**NATIONAL QUALITY FORUM**

**Moderator: Sheila Crawford**
**March 17, 2014**
**3:00 p.m. ET**

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

Reva Winkler: Good afternoon everybody, this is Reva Winkler along with Wunmi Isijola and (Steve Wong) from NQF. Thank you for joining us today on this call of the Cardiovascular Workgroup. I just want to check and see which of our workgroup members have joined this. I know Linda Briggs, Jeff Burton and Judd Hollander are on. Are any of the other workgroup members with us at this point?

(Carl Tumasa): (Carl Tumasa).

Reva Winkler: OK. Is Michael Crouch or Nicholas Ruggiero with us? We don't want to wait too long before we get started, but I want to thank the members of the workgroup for your preliminary reviews and your providing the initial comment. We have collated all those comments and have put those all into your measure worksheet and they're available to you on SharePoint. And during this call, we'll be showing them on the webinar.

So, in my quick review of them, it certainly looks like there are a lot of thoughtful comments that raise a lot of good issues for further discussion.

We're going to try and get through six measures in this workgroup. And so, we do want to be able to talk about all of the measures. So, that really gives us only about 20 minutes per measure. So, we do want to be aware of time and try and focus for time and discussions particularly on the areas where

there were some concerns or some issues – perhaps some disagreement among the workgroup members to provide you an opportunity to share your thoughts. For things for which there seems to be – there's general agreement, we don't need to spend a lot of time talking about them today.

So, any of the other workgroup members showed up? Michael Crouch or Nicholas? (Inaudible) should be a little bit late.

Female: And we have Judd Hollander on the line and Mike Crouch.

Reva Winkler: Yes. I was going to say, so …

Male: Yes.

Reva Winkler: … I don't – I think we might as well get started and we're going to start – I know Judd have to leave a little bit early, so we do want to start out with measures that he was reviewing. And so, our first measure is measure 289. So, Judd, if you would like to just start by giving us a brief description of the measure and then your thoughts on the evidence criteria.

Judd Hollander: OK, so, I'm in a little disadvantage because I'm at the airport, so I can't use the webinar because I'm not online. But I do have the original sheets up in front of me, the copies.

But the first measure is the Median Time, the EKG, which is, you know, at first glance, a relatively simple thing at times when somebody shows up in the emergency department to when the EKG is obtained. All EKGs actually have a timestamp on them. So, that's relatively easy.

This is based on the evidence that in patients who have (ST) elevation in MI, there are sometimes dependence in treatment and identifying these patients early is very beneficial. And so, I think that's where the measure developments are coming from.

And so I think that make sense. Where I see some problems with this from the 10,000-foot view and knowing what's going on in, you know, my emergency department and other ones these days, it is that we are now as a

group getting EKGs on everybody between 18 and, you know, 100 who comes in with any symptoms from the thorax or abdomen, and we are logically meeting the time consistent with the current data that's mentioned in 1B here. But it's prioritizing 20 year olds with (silly) chest pain over sicker patients that's have other chef complaints in order to meet the measure. OK.

And so, one of my concerns is that you in a patient population who is likely to have STEMI recognizing we can't predict it based on the clinical signs and symptoms terribly well, there is some evidence for doing this.

There is no evidence supporting earlier EKGs in patients who have non-ST segment elevation MI and there's certainly no evidence supporting it in the majority of patients who have non-cardiac chest pain.

In most of the data available, no more than 10 to 15 percent of patients who show up with chest pain or chest pain equivalence actually turned out to have an MI and only a third of those have STEMI. So, in essence, we're doing this on 20 or 30 patients for every one that has STEMI.

And so, I would propose and I must do the rest of the sheet, but I would propose that maybe we limit the age groups to where STEMI is a likely possibility and that largely catch up people less than 40, albeit we all occasionally see a patient with a STEMI in the younger and 40-age range.

I don't know if you want me to stop now or do you want me to sort of march through each of the criteria?

Reva Winkler: I think you can march through it. I would suggest that any of the other workgroup members that want to jump in and maybe offer, you know, a response or acknowledgement viewpoint, feel free to do so.

Linda Briggs: Hi, this is Linda. I agree with a lot of what Mr. Hollander said. But it's more than just the STEMI people. You have to differentiate between anybody that has cardiac chest pain and a STEMI. So, the STEMI through the ones that you ought to pick to move them, you know, to the Cath Lab as soon as possible. And that's the major focus of this criteria.

But – so, you also want to be looking for those people that have EKG changes that might indicate ischemia that might be a non-STEMI in this and you're unstable angina. So, that's my only addition is that it's not just STEMI, it's anybody that has cardiac related chest pain that's ischemia based.

Judd Hollander: So, I think that's a fair comment. I just come back to the pure evidence based, and although that makes intuitive sense to me and I certainly would want to see an EKG on the other non-STEMI ACS patient. But the evidence to support early intervention in those patients is entirely lacking. And so, I think it's an easy argument for the STEMI patients. I think it's a little bit of a leap of faith, albeit some common sense, but where people have looked at the evidence for early treatment in the non-ST segment elevation MI and unstable angina, it's safe that I'm able to show any early benefit. So, I think to make it a measure in those patients, it's a little more based on common sense than the evidence.

Reva Winkler: All right, just to be sure we all understand these sort of basic approaches, we can make suggestions about we're evaluating the measure as written. So, you know, if the age range is 18 and above, that's the measure we're evaluating. So, Jeff, what would you – based on the algorithm, how would you rate the measure on evidence?

Jeffrey Burton: Well, so, you know, I think there's evidence for the subgroup that I'm speaking to which is the STEMI patients. I think it's impossible to tell who is STEMI and who's not when they roll through the door. So, is there rating system that I missed – I mean, I think there's evidence to support the measure.

Reva Winkler: Yes. Did you review the evidence algorithm?

Jeffrey Burton: Yes, I don't have them. The evidence – you mean the flowchart?

Reva Winkler: Yes, exactly.

Jeffrey Burton: Yes. So, I think it meets the first point.

Reva Winkler: OK. So …

(Crosstalk)

Reva Winkler: … includes only expert opinion according to what they've …

Jeffrey Burton: And I think that's fair.

Reva Winkler: OK. Well, expert opinion really is in a high enough level of evidence to meet the criteria unless you would want to invoke an exception.

Jeffrey Burton: Well, I think the STEMI, there's more than expert criteria. And I think that that sort of what make this measure difficult. It is – there is a segment of the population where there is great evidence, but there's no way to identify them upfront. So, what they did is include the whole population that may have STEMI based on expert evidence even though there's really good evidence in the STEMI population. Does that make sense?

Reva Winkler: OK. Thoughts from anybody else? If not, why don't you go ahead on the criteria.

Judd Hollander: OK. So, as I looked the performance gap, you know, and this comes down to this thing, the 50th percentile is eight minutes, we've meet the criteria. The 75th percentile is 13 minutes which functionally is more or less the same as eight minutes. And even the 90th percentile is only 23 minutes which is a 15-minute difference. I don't believe there's evidence that a 15-minute difference even in STEMI patients makes a difference. So, I could argue that there's not a significant performance gap here that requires this measure.

Reva Winkler: All right. Thoughts from anybody else? All right.

Judd Hollander: OK, as far as the priority, I think the STEMI patients are our priority. But like I said, that's only a third of the MI patient and that's only 15 percent of the chest pain patients. So since they're trying to propose we do this in everybody and it's only a priority at 5 percent of people, I suppose I can argue that this is not a high priority measure.

Reva Winkler: OK. Comments from anybody else?

Linda Briggs: This is Linda Briggs. I would argue that it is a high priority measure just because the consequences of STEMI MI can be like threatening. And that that's a significant population in the population as whole in the whole making out in everything that comes in the emergency department. I think that is worth having a measure for because I think that while 15 minutes one way or the other may not make a huge amount of difference when you're talking about just to Cath Lab in 90 minutes or less, that 15 minutes is a big chunk of that time and you need to, you know, mobilize your team and get the Cath Lab open if it's not already open, if it's the middle of the night, that kind of thing.

