing the comments. Like I said, we only received a small amount of comments. We have some slides here but it's also following through the memo if you have that in front of you.

We normally theme our comments and we have a lot. So the first theme that we looked at here was some comments around the statins. And if you recall,

we had the (new) statin measure, which we're going to be looking at in a little bit as well.

So the comment was in – the comments were around the issue with the new statin component versus previously measuring LDL levels. The comment that we received for this particular measure around the composite measure was the commenter was opposed to just looking at statins rather than specific LDL measures.

So, the response that the NQF staff came up with is on the screen, and we said, "Thank you for your comments. The committee agrees that monitoring LDL levels remains an important part of providing care for patients with IDD. However, the statin component in this measure aligns 2013 ACC/AHA guidelines for the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults." So the question to the committee today is do you agree with this response? Would you like to edit it in any way?

Tom, would you like to facilitate the discussion?

Thomas Kottke: Sure, Tom Kottke here. I'll weigh in first, and I think this is a good response. I think it's very important for folks who are actually out in the field to be experiencing as much coherence of measures as possible. And so I would encourage us to use this response.

Anybody else? Who else wants to weigh in?

Brian Forrest: This is Brian. I would say that I think it's an appropriate response. I think we discussed at our in-person meeting the idea of, you know, a potent statin versus a moderate statin and some of those things. But I don't think there's a – I think the way we got it is pretty much as good as we can be. And I think given the current guidelines, this is very appropriate.

Thomas Kottke: Other comments?

(Crosstalk)

William Downey: This is Bill Downey. I frankly – I agree with the statement. I did think the one point that the person made, the commenter made, that our other (piece) complements of optimal vascular care are outcome measures rather than process measures or at least pseudo outcome measures like you don't get credit for simply putting somebody on an anti-hypertensive. I think that bears thought going forward, but I think at the time being this is an appropriate response.

Thomas Kottke: OK. We can put that in the parking lot and keep it in mind. I think we – I mean, I think we all believe that we're going to see a revision of the cholesterol guideline again in a, within a couple of years.

Anybody else? Who else wants to weigh in?

Thomas James: This is Tom James. Just to reiterate your own comment, speaking as a primary care internist, having consistency in what comes out to us in the field is important.

Thomas Kottke: Thanks, Tom.

Joseph Cleveland: Joe Cleveland here. I think the comment is appropriate.

Melissa Mariñelarena: OK.

Charles Mahan: Kurt Mahan here. I agree as well. And, yes, I would move forward with it.

Thomas Kottke: Great. Thank you.

Melissa Mariñelarena: Great. Thank you. So we will change this as the – from a proposed committee response to the official committee response.

Go to the next slide. So the next theme was support for the measures. Three commenters expressed their support for two measures, and that was Measure 2939, Statin Therapy in Patients with Clinical Atherosclerotic Disease; and Measure 0066, Coronary Artery Disease, Angiotensin-Converting Enzyme Inhibitor or Angiotensin Receptor Blocker, or ARB therapy, for Diabetes or Left Ventricular Systolic Dysfunction, or an LVEF Less Than 40. The action

item on here for the committee I said was it's consensus not reached. So what we're going to do is actually vote on these measures. So, right now, there's no action item for this measure. We just said, "Thank you for your comment," to the public that made comments on this. And then we're actually going to go through and vote on these measures.

So, have any committee members joined that Wunmi didn't call your name?

OK, no. So we're 13 right now. We do not have quorum. We need a minimum of 16, but we're going to go ahead and go through the discussion. We are going to ask you to vote if you are on the platform, and then we're going to send – I'm going to do a summary. And as soon as we have the transcript, we'll send that as well. But because we have to turn this around, I'm going to write up a summary of today's call with the SurveyMonkey, and we're going to ask you if you don't vote today and anybody is not on the call to submit your vote because we want to get as much participation of as much of the committee as possible so that we can get these votes squared away.

So we're going to go ahead and start with this discussion. The lead discussants for Measure 2939 were Michael Crouch, Joel Marrs, Gary Puckrein, and Tom James. If you would like to give a summary, a brief summary of the measure, and again we're going to focus on validity and then feasibility, and then I'll ask Tom to facilitate the discussion.

Michael Crouch: This is Michael Crouch. This measure focuses on physician – measuring where the physician offers statin therapy or prescribes statin therapy to a patient. My concerns about its validity were that there were – when they – in the pilot data, there were no documentation instances for anyone with a medical contraindication or a statin prescription being offered but not accepted by the (physician).