Wil Mick: If non-member of the committee would like to make a comment, is that acceptable?

Reva Winkler: Yes. Would you identify yourself?

Wil Mick: Yes, Wil Mick. I'm the Chief Executive Officer of the Society for Cardiovascular Patient Care, and a couple comments. Number one, there is no basement on the data that I'm familiar with on time reductions from door to balloon and STEMI patients. So, that's point number one. Point number two, there is a segment, as Mr. Hollander identified, that will end up in the Cath Lab if they are not STEMI patients. So, performing EKGs on an appropriate segment of the population will turn on an array of additional differential diagnostics that will identify those patients that will end up in a Cath Lab not necessary as emergently but (implicitly) end up there for opening up coronary arteries.

So, I would suggest not reserving this just for EKGs, just for STEMI patients, but rather for – to have some better age adjusting group, as he suggested, because certainly the 18 year olds and up are very, very low probability candidates, but in appropriate age selection would be appropriate so we catch all of those patients that they are going to get on for further cardiac cath work up or be triaged to a cardiologist to prevent ultimate coronary artery inclusion.

Reva Winkler: OK, thank you. We need to continue on in the evaluation of this measure. So, Judd, do you want to continue on?

Did we lose Judd Hollander?

Judd Hollander: OK, so, I'm back now. The operator had me muting when I wasn't speaking, so …

Reva Winkler: Really?

Judd Hollander: So, yes. So, I guess the airport noise. So, let's move on to item two and I'll sort of address the – I guess the specifications of reliability and validity testing together. My concern on these specifications is that they don't really specify how they measure arrival time. And if you go to different emergency departments, in some emergency department, it'll be on a piece of – let's assume there's an electronic medical record and it's recorded for purposes of argument now. But in some places and in most places, people will just fill out a piece of paper when they actually get to the emergency department. And the timestamp that shows up on the record is either – if they registered before they're triaged to a triage, if they triage before they're registered.

And so, I think it's hard to standardize what the first time is which is really what people want. And that's not something that may show up in the electronic health records and may not in fact even be recorded. And hence, that may play out in part of why reliability is so bad. So, even when they included reliability testing for possible cardiac chest pain, I think with Kappa value, it was only 0.53. And when they looked at it for EKG which I believe is the EKG time, it was only 0.25 which is poor.

So, I think there's issues with how they specify things and then the reliability I don't think is terribly good. And I don't believe they actually did any validity testing. I believe they assess Kappa which is a measure of reliability and not validity.

Reva Winkler: Great. Thoughts from the other workgroup members?

Do we have anybody from the measure developer on the line?

(Dale Rapp): Yes, this is (Dale Rapp) for – my line is open.

Reva Winkler: Hi, (Dale), how are you?

(Dale Rapp): I'm good.

Reva Winkler: You want to – did you have any comments or response to Judd's thoughts?

(Dale Rapp): So, just a couple of points. So, one, this is a measure that's used in the hospital outpatient quality reporting system. So, many of the patients with STEMI actually end up being transferred to other institutions, in other words, if you're setting in an institution with a STEMI, that actually does do interventional cardiology, you – those patient don't fall into this data set. Those patients are admitted to the hospitals and then they are subject to the performance measure on door to balloon time of 90 minutes. So, this measure is largely moot if you're in a facility that actually does intervention. The measure focuses on patients who are on the ambulatory setting and subsequently not admitted to the hospital, at least the hospital there seen him.

So, this measure was originally developed as part of the transfer measure set of patients who are seen in a small hospital that's non-interventional, they do the electric cardiogram, and make the decision of the transfer. And I would argue that the 15 minutes for STEMI part transfer becomes much more substantial. So, we know that many of these patients aren't making it to the subsequent interventional facility within the 90-minute timeframe.

I don't have the data on the reliability in front of me. We actually did exactly what we were asked to do by NQF in terms of simply testing the reliability data elements of the cardiac chest pain, have been problematic. Arrival time actually is the standard performance or – I'm sorry – a standard data element that we used for multiple different topics and it's fairly standard across every single one of the CMS measure sets.

I'm looking for the Kappa data.

So, Reva, did that make sense, the comment about the outpatient measures? This is one the (HOQR) measures of inpatients.

Judd Hollander: Yes, I think that helps to clarify things a little bit and makes your case a little stronger personally.

So, OK. So, I'll move on. So, the threats to validity (2B3 through 7). My only concern again was the age between 18 and 40 where I think it's been a work that doesn't need to be done. 2D which was composite measures doesn't count. I had and I'll take this altogether because they're all the same.

For feasibility, I got concerns about the probable cardiac chest pain being somewhat subjective which is what the reliability testing showed. And that being hard to define via chart review and then subject to – if your (setting) a little gamesmanship where maybe it only be recorded for MI patients and not be recorded for other people if that was the intention.

And then usability and use, I sort of addressed this early on. You know, I'm concerned about the feasibility and the unintended consequences of prioritizing EKGs in anybody regardless of age range or vagueness of chief complaint over the care for other patients.

So, to me, I think with the comments that (Dale) made, if it was a little more focused, one way to do that is – and I know I don't get to rewrite this, it's not journal. If it was more focused in over 40, then we would cut out a lot of the people that are unlikely to benefit from the measure without actually missing any of the STEMI patients, and that would minimize the unintended consequences.

And so, I think a lot of what I just said is repetitious from what I said at the beginning but pretty much finishes up what my comments were on the measure.

Reva Winkler: Right. Any thoughts or comments from any other workgroup members?

Jeffrey Burton: Yes, this is Jeff. I will just agree and add on to the concern about the feasibility and the collection of data based on the objective nature of a probable cardiac chest pain or other factors, subjective factors that could be difficult I think depending on who's collecting the measure, who's collecting a data.

Reva Winkler: OK. Thoughts from you, Linda?

Linda Briggs: Well, I think that the information is actually abstracted from the chart. In which case, a physician or NP or PAs already made some kind of diagnostic statement, and this is actually on the worksheet form of what too can be – whose information can be used or documentation of the probable cardiac chest pain. So, if, yes, it is somewhat subjective, but, you know, everybody has to make a diagnosis at some point. And that's where the rubber meets the road.

So, if you said in your charting that his person has cardiac chest pain, then they should be included in the measure. And, you know, there's always going to be some shades of gray in any kind of diagnosis. And, you know, and so we get all the information of on the patient, get the enzymes back, get the EKG, all that kind stuff. We don't know for any, you know, reasonable amount of certainty what's going on with that patient. So, I don't have a problem with the way the criteria is laid out.

I was going to suggest though that as we're going through this, if whoever in NQF to scroll upward on the measure sheet so that we can see the part of the measure sheet that has everybody's comments that would be helpful.

Reva Winkler: All right, any other comments about this – move on to the next one?

OK. Have any of our other workgroup members joined us, Michael Crouch, Nicolas Ruggiero, Sana Al-Khatib?

Michael Crouch: I've been on for about 10 minutes. This is Michael Crouch.

Reva Winkler: Excellent.

Sana Al-Khatib: I've been on for 5 minutes.

Reva Winkler: And, Sana, are you there …

Sana Al-Khatib: Yes.

Mladen Vidovich: And this Mladen Vidovich. I'm just listening in.

Reva Winkler: OK. All right. So, then let's move on to measure 964 and measure 2452. Essentially, I think most of you realize this is the same measure. One is a

hospital level measure and one is the clinician level measure which is a new measure. So, why don't we start with 964, and, Sana, I believe this one is yours to lead. If you just describe the measure and then talk about the evidence.

Sana Al-Khatib: Yes, no, absolutely. I'd be happy to.