So it didn't look like this measuring as constituted now with the data that was accessing, was doing a good job, a (volume less) job of ascertaining whether the physician did prescribe statin therapy in certain percentage of cases, which weren't detected with this measure. The patient declined or had some kind of contraindications such as a prior myalgia or rhabdomyolysis in a sense or

something like that. So I remain not convinced that the validity of the measure is sufficient myself.

Thomas Kottke: Joel, are you on?

(Crosstalk)

(Off-Mic)

Gary, do you have – do you want to offer any comment?

Gary Puckrein: I think Michael summed it up adequately. I don't have anything to add to that.

Thomas Kottke: Tom James?

Thomas James: Yes, the only – this is Tom James. The only other comment I would make, though, is this one where there's a wide variation in how it's handled in clinical practice. And I'm concerned that we – that the whole issue of high-dose versus lower-dose statin is one that has been called out in some of the discussions and that we're not really – we don't have a good – we've got a very fuzzy measure at this point in time as far as acceptance.

Thomas Kottke: So I have a question for the committee. We've just approved 0076, which has a statin measure in it, and then we lock at 2939. What's going on?

Female: Well, I think it has to do with dosing, no?

Thomas James: Yes, that's the issue.

Female: Yes, that's the main difference between the first measure and the second measure is the dosing. And I think, you know, the high intensity statin versus moderate intensity statin, the difference is that – I mean I understand where this comes from. We were all there when the developers presented their data. But there are people whose LDL goes from 170 to 70 with just 10 of atorvastatin. And to put everyone on this high intensity statin, I think, you know, people are a little wary. I totally understand the hesitancy here.

(Linda): This is Linda. I was looking back at the report. And one of the things that I noticed was, in particular, on page 40 of the application, it talked about a problem, and that it was unable to distinguish between patients that were unable to tolerate a dose and not meeting that criteria then so that there were some patients that were essentially misclassified as not meeting the numerator when in fact the provider did attempt to do that, but the patient didn't tolerate that level and it couldn't be coded that way.

The other thing that I was concerned about is that when you look at the amount of data that they submitted, only 68 of 206 of the PINNACLE site could be used for the data analysis because their electronic health records couldn't transmit. And then – I'm sorry, 68 of 206 could not be used. And then of the 138 practices that were left, they had, you know, 205,000 patients, but there were like a ton of patients that were excluded. So there was a huge number of patients whose data couldn't be analyzed appropriately.

Thomas Kottke: This is not an e-measure, is it? I mean it – so this – it's assumed that this may require chart abstraction. Is that not true as a point of reference?

(Linda): It's not chart abstraction. This is from the PINNACLE Registry.

Thomas Kottke: I understand that. But in practice, if this were adopted, it is not an e-measure. NQF, is that correct? Even though it used the registry to document validity and reliability, it's not an e-measure.

Melissa Mariñelarena: That's correct. It is not an e-measure, but they did (pull) the data electronically from the medical records into the registry.

Thomas Kottke: Right.

Melissa Mariñelarena: But it's not an e-measure.

Linda Baas: So my concern is that because they pull the data from the electronic health records and there were some – they admitted to the fact that there were challenges in reporting the statin dose that mapping via electronic health record in such a way that people could actually report this information could be a problem for people. It was a …

Thomas Kottke: Right.

Linda Baas: … problem here for them, and it would be a problem going forward for more diffuse groups of generalized practice.

Thomas Kottke: Right. But, again, it's not an e-measure. So let me ask the committee if they'd be more comfortable if – I was going back to 0076, and that it's just on a statin unless allowed contraindication or exception or present. So the real hang-up – or here is the moderate to high-dose. Is that what's holding things up?

Male: At least from my perspective.

Male:: Is that a fact that the …

Female: I don't think that's true, and that will be consistent.

Male: The way they collected the data, they didn't get any data on people declining statin or doctors documenting a contraindication to statin. And I don't know what's up with that. And unless the measure data collection is modified for that, I still think it's a very flawed measure in terms of validity.

Male: But, again, their collection of the data is not identical to – I mean we're not grading on whether PINNACLE can meet this, the criteria here. We're …

Male: Right. (But I'm not sure if this) (inaudible) electronic health record to (anybody who could) …

Male: Right.

Male: … that any data collection process could. We don't document in our electronic medical record in any systematic way that could be easily abstracted when a patient declines a prescription for statin or when they have a contraindication (inaudible) (allergy), you know, allergic reaction (is listed) as rhabdomyolysis, which the majority have myalgia but not rhabdomyolysis. And majority of my patients who refuse statin therapy who have taken it in the past did so because of muscle soreness from …

(Crosstalk)

Male: Right.

Male: … a lot of patients. And they get – they identified nobody with that. And I'm not sure that we opt out to this measure that that data could be gathered (inaudible).

Thomas Kottke: Right.