So, this measure has to do with therapy with aspirin and P2Y12 receptor inhibitor and statin at this charge following PCI ineligible patients. And, you know, I'm not sure if I need to go over the specifications. I'm sure people can see them right in front of them. I do have a couple of comments before I talk about the evidence here which I think there's either like a typo or some sort of mistake by the ACC because in the subject of the, you know, in the document that was shared with us, you listed Ticlopidine and Prasugrel and Ticagrelor, and I think Ticlopidine is a typo. It's a mistake.

I think that, you know, whoever brought this meant to write the Ticagrelor and not Ticlopidine because Ticlopidine is a very old medication that we don't use. It's not in the current guidelines, the 2011 guidelines. And I don't know if this is something that others, you know, picked up on or if you've question, but I don't think they meant Ticlopidine.

Reva Winkler: OK.

Sana Al-Khatib: So, that's the thing. And if we actually talk about these three different medications, then certainly there's evidence for aspirin for sure, we have evidence for Prasugrel, you know, Clopidogrel, as well as Ticagrelor. I think there are data certainly to support that. One of the comments that I had is that, you know, while they clearly spelled out the different receptor inhibitors that we have evidence for, you know, when they talk about the statin in this measure, they kept the generics, they kept it at the class level, they did not delve into the different statins which is something that they may want to do because, you know, we don't have, you know, data for all the statins. We do have data for most of them, but in terms of the level of evidence supporting the use of statins in this patient population, we have data for most of the

statins but not all of them. So, I wonder if this is something that we could recommend that they – maybe they need to spell out what statins they want.

In terms of what they're looking at, basically they, you know, they want to look at all patients undergoing PCI who are eligible for this medications and then of course the numerator will be all patients who are eligible for these medications (and I will) prescribe these medications.

And the exclusions, when you look at this measure or, you know, if the patient dies before discharge or the presence of a contraindication, what I thought was a bit weird is when you look the measure that you brought up, you know, the 2452 measure that is very similar to this measure, you know, they – in their exclusions, the exclusions are not aligned, they're not harmonized. And they present at least for the 2452 a measure rational for why they did not include the presence of a contraindication in the exclusions. And I personally think, you know, either way, whatever we decide to do, I think both measures need to be harmonized.

In terms of the registry that they want to use, they do want to use the CathPCI registry which I think is pretty good for this type of measure. You know, and in terms of the testing that they did, you know, I felt like the best thing was at least adequate for what they're trying to do here.

Reva Winkler: Sana, just a second. Can I stop you for a minute and …

Sana Al-Khatib: Sure.

Reva Winkler: … make sure we've had a chance to let every weigh in. You talked about the evidence. Did you – how about the performance gap?

Sana Al-Khatib: I actually – I think that there is a gap, I mean, and many people look at the 88 percent that they shared with us in there, you know, testing, as a result of the testing and say, "Well, that's actually pretty good," but I see a reason why we cannot be, you know, as close to 100 as possible like, you know, what we actually, for example, with the use of aspirin, you know, post-MI. So, that's why I think there is a gap, but I don't know if others agree.

Reva Winkler: Any other comments from other members of the workgroup on either evidence or the performance gap?

Michael Crouch: This is Michael Crouch. I was less clear that the gap was significant enough to justify it, but there's room for improvement. There's not a lot of room for improvement. And when you don't have much room for improvement, it's much harder to get improvement.

Reva Winkler: Thoughts from anybody else?

(Crosstalk)

Judd Hollander: Go ahead.

Male: Go ahead, Judd.

Judd Hollander: Yes, I was going to say, you know, I'm sort of middle, there's a little bit of gap, but it sure isn't that impressive. And, you know, at some point, I guess there needs to be a decision made on, you know, are there better measures are there other things or other priority. So, if there was only going to be one measure in the world, then, you know, 88 percent is decent and there's a little bit of a gap. But if there's going to be lots of measures and lots of work, then maybe this is not the one that has the most compelling gap.

Reva Winkler: Anybody else?

Male: I also wanted to bring up the measure 2379 which I think we're going to get to today as well as either our competing measure or measure that maybe considered for having a patient as it also looks at the P2Y12 inhibitors. But it only looks at those and it's a medication adherence measure where this measure includes the aspirin and statin focus on medication adherence. But I'm just wondering if there is – if that would be (inaudible) not on the competing PCI measure sheet there that our developers submitted.

Reva Winkler: Right. Certainly, it's open for the committee and the workgroup to discuss and consider. So, it's certainly not off the table. Why don't we talk about that when we get to that measure?

OK, if we're done with the importance criteria, then, Sana, please continue with your thoughts about the testing or the specifications and the testing.

Sana Al-Khatib: Yes, no, absolutely. So, as I mentioned, again, in terms of the specifications, I personally was happy with them. The only point that I would make is especially if we are going to review the other measures that overlap with this measure favorably, you know, harmonization is going to be really key. And the one that is closest to this measure is this measure that's almost actually identical to this measure. I have two which will be at the physician level and they're not harmonized in terms of their specifications. So, that's the only comment I have about the specifications.

In terms of the testing that they did, I actually thought that it was pretty reasonable in terms of, you know, how they did the testing, the, you know, the numbers that they shared with us. I'm actually looking at the document right here. And, you know, I'm very pleased with the fact that they used the CathPCI, you know, to do the testing because this is exactly the database that they will be, you know, hopefully using for this measure.

So, overall, I didn't have concerns about their testing for this particular measure.

Reva Winkler: Thoughts from any of the other workgroup members?

Michael Crouch: We're still under reliability, right?

Reva Winkler: Yes. Testing for …

Michael Crouch: OK.

Reva Winkler: … liability and validity, right.

Michael Crouch: OK. Yes, my comment – this is Michael Crouch again. I thought that the reliability testing was OK. But except that there was no empirical validation of improvement making a difference in outcome and the validity testing is expert based and there's no empirical testing for that for the validity of the concept.

Reva Winkler: Just to clarify, it's not absolutely required without empiric testing the highest rating you should give though is a moderate.

Michael Crouch: Yes, yes.

Reva Winkler: It does require empiric testing to get a high (inaudible) …

Michael Crouch: And that's why – yes, that's most of the comment is it's limited by that.

Reva Winkler: Any other thoughts from the committee? Do we have anybody as a measure developer on the line?

(Fred Nasuti): Yes.

Reva Winkler: OK, I just thought maybe you could speak to Sana's comments about the one medication and also including a listing of the statins.

(Fred Nasuti): Yes. This is (Fred Nasuti), Senior Medical Officer at the (NCR). Thanks for allowing us to join your call today. And thanks, Dr. Al-Khatib, for your comments.

With respect to the issues, yes, I believe that Ticagrelor, it should be Ticagrelor, not Ticlopidine. There are a few people who are on Ticlopidine, they're vanishingly few, but Ticagrelor is the medication in question and we apologize for that, that error.

With respect to the issue of statins, we have followed the guideline recommendations. And the guideline for MI are not – do not specify specific statins that should be used, and that we are mirroring the measure unlike say the beta blockers that are recommended for heart failure where there are specified beta blockers that are recommended. There's no specific recommendation in the guidelines for one statin over the other.

And then, finally, with respect to the inclusion for contraindications, I will say that it's potentially difficult see, but in the denominator statement on page one, patients – the denominator was patients were eligible. That is to say patients without a documented contraindication is listed in the first line of the denominator statement.

Sana Al-Khatib: You mean, for this particular measure, the 964, (Fred)? Because I have no concern about the wording for – in terms of the, you know, the exclusion for this particular measure. The only concern I had is that the other measure that it overlaps with – it's basically identical to the other measure is measure 2452 and they're not harmonized. That's what's my only comment is that I'm actually pleased with the exceptions here, but it just – the exceptions are not harmonized for the two measures.

(Fred Nasuti): OK, very well.

Reva Winkler: Any other thoughts on the criteria for scientific acceptability from the workgroup?

Judd Hollander: So, this is Judd. I have one question. I would like to – I can easily see the scientific or biologic rationale for combining a composite outcome measure including expert in the anti-platelet agents. I'm less clear on why the composite measure should include statins and why it should be two separate measures. So, I would like to hear thoughts on that.