William Downey: This is Bill. I have a bit of a broader question. I'm trying to understand what the intent of this new measure is versus if we – though it doesn't sound like we do, if we happen to believe that we were comfortable with specifying moderate to high-intensity statin for patients with atherosclerosis, why would we create a new measure that talks only about that as opposed to making that explicit in 0076 as well as the seven other statin therapy measures for patients with atherosclerosis that are listed as the related and competing measures. It seems that rather than adding a new measure, we would simply update those measures if we felt this was appropriate.

Thomas Kottke: Tom here. I think that's …

(Crosstalk)

William Downey: I'm struggling to see how we would actually operationalize this in any way other than an additive way when people are already feeling some degree of measure overload.

Thomas Kottke: Yes, 0076, Optimal Vascular Care seems to subtend 2939, isn't it? I mean everybody in 0076 or – sorry, everybody in 2939 would be included in 0076. Is that not a true statement?

William Downey: It seems to me to be true, and that was the genesis of my question.

Thomas Kottke: Yes, right, right. I'm agreeing with you, yes.

William Downey: OK, sorry.

Thomas Kottke: Maybe this is – yes, we don't need this measure.

NQF, is ACC on the line? They're the steward, right?

Penelope Solis: Hi, this is Penelope Solis with ACC.

Thomas Kottke: Go ahead.

Penelope Solis: I have heard some of the concerns that were raised. Again, when we submitted this measure, it was a proof of concept. It is again run through PINNACLE Registry. We did not submit it as an EHR measure. We do think that there's a lot of validity in this measure given that it's the only one that actually looked at what is included in the guideline recommendations currently. All the other measures don't look at moderate and intensive statins.

And, again, we would reiterate sort of what we had presented at the meeting that took place a couple of months ago, which was that when you're implementing sort of these measures that gauge different components, it does sometimes take a while to get adopted such as in the case of capturing LVEF data or, you know, NIH Stroke Scale. All those things took a while before they were actually wildly adopted.

And we do strongly feel that this measure does actually work to improve patient care for those who, you know, need to be placed on statins. And it's something that the PINNACLE Registry does support and will move forward with. But, again, you know, we would like you to consider endorsing this measure.

Obviously, it does take a while to increase adoption. And, you know, although there's other competing measures, there's no way to accurately gauge if they would adopt to this sort of component of dosage, so. But if there's any other questions, I'd be happy to answer them.

William Downey: Yes, it's Bill again. I would just ask if the ACC feels strongly about that about the dosing as it sounds like you do, and I think there are some justification for that. Would not a more straightforward approach to that be

for you to come back and say we would like you to revise the ACC-sponsored Measures 0074, 00964, 2452, all of which speak to statin therapy in patients with atherosclerosis as well as 0076 …

Penelope Solis: To answer your question, we …

(Crosstalk)

William Downey: … a new one.

Penelope Solis: We actually did iterate at the face-to-face meeting that we're no longer moving forward with 0074. In an effort to sort of streamline and, you know, bring forward to NQF one measure that would encompass various disease state, we have put forward the ASCVD measure, which was included in the ACC/AHA Task Force Lipid Measure Update that we had done. And it's the measure that we had proposed. We're not planning to have 0074 move forward anymore.

So I know that it actually has been sort of noted by NQF staff, I think, at the last meeting as well. But, again, we think it's important to have a more comprehensive measure that looks at all of the clinical conditions that are appropriate.

Thomas Kottke: Other comments?

Female: As ACC revises their cholesterol guidelines, it will be interesting to see what happens to the moderate high intensity statin recommendation, though.

Thomas Kottke: So, hearing no other comments, should we move forward?

Daniel Waxman: This is Daniel Waxman. Sorry, just one quick comment. Looking at the Optimal Vascular Care measure, I mean, the difference – one could make the argument that, you know, the Optimal Vascular Care measure is a yes or no measure and you need to meet all of the components. So they're not exactly, you know, if – and to the extent that one believes that high-dose statin therapy is important, you know, it does measure something that's different, you know, because, you know, for example, if you – I believe if a patient is a smoker,

then that measure is – then they will not pass the Optimal Vascular Care measure. You know – and one could argue that the high-dose statins are still important, you know, would still be important to encourage separately.

And, you know, the other thought is that as there is an exclusion now for people who decline or can't tolerate a statin, a developer could consider adding an exclusion for a response, you know, for – it's not felt to be necessary, you know, because of – because of a good response to a lower dose. Just a thought.

Thomas Kottke: Right. And I think on the other end of the spectrum, Leslie raised the issue that the 2939 would not be met if the patient were on a low-dose statin because they didn't tolerate the high-dose statin. So we have both ends of the spectrum.