(Fred Nasuti): May I speak from the developer's perspective so I can answer that question directly if that's OK?

Reva Winkler: Yes, go ahead.

(Fred Nasuti): Which is to say that we actually – so, these were actually submitted in the last cycle as individual measures and we were requested specifically by the committee that reviewed the measure the last time to consolidate these into one composite measure including both aspirin, the other platelet inhibitors and statins in one. So, this is just in response to previous review committee's recommendations.

Judd Hollander: OK, then I won't (put CHOPs) on it.

Reva Winkler: All right.

Male: You're very kind, thank you.

Reva Winkler: All right.

Linda Briggs: Hi. This is Linda Briggs. Another comment along those lines is the evidence is much clearer for the aspirin and for the P2Y12 than it is directly related, you know, to statins in terms of the immediate outcome. So, stenting related to stent thrombosis and early death and that kind of thing.

(Fred Nasuti): Yes, these are all derivative of the class 1A recommendations in the guidelines for the care of hospitalized patients undergoing PCI or with MI. So, again, they're derivative directly of class 1A guideline recommendations.

Reva Winkler: OK, any other comments from the workgroup? Then, Sana, why don't you continue on with feasibility and usability.

Sana Al-Khatib: And before I get to that, I just wanted to either raise a point or ask a question. In looking at the disparities and, you know, one thing that at least the testing study showed was that there was, you know, there were significant differences based on the insurance status, and I wonder if this measure will be reported, you know, based on, you know, certain demographics, although the testing didn't show significant differences based on, you know, gender, race, what have you, but in terms of insurance status, is that something that they're considering?

(Fred Nasuti): Well, I would say that this I think represents sort of a deeper diving to this issue of are there gaps which is that, you know, the population, you know, performance doesn't necessarily speak to whether or not like, you know, there are important gaps in care, and I think you've highlighted one, Sana. I think, you know, the, you know, we can certainly address. I don't know that we really have a time to go into issues around, you know, reporting policies in the future, but I would respond in that respect.

Sana Al-Khatib: OK, sounds good. In terms of the next criteria then in terms of feasibility, I actually think that it's certainly feasible because, you know, especially in, you know, people who are, you know, practices that are using the CathPCI registry, I see no reason why this, you know, couldn't be feasible, I mean, it's electronically collected data, it's part of the collection – data collection process, extending from looking at the quality audits of CathPCI, there are no

concerns about the quality of the data pertaining to the different elements important for this measure. So, I personally think that the feasibility is certainly feasible.

Linda Briggs: This is Linda Briggs. I agree that it's well within feasibility for anybody using the CathPCI registry, but that's – not everybody, they have the Cath Lab, although we would probably all like for that to be the case. And there are fees and costs that are related to that. So, if someone – or keep trying to report this data without that, I think it would be very difficult for them to do because to pull – having to pull that information together and I just wanted to know what other people's thoughts were about, you know, national application of something that requires you to have a, you know, software package and a license.

Sana Al-Khatib: I mean, that's actually an excellent point, and I couldn't agree with you more. But, you know, I'm hoping that as more practices adopt in electronic medical record that these data elements that you need for this particular measure that should be easily, you know, incorporated or gathered from, you know, electronic medical records. So, I agree with you, you know, CathPCI is a voluntary program and not all the, you know, sites, practices participate in it, but especially if we use this and learn lessons from it, hopefully it will be – either it will facilitate being able to incorporate this measure in other, you know, electronic medical record systems. I don't see how that will be, you know, difficult, but, yes, absolutely, be happy to hear other people's perspective.

Male: And (you hear) that too, Linda, it looked like you said, I think I actually made that comment in the measure that you're going to be leading. So, I agree with your comment about the access to the CathPCI.

Reva Winkler: OK. Anything from anybody else? All right, how about usability and use, Sana?

Sana Al-Khatib: You know, again, I don't have any concerns about that either. You know, but the whole issue of, yes, this will be limited at least early on to, you know, using it within the realm of the CathPCI registry can certainly be viewed as a

limitation. But I personally don't have any concerns about it for sites that are participating in CathPCI.

Female: Sure. Perhaps, Dr. (Masudi), do you have any idea what percentage of the PCIs that are performing in the country would get and participate in the registry at this point in time, do you know?

(Dr. Masudi): Yes, it's the last – the last reported is over 90 percent. So, it's not necessarily 90 percent of facilities participating but of the patients getting PCIs is approximately 90 percent or higher.

Female: Wow, that's really great.

Reva Winkler: All right, anything else from anybody in the workgroup about this measure and specifically the 964 which is the hospital level measure? Sana did bring up the issues with harmonization with the clinician level measure which is 24 – I'm only getting my numbers …

Male: Fifty two.

Sana Al-Khatib: 2,452.

Reva Winkler: 2,452. The clinician level measure is a new measure. And so, I don't think we need to repeat the things for which they're similar in terms of the review, but I think there are a couple of things where, you know, measuring at the facility level versus measuring at the clinician level may have differences. And so, Michael, I think this is your measure to lead, correct?

Michael Crouch: Yes.

Reva Winkler: And perhaps I don't think there's much difference on evidence, but if you have any comments, just please do, but perhaps the gap and care or the uptake for improvement.

Michael Crouch: Right. Well, from my recollection, I didn't look back at the data on the 964, but the data I thought were a little bit less high for that one than for the individual (value) which I didn't understand the difference. But the 88 percent, 88.3 – 88.29 to be focus-wise. But for average performance rate,

again, least little room for improvement. Well, modestly – modest around with improvement. So, I have the same reservation that we talk about the other one.

Aside from that, I don't have any other problems with it. It's important and there's a little bit of room for improvement. I didn't have a good feeling for what the variance – the variance was big enough to see that there were a fixed number above poor fully performing individual providers, if that's the case. Then even if the average performance is good, if there were a significant number of poor performers who could get feedback about the performance and that would improve care, it would be a worthwhile measure.

Reva Winkler: All right. Any other thoughts from any committee members?

Judd Hollander: Yes, this is Judd. I just had one question, and it looked to me that the person who was going to be tied to the, you know, success of providing the therapy was the cardiologist who did the categorization most of the time. And, you know, others on the phone may better be able to answer this than me as an emergency physician, but I wonder how often the ultimate final decision really rest with that person or how often that's changed by the person whose service the patient is on before they head home. And I'm just wondering if we're tying the therapy to the right provider.

Michael Crouch: Well, let me just make a point as well the developers. It's got to start somewhere. And our measures were pointed at the intervention list. And at the intervention list and his host – or orders includes Aspirin and P2Y12 and a statin, and we think he's in agreement with these measures. If a cardiologist or an internist or a hospitalist decides not to send someone out on one of those, then we would have another issue. But I think that our goal was to look at the intervention list and have them start with those orders.

Judd Hollander: OK, I think that's fair.

Thomas Kottke: Yes. Tom Kottke, I would agree, I mean, in our practice, those orders are never overturned.

Reva Winkler: Anybody have any issues with the reliability or validity testing at the clinician level for this measure?

Sana Al-Khatib: I do want to bring up just one point about the testing that they did in relation to 2452 where they said that in the CathPCI data, the degree of missingness in terms of the MPI which is how they're going to identify patients, I mean, physicians, and this is important because here you're attributing it to the physician. There was a really degree of missingness in relation to the MPI. They did say that this actually has improved over time and most likely they're working on, you know, continuing to improve that but that would be my hesitation is that especially because this, you know, measure is being attributed to the physician, we really need to make sure that they have accurate data on the physician's MPI.

Michael Crouch: I agree.

Reva Winkler: OK. Any other thoughts from anyone else? Michael, is there anything else on this – the clinician level version of the measure that we haven't talked about already?

Michael Crouch: Well, we already talked about the lack of match up with the previous, so I agree that the acceptance need to be harmonized one way or another and I have ambivalent thoughts about which way it's ought to go, but I think they should be harmonized.