Other comments? Hearing none, we'll move on.

Melissa Mariñelarena: OK.

(Crosstalk)

Melissa Mariñelarena: If we are ready to vote, we are going to vote. That's the wrong one, wrong slide, wrong slide, wrong slide.

Yes, validity. For Measure 2939? There you go.

OK. And your options for validity on Measure 2939 are moderate, low, and insufficient. And…

(Crosstalk)

Thomas Kottke: … do you want to explain why the – we can only get moderate, reminding the panel I can't get high?

Melissa Mariñelarena: Yes, moderate is the highest that it is eligible for because of phase validity. They only did phase validity testing on this measure so it is not eligible for high. So moderate is the highest rating that it can get.

Operator, can you give instructions on how to vote on the slide, please?

Operator: Certainly. When you see the voting question on your screen, click right on your screen directly in the box next to the answer of your choice for your vote to be registered. Thank you.

Melissa Mariñelarena: Thank you. And we are looking for 14 committee members to vote.

Operator: And I believe that count is down to 12 at this time.

Melissa Mariñelarena: OK, thank you. Come on, come on. So when we could see it live? It's not what's on the screen right now. I just can't see. And …

Female: If you haven't voted, please click on the screen.

Operator: We currently have 10 votes on the screen, so we're looking for two more.

Melissa Mariñelarena: Thank you. Do we have them yet?

Thomas Kottke: You should see a little checkbox, I mean, a little check in the box if you voted.

Melissa Mariñelarena: Is anybody having trouble voting?

Operator: There was one person who submitted their vote right into the chat box. If you haven't clicked directly on your screen on the slide, please do so now.

Melissa Mariñelarena: Do we have our votes?

Operator: It's still at 10.

Thomas Kottke: So that …

(Crosstalk)

Female: I have a question.

(Crosstalk)

Thomas Kottke: … whether we all have …

(Crosstalk)

Melissa Mariñelarena: Yes?

(Crosstalk)

Female: As long as the checkmark stays on the screen, it's recorded by you.

Operator: That is correct. We can see that vote as it comes in.

Female: OK.

Melissa Mariñelarena: Does anybody else have any questions? Are you having any trouble voting?

OK. Wunmi, what are the results? We'll record these. And then if not, we can tell who was able to vote or whose vote we captured. And if we weren't able to capture your vote, we'll send you the SurveyMonkey afterwards, and we'll ask you to revote if we don't have it.

Wunmi, do you have the results?

Wunmi Isijola: Well, the result on the screen is four moderate, two low, and four Insufficient.

Melissa Mariñelarena: OK. And just a reminder, these are not final because we don't have quorum, but we're going to go ahead and move on and vote on feasibility for this measure. I'll ask the discussants if you want to add anything on feasibility for the measure that we haven't already discussed.

Michael, Gary, anything else? If not, we can …

Thomas Kottke: Move on.

Melissa Mariñelarena: Oh, go ahead and vote.

Michael Crouch: I already made feasibility comments during the validity comment, so …

Melissa Mariñelarena: OK.

Michael Crouch: … I don't think it meets it well.

Melissa Mariñelarena: Gary, do you have anything else to add?

Gary Puckrein: No, I have nothing.

Melissa Mariñelarena: OK. Does anybody else on the committee – would you like – do you have anything to add? Or would you like – have anything to discuss?

If not, you can go ahead and start voting.

(Off-Mic)

Melissa Mariñelarena: Do we have all the votes?

Wunmi Isijola: So the votes are one high – we're receiving votes within the chat. So one high, six moderate, four low, and one insufficient.

Melissa Mariñelarena: Great. Thank you, Wunmi. Again, these are not final. We will send the SurveyMonkey to those who weren't able to vote. Today, we did capture your vote and anybody who is not on the call.

So we are going to move on. I'll let Wunmi, who is the co-pilot – I'll switch over to the slide. And we are going to move on with the discussion. And just a reminder, for Measure 2939, it must receive greater than 60 percent of the votes, which includes high and moderate for the validity (stuff) criterion which is a must-pass sub-criterion for the measure to be recommended for endorsement by the committee. If it does not receive greater than 60 percent of the vote, it will not move forward to NQF member vote which is the next step in the process or to the consensus standard approval committee.

So the next measure that we're going to discuss is the measure that was deferred during the in-person standing committee meeting. And this is Measure 0288, Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival. And, again, if you remember, the committee had a lot of questions and there was confusion with the submission. We did talk to the measure developer, and they provided just some clarification and an algorithm to talk you through the measure.