Reva Winkler: OK. That would be certainly a discussion point when we meet as an entire committee in April.

OK. So, are we – is everyone comfortable? We've finished the discussion for the – that measure and we can move on to another one?

OK, why don't we go on to 2379, Adherence to Antiplatelet Therapy after Stent Implantation. Jeff Burton, I think this is your measure.

Jeffrey Burton: Yes. Sorry, taken off the mute there. So, this is the Adherence to Antiplatelet Therapy after Stent Implantation. They're measuring the average proportion of days covered for individuals with antiplatelet therapy during a 12-month

period following a drug-eluting stent and the bare metal stent. It's a process measure in these – new measure submitted to NQF. I think there – as far as the evidence goes, there were three practice guidelines included with notes to (QC). They did have a high gradient across one (ARD), but those type of skylines didn't specifically air directly address medication adherence, however, they did submit a systematic review where they say there's 12 studies.

And just looking at the algorithm and the nature of the studies included, I think as far as the quantity goes, there was enough study I think to rate it as high. As far as quality, there were two – there's only one actual study that was a review of two randomized trials. The rest were either cohort studies or case control. So, I think there's an ad hoc analysis in there too.

So, maybe moderate on the quality, and then the consistency, according to submission for both the stent thrombosis outcome and the other composite adverse cardiac events, half the study did point in a consistent direction in favor of the Clopidogrel continuation but did different magnitude with the other half. I did cite that there wasn't any noted effect of the Clopidogrel cessation on stent thrombosis.

So, there was a little question I feel as far as the consistency one taking all that into account as far as the evidence dose. I think there's a potential that the measure could be – they have a moderate rating. I wasn't quite sure with the rest of the committee but as far as the consistency of the evidence in this (fact) or two.

Linda Briggs: This is Linda Briggs. I have just a question about the recommendation from the PCI guideline. I do agree that the bulk of the evidence is definitely in the direction of the PQI12 being beneficial for patients. But in the PCI guidelines, for the bare metal stents that are non-ACS indications, the indication and class one recommendation is considered to be – will all be given for a minimum of one month. And then it says ideally for up to 12 months. It does not say that it should be given for 12 months. And the measure that we're talking about does say that we're looking at 12 months for both bare metal and for DEF.

Reva Winkler: Do we have anybody from the measure developer on the call?

Kyle Campbell: Yes, this is Kyle Campbell from FMQAI. We do the proportion of the measure denominator for the bare metal stents without ACS. It's about a little over – between 6 and 7 percent of the denominator. And you're correct that the guideline, you know, are not specific for this indication for – it says ideally up to 12 months instead of requiring 12 months. However, in consultation with our technical expert panel workgroup and interventional cardiologists felt that these patients should be included as well. And I don't know if, (Inaudible) DMC, are you on the line?

Male: I'm on the line.

Male: Yes, like what Kyle was saying is majority of bare metal (placed) are typically only if it's in acute coronary syndrome. Otherwise, I would say over 95 percent of the cases are getting drug eluting stent. So, this number would be very small to just – to separate the two variables.

Male: And to add to this, this is (Inaudible). It's not that the guidelines says by definition one month insufficient for bare metal stent, but it still says ideally it should fill anti platelet therapy should be continued for a year unless the risk outweighs the benefits and the risk benefit calculation is slightly different with the biometrics than compared to the drug-eluting stent, and therefore the evidence is slightly weaker. But on average, we felt it would be superior to also include those stent as opposed to excluding them on (trial).

Linda Briggs: I guess that it won't make that big a difference in compliance probably at a larger level. But if you had a single patient and you're an individual provider that you (took off) this medication for one reason or another during that time period because you thought the benefits didn't outweigh the risk, you could potentially get dinged for that even though you're well within the timeline. And that was my concern.

Kyle Campbell: Right. So, this is Kyle Campbell from FMQAI. And the other issue is this measure, we're not proposing for measurement at the individual clinician level. This would be for large physician groups, ACOs or health plans.

Linda Briggs: OK, I got that, but one of the other things under the reliability says there are only 13.3 percent of the physician groups had adequate numbers of patients for this measurement to be reliable.

Kyle Campbell: Right. So, based on those reliability threshold, if the measure were to be implemented at the physician group level, we would, you know, potentially recommend those thresholds so it would only be applicable to those physician groups within us. In this case, the denominator is covered days. So, it would only be – it would only be applicable to those physician groups within those covered days to establish reliability.

Linda Briggs: In relation to the covered days, I have a question because we're talking about the Medicare Part D patients. And Medicare Part D has that donut hole period where when people get to having used a certain amount of dollars of medication during a period of time, that there is a couple of thousand dollars gap in what this Medicare Part D will pay for. And depending on how many other medications the patient is on and how expensive they are, how quickly they get to that donut hole and how long they stay in it, how is that accounted for in terms of the proportion of days covered when it's only looking at administrative claim?

Kyle Campbell: Yes. So, there is no provision and specification for the issue related to the donut hole. I will say that the denominator, in order to get into the measure denominator, the patient have to have at least two claims for the P2Y12. And that's for a couple of different reasons. One is to establish the physician's intent, help to ensure that there's not a contraindication or adverse effect of therapy and that the individual is actually being covered under Part D. So we do have that provision in the denominator, but we don't have anything specific with regard to the donut hole. I could investigate that a little further and bring information regarding back to the full steering committee.

But this measure, I will add, is consistent with, you know, it is consistent with adherence measures, NQF endorsed adherence measures that we have in the portfolio that use Part D data for chronically administered meds.

Linda Briggs: OK. But if you're looking at a 12-month period and there isn't anything about how long the prescriptions are for either. It could be two to three months prescriptions, it could to one month prescription, you can't usually get anything more than three months at a time.

Well, I would agree to having two prescriptions makes it an established medication for the patient. You know, if you're not accounting for the patient potentially getting into the donut hole and taking for that medication on themselves – for themselves, you're not really giving credit or adherence to the medication during the time that you don't see an administrative claim for that.

Kyle Campbell: So, those (CAS) prescriptions, the one that – if the patient were in fact pained or the medication when they're in the donut hole, because that needs to be tracked by the plan, that actually will show up in the administrative claims data. But I can investigate and I'll certainly investigate your concern and provide additional information for you at the steering committee.

Male: Yes, in addition – please keep in mind that a patient has an interest that with the trans prescriptions of the track, because once they've passed through the donut hole then their prescription is really covered again that if they're in the donut hole, they have the best interest to make sure that the prescriptions are being recorded under their benefits even if they pay the full cost.

Linda Briggs: That's true, as long as they get out on the other side. But some of them may finish, they are still in the donut hole and maybe they've submitted that information and maybe they didn't.

Male: That is correct, but again there are plenty of NQF-endorsed (inaudible) measures and this belongs to the limitation of claims-based measures but on the other hand have the advantage of being very cost-effective to construct.

Reva Winkler: All right, can we suppose to say we talked about the evidence as Jeff did you want to talk about the performance gap a little bit?

Jeffrey Burton: Yes, sure. So that means value when they were looking at all four levels of the state level that are prescription drug plan level, physician group and ACOs

was 75 percent to 78 percent compared to the 80 percent proposed as critically special and in the evidence that's showing higher level rates of mortality for people with less than 80 percent compliance, I thought there was a significant gap there.

And as far as the disparities go, they provide us their information comparing age ranges and race to show that there was possibility for stratification of this measure.

Reva Winkler: OK. Thoughts from any other members?

Somebody was going to say something?

Male: I was just going to go on to the reliability.

Reva Winkler: Go ahead, show on.

Jeffrey Burton: So the signal-to-noise analysis was used. They had a 99 percent for the ACO group and for the drug planning group. I think Linda had mentioned that the physician group testing was inadequate only 13 percent of the patients that were measures. However, given the ACO and the (inaudible) plan and (inaudible) samples, obviously the 99 is a very high rating that attributes the measure.

And as far as the validity, 80 percent from the face validity which I think can only be moderate, you know and these levels I think that we can reach are given the face validity testing.

Feasibility I think was pretty straightforward, the administrative claims data, privacy claims required – and no other significant gaps and any collection was noted and then as far as exclusions go, I didn't know if the group had any – any comments on these exclusion criteria that I found it's pretty straightforward?

Sana Al-Khatib: Just a quick comment on questions – like you know in general when we talk about contraindications and the setting of a measure, we just use the word contraindication and we don't necessarily specify what we think the

contraindications are because there maybe other contraindications that you know, clinicians face in clinical practice that we may not be you know, fully, you know, that we may not comprehensively address there.

For example one thing that comes to mind is a patient who's allergic to these medications and yet if you specify that the only contraindications are peptic ulcer decease and intracranial hemorrhage and GI bleeding I think you didn't allow for any other potential contraindications that the clinicians say it in clinical practice, are there any thoughts on that?

Kyle Campbell: So this is Kyle Campbell for the measure development. I mean, we have some limitations with regard to using administrative claims to construct the measure and therefore in terms of contraindications, you know, we don't have the ability to ascertain, you know, every potential clinical scenario. That said, we felt like we had included the major contraindications as well as by requiring two prescriptions in the denominator, you know establishing a physician's intent to prescribing, continue the medication and as a patient you know, didn't have an allergy or adverse reaction, you know, with the subject themselves.

Linda Briggs: This is Linda Briggs. I'm not that well-versed in all the ICD 9 codes, but is there an ICD 9 code for hypersensitivity to a medication?

Kyle Campbell: I will have to check on that. I'm not certain, this is Kyle Campbell again from the …

Michael Crouch: There's not a great – this is Michael Crouch. There's not a great (code). There's adverse reaction to medication. There's some specifics – a few specific medications. And then, I think that the new – yes, the new disease classification coming out is going to, you know, ICD-10 is going to have much more specific. But right now, there aren't good coach to identify that especially …

(Crosstalk)

Michael Crouch: With this medication specifically.

(Tom James): Yes, this is (Tom James). The ICD-10 will be very medication-specific (inaudible) at that juncture after October.

Female: And can I erase the question regarding reliability testing that I just see here on page three, where it says that the developer reports that due to sample size issues, only a small percentage of division groups have an adequate number of patients for reliable measurement. I mean, is – does that concern other people? Because I find this a bit concerning.

Kyle Campbell: So this is – this is Kyle Campbell again for the measure developer, and that just indicates of the total sample within that – we look at 10 states for the administrative data. Within that sample, the physician groups that had enough patients to have a reliable measure were approximately 13 percent in these physician groups.

And so, as we mentioned earlier, you know, in terms of recommendations, if the measure will be implemented as a physician group, it would be recommended with the threshold to establish reliability. And so, it would apply only to the larger physician groups that have enough patients for reliable measurement. At this point, you know, in terms of where it has been to minute to the NQF map within any ACO shared savings.

Female: All right. Just to do – I think you talked a little bit about feasibility and usability. Well, is there anything else you wanted to talk about or anything else from any of the other work group members before we go on to another measure?

Male: I didn't have anything else. I didn't know if there was a comment made relating to the competing measure section. And I wasn't quite sure with the nature of how kind it was – I didn't understand what's in relation to the measure we did already cover which I've mentioned (inaudible) (PCY 12) and statin at discharged after PCI. And what if any consideration would we have?

Yes, I understand that this is looking at my patient adherence. However, if there is – if there's something we need to talk about as far as organization for possibly competition with this other measure that just to note at …

Reva Winkler: This is Reva. I think this would not be considered competing measures but related because …

Male: Yes.

Reva Winkler: Really one follows on from the other. And I think when we have the in-person meeting, we will want to take a look to see if there are – if how well the measures are formalized. And in this particular case, I think we would look at, you know, what medications are included in both measures and specify it in both measures just so that immunization is as good as it could be.

Female: OK. Anything else on matter? Can we move on to another measure? All right. And the next measure is measure 2411 PCI comprehensive documentation of indications for PCI. Linda Briggs, I think this one is yours?

Linda Briggs: Yes. I see you have that one. So, this measure was at whether within and we're using the PCI – cath PCI registry again, whether all of the indications for appropriate use are documented or a particular PCI that's been performed. And according to the appropriate use criteria, there are four – five main areas where there needs to be some information.

One is related to the patient's clinical presentation. Are they in stable angina? Are they in some kind of acute coronary syndrome, do has to do with their symptoms' severity and the Canadian classification? It is recorded within the CathPCI registry for that. And then, we use the ischemia severity and that's not invasive testing prior to PCI which includes a number of things, the various kinds of stress testing. It could be angiogram as well. And like I said, pretty much any noninvasive test.

And then, for the extent of medical therapy, two weeks prior to the patient procedure which is antianginal medications. And then, the last one is the extent of the actual disease, anatomical disease as it present on the angiogram.

So, all of the data points have to do with those by things. And I would say that one of the major assumptions that's made is that documentation then is leading to appropriate use.

And so, whether there's a direct correlation or not, we could argue that point, may deal with it later. In terms of the evidence, the evidence is two clinical practice guidelines. The first of which is the actual criteria for appropriate use of percutaneous coronary interventions. And that actually was it is a scientific method but basically it was a count of experts that were conveying to look at 180 different clinical scenarios and write down according to whether it was appropriate use of PCI or not. And then, recommendations made on that.

And that's kind of the basis for the mapping, is all of those scenarios when they talk about mappable or unmappable a little further down. The actual clinical guideline is the actual guideline for PCIs which has a great deal of studies behind it. They're not all listed in the form but if you go back and go through the actual PCI guideline, each of the indications has the citation next to it for the evidence that goes there.

And almost every one of them is – are randomized control trials or a retrospective review of patients of some kind. There's a good bit of evidence for the PCI guideline information. So, one of these criteria come from those two things, the five criteria that I talked about in the beginning come pretty much directly to the appropriate use guidelines. So, in terms of a performance gap, they talk about the proportion of unmappable.

And if you look at the proportion of unmappable, meaning, that they couldn't find within the day that element had clinical scenario that kind of came from that – those data elements that map to one of those 180 different things in the appropriate use. And that's a little bit complicated to do but I'm sure that they have created a computer program that makes that happen.

But anyway, unmappable, the mean was 41 percent unmappable. In 2012, it was a little bit better at about 36.8 as being unmappable. I think this – that amount is a reasonable amount for – to be considered a performance gap. In terms of the priority, I would say that because PCI procedures are not without risk, there are complications that can occur and there were costs that are associated with that. One of the PCI indicators, and I don't think it was this one actually, gave a number of approximately 600,000 PCIs done in like 2011.

That being said, we've seen a lot of patients and absolutely 2,000 dollars or so, a piece of a lot of money. So, I would say this is a high priority.

(Crosstalk)

Female: Those of a …

(Crosstalk)

Female: Yes, just pause and see if any up here – if work group members have anything to add on this for the first …

Linda Briggs: OK.

Female: Period, important. Anybody, evidence gap or priority?

Female: Yes. I mean, I completely agree with what was said that this is a certainly a high priority area. There's clear documentation of the gap and variation in care. I personally – I completely agree that this is an important measure.

Female: Anything else? If not, go ahead on to the next one, Linda.

Linda Briggs: OK. So, this is a composite measure. And the elements appear to support different composite. As I said, when you look back to the appropriate use document, the five criteria that I gave you map directly to that. And pretty much every data elements if you look at the PCI registry, you can see that it either literally translates or it's, you know, pretty close in terms of information that they are looking at.

So, I would say that the composite, you know, does have good construct and rationale.

Any comments on that? OK. In terms of – do you want me to go to the liability and validity next?

Female: Specifications, reliability, and validity, yes.

Linda Briggs: OK. So, in terms of the classifications, I will say that there is one element that seems to be very problematic. And I don't know what the PCI registry are thinking about doing or have done to do anything with that. But the area of missing data the most which we'll take about further down is stress test under the non-invasive.