The lead discussants on the call today, I believe, are Daniel Waxman and William Downey. Are you the only two that are on the call today? I will turn it over to you, again, to give a brief review of the measures, some of the issues. We're going to start voting on the liability with the validity, feasibility, use and usability, and then overall suitability for endorsement. And then I am going to turn it over to Tom to facilitate the discussion.

Daniel Waxman: This is Daniel Waxman. I can start I suppose. So this is a measure that is – you know, it speaks to a longstanding guideline that patients who receive fibrinolytic therapy for acute ST segment elevation MI should receive it within 30 minutes of arriving to the emergency department.

And so, you know, there was not much question back. You know, this would have seemed like a reasonable measure in the era where fibrinolytic therapy was the predominant reperfusion method. But in the current setting and particularly given the very small number of patients who were eligible for the measure and the data we were given, there are questions – I think the primary question is whether in the patients who are eligible for the measure whether the guideline is still appropriate for the reason that if these – if the patient – if we included – hello?

Male: Yes?

Daniel Waxman: Yes, I'm sorry. If – the real question is whether the measure is being used among a large proportion of patients with STEMI at centers where primary PCI is unavailable or whether …

Male: Hello. I think you've got transferred to me accidentally.

Daniel Waxman: Oh, OK. So I'm not on the conference call anymore?

Male: No, you're not.

Female: Are we not still on the conference call?

Male: Well, we are still on the conference call. I don't know who that …

(Crosstalk)

Daniel Waxman: OK, so the question is whether these are – whether the patients who are qualifying for this measure are outlier, inherently outlier patients because by virtue of the fact that they're receiving thrombolytic therapy.

And I think a secondary question is – surrounds the exclusions, and it would be helpful to understand whether the exclusions are something that – you know, whether there is the possibility of kind of introducing (bios) by – particularly by the requirement that the EKG be documented to show ST elevation.

Thomas Kottke: Tom here. I think I disagree with the first – this has nothing to do with the number of patients or whether what custom is, how ST elevation MI is treated today in the United States. The question is very specific.

If hospital decides to give fibrinolytic therapy for ST elevation MI, do they give it within 30 minutes and that's it? And, sorry, (inaudible) just not to think beyond the actual scope of the guideline.

Daniel Waxman: Well, let me just – just the – if you don't mind a quick response to that.

Thomas Kottke: That's all right.

Daniel Waxman: The question is whether by virtue of the fact that whether the guideline is still appropriate in the patients who are left in the measure because if the usual procedure in the hospital is to send the patient for primary mechanical intervention then it might not be appropriate, you know, to expect that under, whatever circumstances made the particular patient who is eligible different, you know, 30 minutes might not be an appropriate standard.

(Crosstalk)

Daniel Waxman: The decision-making process might reasonably take longer.

William Downey: And I think, this is Bill, to emphasize that point perhaps in the words that Dan used a moment ago, I think our concern around this is not what you see to, Tom. It's, are these inherently outliers at the facilities at which it's being

used, even in a measure that focuses on unusual cases, is not really what we're about.

Many – we know that 15 percent of the time in the data presented, they were said to be delayed for a given reason. The question at hand for me is, are there undocumented reasons that may be the vast majority of these patients? I can tell you that would be the case in my organization and I think is the case in the majority of the organizations. We had a long discussion about this at the last meeting and wanted to ask for data that said, begin to fair it out, the primary reperfusion strategy at a given institution, as a means of getting some comfort that this was not focusing mostly on unusual cases at systems and hospitals that had PCIs their primary reperfusion strategy.

The developer stated without evidence at the time that, no these are – this is, for the most part, the primary reperfusion strategy. We have asked for that data, and I reiterated that in an email two weeks ago. But at least as of yet have not received the stratification by the percentage of MI cases at that facility.

If we had that, I think we would feel much more comfortable and could, for example, set a percentage threshold so that we said, we really know we're talking about the strategy at a given hospital. Maybe the developer can speak to that.

Colleen McKiernan: So this is Colleen McKiernan from the Lewin Group. So we are not able to provide information about the total number of AMI cases that occur at each facility. This measure is one of five measures that are chart-abstracted, and CMS has explicit guidelines on how cases are selected in order to reduce burden of reporting for providers. So they do not submit all of their information.

And so we have a subset of cases for which the facility use the CMS guidance to identify sample cases and then gave us the information. So, unfortunately, we cannot tell you what's the total population of AMI cases is per facility because we don't have access to those data for these measures.

Daniel Waxman: As a follow-up, do you – can you tell us the – and apologies if this was included in the original material. Can you tell us the number of cases per hospital or the number –and the number of facilities that submitted cases?

Colleen McKiernan: So every facility that participates in the outpatient prospective payment system, the regulatory rule for CMS that governs these measures, is required to use a sampling algorithm. They have the option to submit all of their cases but I believe most facilities sample. And so, we apply a minimum case count to the number of cases that before publicly reporting the values. So facilities are not reported if they have a very, very small number of cases. I don't have the distribution of numbers in front of me but maybe we can pull that up during the – while we're chatting. But we do have the numbers within the algorithm itself breaking it down at each step.

Thomas Kottke: Right.

Colleen McKiernan: So I don't know if you have a specific question about a certain step.

(Crosstalk)

Thomas Kottke: We have in the algorithm, if you look after box 1, there's 26,253 patients with ST elevation and 4,599 got fibrinolytic therapy. And so these aren't rare outliers. I mean they're not the majority by any means but they're also not (definite to us). I mean there were about – there were about six of the – a little more than a six of the total population.

And I'm – I guess I'd like to hear why – you know, if the institution does not use mechanical reperfusion, why they should be off the hook for making a decision within 30 minutes to use fibrinolytic therapy, an example of, you know – is it that they weren't able to decide whether the helicopter could fly or not? Or what would be good reasons for a delay in delivering fibrinolytic therapy?

William Downey: I think the case you gave is exactly the best case so that if this is in a system that has a primary PCI strategy, which is the overwhelming strategy in the United States, then these are, by definition, outlier cases. As you say, you know, what is it, quite 20 percent almost, not quite 20 percent did get (lytic)

therapy. I suspect that that's a mixture of a lot facilities where it's a secondary strategy, but a sizable number of facilities where it's a primary strategy. If we could …

(Crosstalk)

William Downey: … dust the data and dust up the measure where we focused as a primary strategy then I would be completely supportive of this.

Thomas Kottke: So you don't have responsibility to deliver fibrinolytic therapy within 30 minutes if you use PCI as your primary therapy?

Daniel Waxman: Well, maybe not. I mean it may not be in a population level. It's possible that you're doing more harm than good by trying – you know, if people did try to comply with that at the expense of delivering people to – you know, if it was felt that the decision-making had to be constrained, you know, to meet that goal. So it's not completely clear. It really does kind of change the risk benefit calculus of the difference between, say, half an hour and an hour.

William Downey: And please, I think (you're) – but don't create a …

Daniel Waxman: Right.

William Downey: … (silly straw man). I am not advocating delays for reperfusion therapy. I frankly get up in the middle of the night all the time because that's my life, and I believe that's not fair.

But – and we shouldn't judge outlier cases in the same way that we've said we're going to, you know, exclude patients from the statin registry who have rhabdomyolysis because that's the safe thing to do. In unusual cases, these should be excluded. But it should be done on a hospital by hospital basis.

Thomas Kottke: But rhabdomyolysis is what case per 10,000 or case per 100,000. This is one out of five.

William Downey: And again, if we can find a threshold percentage where we say this applies to X hospitals, then I think that would be wonderful.

Colleen McKiernan: So this is Colleen again. I just wanted to jump back to a comment related to exclusions for system reasons like delays due to traffic, the patient can't get to a – from hospital (HPE) because of traffic or the helicopter can't land or something versus other reasons.

So clinical reasons for delay in administration are acceptable. So, for example, if the patient is coding or if there's a patient-centered reason for the delay, that's an acceptable reason to not administer fibrinolytic therapy within the 30 minutes. But we don't currently allow for exclusion of those system cases for traffic or whatever, the other facilities doesn't answer the phone. If that is an issue that you think we should bring back to our expert panel and we do meet with them periodically and that's something that we can discuss, if you think those system reasons are appropriate for exclusion, we're happy to bring that back to our expert panel to discuss that.

Thomas Kottke: Who else wants to weigh in?

(Off-Mic)

William Downey: I did have one question for the developer. This is Bill again. If we go to page 38 of the memo, there is a nice table that shows the number of facilities from Hospital Compare where there is data collection.

Are you with me there?

Melissa Mariñelarena: What page is that again?

William Downey: Page 38 of the review draft.

Melissa Mariñelarena: Oh, of the report?

William Downey: No, of the review draft that was …

Thomas Kottke: Oh, that's the original submission.

Melissa Mariñelarena: Oh, the submission?

William Downey: Basically, you, guys, provided a table that showed facility level performance rates from Hospital Compare from 2010 through March of 2015. And in 2014 and 2015, we saw in Hospital Compare at least a total of 76 hospitals measured on this.

Melissa Mariñelarena: Yes, that was the original submission.

William Downey: Yes. Out of – so we're – I guess you're wanting to apply – we're having this big conversation around, is it valid? But at most, it's applying to 76 hospitals out of the 4,000 hospitals in the United States. Am I misreading something there?