And in some cases, I believe it is close to 30 percent of the stress data cath missing. And I think part the problem there if you look at the actual Cath registry of that, noninvasive data can go back as far as six months. And, you know, ramifications in that cath lab and – or they're admitted for their PCI. It may be that the person who's doing the data collections so if we hand that information.

And yes, the registry asked them to go back and fill that in. But there maybe some problems that particular just coming from another provider of getting that information. And then one should say yes or no, even you have to give more specifics about the – not stress that information which includes the (Dupe) treadmill information and not all cath report are noninvasive tests that will have that information on it. So, I can see how there can be a lot missing data around that we pictured particular data element.

For reliability, they use a signal to noise ratio. And for all of the reporting hospitals, entities, that did 10 or more procedures. The overall was acceptable as 77 percent or 0.77. Those who had higher volume obviously had better numbers. And for the highest 75th percent power more, it was pretty good at 89 – 0.89 too. And for anybody that did more than 50 percent of – 50 procedures I guess or the 50 – hospitals that did the 50 percent highest number of procedures, the liability was 0.84 and that's really good.

So, I thought the reliabilities was acceptable, probably moderate, for that. One thing that I did question in terms of the codes that were listed for the denominator is in this particular indicator, it only talks about codes for single vessel. And several of the other measures that we've looked at that relates to PCI, they had multiple vessels in some of the coding. So, I was wondering if the developer had anything to say about that piece?

(Crosstalk)

Male: I was under the impression when we developed this that was multiple vessels. And as you probably know, the codes changed in the beginning of 19 – of 2013. And there were specific codes for single disease. And I wonder if some of the things that either we mentioned or you looked at were old codes?

Female: They were ICD-9 codes rather than 10.

Male: No, no. They're not – it's not ICD-9 or 10. It's procedural codes, CPT codes.

Female: OK. They're both included actually and they don't list them as CPT codes. They list them as N something code? Just what was sent to us was this particular indicator anyway.

Male: If someone could scroll that down so I can see the codes?

Female: Look at the denominator information. I think that's where the codes are. While they're doing that, I would say that talking about validity, it didn't have – this is base validity and it had high base validity at 93.8 percent.

(Vermaji Demoto): This is (Vermaji Demoto), the one of the developers along with (Carl Tumasa), and I agree with him that if that wasn't the case, there is probably just something that we can easily correct and address. The other point that you mentioned …

Female: OK.

(Vermaji Demoto): I just wanted to briefly talk about just number one there is an algorithm that's specifically set up for determining the unmappable rates. And so, that's clear. But that's something we need to make better in the application as well.

And then the final thing you mentioned which is really important, you know, which is this idea of like let's say older data that might not necessarily be available, like a stress test? I think at some way, that's actually the motivation for the measure is that, you know, again, this is the type of information that should be available to an interventionalist before they do a procedure.

And something like the stress test even if it's a few months old and it's something that they might know, it really does need to be a part of the record especially as we think more about documenting appropriateness and being able to evaluate the need and values of these procedures.

(Crosstalk)

Female: I would agree that the information is important. But I'm just wondering if there's a way to capture that information that, you know, maybe you need to flag those that are not – that are coming through that don't have it? Doesn't – it gets kicked back earlier in the process for people to get that information? But it looks to me from this slide as if the information is done for that hospitalization, there's – if the data isn't there, there isn't anybody going back necessarily to retrieve that information sort of after the fact. That may not be true but, you know, it looks that that particular piece in particular.

(Vermaji Demoto): No, you're absolutely right. And in fact like you have part of the challenge is that, you know – and sometimes this gets done in an outpatient setting. They get done at a clinician's office. It might not even be the individual who's doing the catheterization.

And so, you're absolutely right in terms of a (inaudible) whether or not it's captured. That, I think, in some ways why we kind of thought that the document prior to the procedure being done is kind of the place where all this information needs to be aggregated at least in one spot on the record. And this will actually align with – here's another document that's not obviously ready at the time of the submission for this, but a health policy statement that's also arguing again about the ideas of standardizing documentation.

So, it's not just that this information isn't available on the registry first, you know, for example. A shift that it's not being documented anywhere within the record a week in time at the time of this PCI being performed.

Sana Al-Khatib: OK. Could I ask a couple of questions? I think these are directed to the developer. I actually have a lot of experience with the ICD registry which is one of the NCDR registries. So, I don't have as much experience with

CathPCI, but at least our experience with the ICD registry is that unless the record that you're completing on a particular patient is complete.

You know, meaning, that if you don't have any missing data, we cannot submit the form. But given that you do have some missing data here, does this mean that, you know, it's OK for, you know, sites not to complete all the form before they submit? I'm not sure how that works out or plays out with the CathPCI.

Male: The data may not be as expensive as we would like it, and that we have some reasons …

Sana Al-Khatib: OK.

Male: … of these measures here.

Sana Al-Khatib: OK.

Male: This data…

Sana Al-Khatib: OK.

Male: … maybe is was the stress test done …

Sana Al-Khatib: But, they don't provide you with the details, I see, OK, OK. And then the other question I have for you is, since this measure is intended for use for all types of PCI, why was the testing limited to elective PCIs and didn't include the urgent and the other situations where a PCI may be done.

Male: If you look at the registry for acute coronary syndrome and STEMIs, that it's almost a 100 percent in agreement with the AUC. If you look at the patients who are elective, there's probably anywhere between 25 and 35 percent depending on which quarter we look at of inappropriate or not appropriate procedures being performed in the elective arena.

Female: Where did you see that it's only for elective?

Sana Al-Khatib: On page three, I believe, trying to find where this was mentioned.

Female: It does mention that the cath sample was totally on elective …

Sana Al-Khatib: The testing was just (inaudible).

Female: But the measure is for everybody.

Sana Al-Khatib: Exactly. That's exactly my point, yes.

Female: Yes, yes.

(Crosstalk)

Female: Another important point related to acute versus the elective is that you need less criteria to meet one of the scenarios where the acute phase. So, you don't get to the point where you actually have to give them any stress test to you. So, you know, that kind of piece – that piece completely falls out and if they have ST elevation or they have ST depression in an unstable angina or whatever, that meets one of the mappable things and they go on and you know, they satisfy the criteria for appropriate use, whereas, these other patients that are elective, they have to have more documentation about why it's appropriate or not appropriate.

Male: That's absolutely right. And I think one of the reasons why we focused the testing sample on just the electives was to emphasize that, you know, that that particular aspect of it.

If I could go back to our previous discussions, looking at the CPT codes, there should be a nine to nine to nine which is an additional branch or additional vessel. And we can certainly add that.

Female: Yes. And if it is there, I didn't see it and I kind of really look for it, because like I said, as going through the other indicators measures that we were looking at, I didn't see them coded and I didn't see it in the set.

Male: The nine to nine to nine should be added.

Female: OK. Anything further on the testing reliability and validity of this measure? And Linda how about the feasibility-usability criteria?

Linda Briggs: OK, for anybody using the CathPCI registry I think it's perfectly feasible to do this study. And again, for those places that are not which apparently are fairly small number of facilities at this point, collecting the data could be a little bit more for some of the reason that we just talk about in terms of getting all that critical data that you want including all the different parts of the stress information that they want.

I do think that it's, you know, important quality data. I know that in Baltimore we had a very serious problem with inappropriate use, and that that may had been one of the things that has been a few years back now that kind of help us fund appropriate use criteria for this and a number of other things. But I think it is an important thing to do and it's a good indicator, again, quality of role if you're at least few things appropriate criteria for taking care of your patient.

Male: To address one of your points, one of the close common reasons for not belonging to NCDR is the institution is already covered by a mandatory state reporting system. So a lot these laboratories in Pennsylvania, New York, Massachusetts don't belong to NCDR because they're already reporting to the station and similar data is reported by the state.

Female: Very interesting.