Colleen McKiernan: So you're correct, but to give a little context, the numbers to which you're referring, so 76 facilities report the distribution of their performance score. Those are the facilities that are reported on Hospital Compare.

So as I talked about a couple of minutes ago, we apply a minimum case count before our data are publicly reported to ensure that the numbers are valid for many reasons. And so in order to be publicly reported, the facility has to meet those that minimum threshold. That 76 value represents the publicly reported facilities. The measure applies to all 4,000 roughly facilities, and so they are abstracting cases but the patients may fall out earlier because they, for whatever reason in the algorithm, they might have fallen out at some point. And so it's only until you get to the very end of the algorithm when you identify those facilities that have enough cases to meet minimum case count and thus be publicly reported.

Daniel Waxman: Well, public – I mean presumably the public reporting is – the threshold is similar to whatever else the measure would be used for, you know, if it were, you know, for reimbursement or whatever. So isn't the argument, you know, if only 70 – your know, 4,000 hospitals are abstracting but only 76 have usable numbers? I mean is that not an issue?

Colleen McKiernan: So these measures were all pay for reporting not pay for performance. So long as the facility engages in the effort, so the care – they engage in an effort to provide the data, they qualify for inclusion in that payment, so it's just based on reporting not on performance. Theoretically, that means that the

standards that the measure is evaluating, the hospital will adopt whether or not they're going to meet the minimum case count because that minimum case count is applied retrospectively. So they don't – you know, they don't know when they're actually performing the care whether or not they're going to meet the minimum case count, so thus they should be using – applying the standards from the measure in their daily practice.

Kelly Anderson: Colleen, do you mind if I jump in here as well?

Colleen McKiernan: Please do.

Kelly Anderson: Hi, this is Kelly Anderson, I'm also part of the Lewin Measure Maintenance team. I just wanted to note as well we've talked about how this measure is one of the suite of five AMI measures. And I think your point about burden in terms of chart-abstracted data is well-taken, but most of these data elements are used to measure the whole suite of measures. So it's not just collecting this data only to report on 76 hospitals; rather collecting this data to report on a suite of measures across the 4,000 facilities.

Colleen McKiernan: And that's the first algorithm in this PDF. So that identifies the total AMI population for the five measures that Kelly just described.

Daniel Waxman: Thanks.

Thomas Kottke: Other comments? So are we ready to move on?

(Crosstalk)

Melissa Mariñelarena: OK, if there aren't any other comments, we can go ahead and start voting. Wunmi is getting to the slides. Reassigning with reliability. OK. So we're going to vote on reliability for 0288. The options are high, moderate, low, and insufficient.

Operator, how many members do we have on the line?

Operator: We have currently 13 voting members.

Melissa Mariñelarena: Thank you. Let us know if you're having any trouble. You can either let us know over the phone or via chat. We need two more votes. You could submit your votes.

We still need two more. Is anybody having any trouble? Operator, you said 13, correct?

Operator: That is correct.

Melissa Mariñelarena: Where are we at, Wunmi? We have 11? OK, we'll go ahead and record this. Again, we'll be able to see who was able to place a vote. If we weren't able to capture it, we will contact you and send you the SurveyMonkey.

Wunmi Isijola: And just for record purposes, we have two for high, five for moderate, four for low, and zero for insufficient.

Melissa Mariñelarena: Thank you, Wunmi. And, again, these results are not final. We will follow up with a SurveyMonkey after the call for those of you that we were not able to capture your vote, you didn't vote, and for anybody who is not on the call this afternoon.

The next criteria that we're going to vote on is validity. The options are moderate, low, and insufficient. Moderate is the highest that you can vote because for this measure, the measure developer has done data, patient level data element validity testing. Again, so moderate is the highest that you can vote. You have one moderate, two low, and three insufficient.

And we're still looking for 13 votes if possible. We've got 12, 11. You want to stick with the 11, OK?

Wunmi Isijola: So the – for record, six for moderate, five for low, and zero for insufficient.

Melissa Mariñelarena: Thank you. We will move on. Feasibility, do we need – I'd like to have additional discussion on feasibility of the measure.

(Crosstalk)

Male: Yes, if I could just ask for a clarification from the developer. In terms of the documentation of ST segment elevation, do you know how – what defines that? Does it need to be explicitly written somewhere that there is ST elevation? Or what does that mean?

Colleen McKiernan: So this is Colleen again. So, yes, the abstractor is not allowed to interpret anything. So there has to be explicit documentation by an APN, a PA, or a physician that there was suspected – that there was ST segment elevation. And there's explicit inclusion and exclusion terms; so it has to be obvious. It can't be potentially ST segment – or ST – or, I'm sorry, potentially a STEMI. It has to be pretty clearly defined. We're only looking at those cases for which the clinician was pretty sure that there was ST segment elevation. No – there can't be any doubt.

Kelly Anderson: I would just add on to that though that there are a variety of different ways that that could be documented. So it's not like they have to have one specific (place) in order to be included.

Colleen McKiernan: Exactly. The data element has, I think, three pages of inclusion and exclusion terms that are acceptable.

Male: Thank you.

Thomas Kottke: Other discussion on feasibility?

Hearing none, let's move on.

Melissa Mariñelarena: So feasibility options are one high, two moderate, three low, and four insufficient. And, again, if possible, we are looking for 13 votes. We have 10. We need one more.

If one more person can vote – or, operator, did we lose somebody?

Operator: No, we still have 13 voting members that are logged in.

Melissa Mariñelarena: Thank you. If you could submit your vote.

Are we still at 10? Go ahead and read off 10, and again we'll follow up.

Wunmi Isijola: OK. So zero for high, 10 for moderate, zero for low, and zero for insufficient.

Melissa Mariñelarena: Thank you. The next criteria is usability and use. Are there – is there a discussion that you'd like to have around usability and use or any questions?

Thomas Kottke: Hearing none, why don't we move on?

Melissa Mariñelarena: OK. The options are one high, two moderate, three low, and four insufficient. We have 11 votes.

Wunmi Isijola: So the votes are zero percent high, nine moderate, two low, and zero insufficient.

Melissa Mariñelarena: Great. Thank you, Wunmi. So the last, though, because we're doing this online and we don't have quorum, we're going to go ahead and get a vote for overall suitability for endorsement for Measure 0288. The question is does the measure meet NQF criteria for endorsement? And we have a note here that this may not yet be a recommendation for endorsement. Final recommendation for endorsement may depend on assessment of any related or completed measures, which we have sort of touched on that, and they will also depend on the must-pass criteria, reliability, and validity, but your actions are one yes and two no.

We have 10 votes. Is there an 11th vote? OK.

Wunmi Isijola: So we have five for yes and six for no on the overall suitability for endorsement.

Melissa Mariñelarena: OK. So just a reminder, again, these votes are not final. We will follow up with SurveyMonkey. If you did not vote today or were not able to vote, we encourage you to please submit a vote. We want, you know, the votes to reflect representation of the committee.

And, again, I want to remind you that this measure must receive greater than 60 percent of the votes, just like the other measure for reliability and validity, and that includes high and moderate, for the measure to be recommended for endorsement by you, the standing committee. If this measure does not receive

greater than 60 percent of the votes, it will not move to NQF member vote or the Consensus Standards Approval Committee or the CSAC.

Are there any questions from the committee? Any comments? We are a little bit early. If there aren't any questions, we can open the line up to NQF member or public comments. Operator?

Operator: At this time …

(Crosstalk)

Melissa Mariñelarena: Thank you.

Operator: At this time, if you'd like to make a comment, please press star then the number one on your telephone keypad. Again, that's star one to make a comment.

And we have no public comments at this time.

Melissa Mariñelarena: Great, thank you. We don't have any comments in the chat box.

Wunmi Isijola: OK. So as Melissa mentioned, we do have some of the votes (inaudible). Following this call is summarize the discussion today and provide that in the SurveyMonkey for those who are unable to attend. And then thereafter, we will submit and provide the final votes for these measures.

Next step for us is once we do receive all of the votes, we will inform the committee but also the developers. But then we will present those recommendations to our NQF membership during the October 17th to June 31st time frame, but we'd still be able to vote. And then all of the recommendations will be presented to our CSAC for review and final approval. We'll have Tom Kottke and Mary George help represent the committee. And then after, those recommendations by the CSAC will be sent to the board for ratification. And then we'll open up a 30-day appeal period for any endorsed measure within this project. Any party can submit an appeal.

So we will ensure that you are provided all the next steps as we move throughout the project. But, again, we thank you, all, for your continued support on the Phase 4 project. And, Melissa, do you have any final words?

Melissa Mariñelarena: I just want to thank all of you for taking time out of your day to participate and the beginning of a beautiful fall day at least here in D.C. Thank you, again, thank you, Tom. And I want to thank the measure developers and anybody else that joined us.

Tom, would you like to say anything?

Thomas Kottke: No. I just like to thank everybody for thinking about this and for signing in and participating in what I consider to be, you know, a very important work in improving the health and well-being of the folks we serve.

Melissa Mariñelarena: Great. Thank you, everyone. And we will be following up. You'll hear from us shortly.

Male: Thank you.

Melissa Mariñelarena: Thank you.

Male: Thank you.

Female: Thank you.

Male: Thank you.

Female: Thank you.

END