Female: OK, anything else on this measure that anybody on the work group wants to bring up? OK, then it sound that we can move to our last measure which is 2459, In-hospital Risk Adjusted Rate of Bleeding Events for patient undergoing PCI. Sana and Nicolas, this is your measure. Sana, did you want to introduce it? Nicolas, feel free to jump in.

Sana Al-Khatib: Absolutely, that sounds good. So, as stated, this is related to In-hospital Risk Adjusted Rate of Bleeding Events for patients undergoing PCI, the numerator as proposed by the developer is all patients18 years of age and older undergoing PCI and develop those PCI bleeding. And the way they define bleeding is either a bleeding event within 72 hours in all definition use a 3 gram per deciliter or greater drop in hemoglobin or transfusion or an

intervention was done to stop the bleeding, or hemorrhagic stroke or tamponade or piece post PCI transfusion is the way they list it here.

In terms of the exclusions, they say NCDR registry patients who do not have a PCI and they – you know, this explains that there are also some patients who just have diagnostic (cast) only during that admission. And of course who died on the same day of the procedure, patient who had CABG during the admission and patients who had pre-procedure hemoglobin of less than eight, so they were severely anemic.

I personally did not fully understand the rationale for this number four exclusion of patients with pre-procedure hemoglobin of less than eight but I suspect that touches small number of patients that I wasn't too bothered by it. The denominator is all patients who are 18 years of age and older undergoing PCI.

The level of this measure is the facility and unlike all the measures that we discussed today this is an outcome measure, and it will also what use the CathPCI registry.

In terms of the importance of this measure I think it's pretty important. The question – I mean these are certainly, you know, complications that we see after the procedure and anything we can do to lower this risk as much as possible I think would be really good and will impact patient care positively.

If we look at the gap in care, the developers look at that and they said that the rate of significant bleeding in the studies that they did was 5.5 to 5.6 percent, which I actually think is more than what I would have wanted to see but they also say the developer indicated that the distribution of these bleeding events was significant in that at some sites, you know, they saw really excellent performance where the rate was lower – significantly lower than that. And at the other sites where they said that the rates of bleeding were 80 percent greater then expected.

So, it looks likes this major variation in outcomes that they observed in their study certainly justifies the existence of this measure. So I think at this point

I'll stop and see if other people want to add anything regarding the significance or the depth in care.

Female: (Inaudible). Nicholas, did have any comments? You're the secondary for this one. Hey, why we don't we move on to scientific acceptability.

Sana Al-Khatib: OK. So, when we look at, you know, the scientific acceptability of this I think it's pretty – very, very reasonable in terms of, you know, what they're proposing in the different components of the measure. As I said in terms of their specifications, those certainly make sense to me except for that one exception. But as I said those patients who had a – who were severely anemic at baseline, again, I don't think that those will constitute an appreciable number by any stretch of the imagination. So I felt overall the construct of the measure was very reasonable, very much in line with the accepted definitions in our field for major bleeding. They're complicating again these types of interventions.

When we get to the testing updated, I think they did everything they could to think I have some questions about the methodology that I raised in what I submitted you know, online. And one thing that I wasn't sure on is understanding the number of patients on whom data on bleeding were missing. They may have provided that number in the documents but I look everywhere and I couldn't find it, so trying to understand that number from the developer for me would be helpful. And, you know, as I mentioned in terms of how do they define major bleeding, there different components that constituted major bleeding.

So I think it would be interesting to know like which of these components if they had missing data, was there one that had more missing data than others and how they would propose to address that.

The other issue that I saw because they modeled and to adjust for different potential confounders in terms of looking at the major bleeding as an outcome, the left ventricular ejection fraction was one of the covariance that they use. And the degree of missingness for the EF was pretty high. So it was not clear to me how they would address that at least with the methodology that

they used if they imputed and what type of imputing they did when it come to, you know, being practical in how this could be implemented even within the CathPCI registry if the EF is going to be one of the covariance that they will be adjusting for in the risk adjustment.

I think it will be important for us to know how they planned to address this issue with missingness.

And so, the last piece that I had with regard to the testing is the weighting system that they used in terms of how, you know, what weight they gave the different components of this.

I didn't see that I fully understood their waiting system. I think it would be good to have a weighting system but understanding what exactly is and what data support the weighting system I think will be key.

Female: Measure developers want to respond to Sana's question?

Male: Yes. Sure. In terms of individuals that's missing bleeding data is outlined in the paper that I report the bleeding model, the missingness is about 0.4 percent, so potentially negligible. But the point score system is also a delineated within that paper which I'd be happy to forward on to the group if you would like, basically based on a regression analysis within standard methodology.

Female: Sana submitted with the whole package?

Male: I'm sorry. Go ahead.

Female: It was one of the site patients.

Sana Al-Khatib: OK.

Female: I just look at that.

Sana Al-Khatib: I would love to see that and have the opportunity to review that as well. And (Fred), the last comment with regard to the degree of missingness for the ejection fraction which was I think close to 28, 30 percent something like that.

Male: Right.

Sana Al-Khatib: What's your response on that?

Male: So, according to the methodology the missing values were imputed to the lower risk groups for discrete variables were placed with (inaudible) medians for BMI (inaudible) renal failure and so on.

Sana Al-Khatib: OK. All right thank you.

Female: Nicholas, did you have any comments about this measure? Still with us?

Sana Al-Khatib: Maybe not.

Female: OK. Anybody else on the workgroup wanted to talk about anything around the specifications, the risk adjustment model, the testing for reliability and validity?

OK. Sana, perhaps anything else from you if not we can go on to the remaining criteria of feasibility and usability.

Sana Al-Khatib: I'm ready to move on to feasibility. I don't have anything additional.

Male: Apparently, the paper was included with the application material.

Sana Al-Khatib: Sorry, I missed that.

Male: I just got a message that that was the OK.

Female: OK, let me verify, because they should be up on the SharePoint site with your document sets for each measure but we will double check to be sure that is there.

Sana Al-Khatib: OK. Sounds good. Thank you. And then in terms of feasibility, usability and use, you know, within CathPCI, again, this should be – it should be certainly feasible. I don't see any concerns about feasibility, usability and use especially for the sites that used CathPCI. And it was very good to hear that actually that and most likely captures the vast majority of the sites so, you know, I have no concerns about those.

Female: Anybody else?

Reva Winkler: All right. Well, this has been a terrific discussion and a timely one as well. Thank you everybody for focusing and getting it through all six measures. I don't have anything more to add. The purpose of this was to allow the committee members, the workgroup members to share you initial thought.

Thank you all for the work that you did ahead of time in submitting your comments. As I mentioned those comments have been entered into the worksheet so if you go back into SharePoint into your document sets you'll find that this new information is now part of those documents, and there's a lot of rich comments that your colleagues have provided.

I'm going to turn it over to Wunmi now to just talk about next step. Certainly, we're having three more workgroup calls. All committee members are welcome to attend all of the calls. I know your time doesn't allow you but certainly you're welcome to do so if possible. And then we'll be preparing for in-person meeting in April. So Wunmi just want to talk about the next steps?

Wunmi Isijola: Definitely. Thank you again everyone for participating on the workgroup. And we do think that this is very insightful moving forward in this project. As Reva mentioned, we do have three other calls. Our next working call is on March 20th on Thursdays and 12:00 to 2:00. So you are more than welcome to take part in that. Also, just a lot of the conversation that took place today, we will be incorporating some summaries based on this call and others within the measures set. So if you do want to reference any of the information we will be including that in the measure sets as well.

So if there are any questions before we close out? OK.

Female: This is the – I do have a public comments from (Zel Drexlex).

Wunmi Isijola: All right. OK. My apologies.

Female: As he (inaudible) on the line measure is – pertaining to measure 0289.

Wunmi Isijola: OK. And, if you want to go ahead and read that?

Female: Well, (inaudible) is on the line, if he is then I can let him (inaudible).

Reva Winkler: Yes, we should have all the lines open in case there are other public comments. My apologies.

Female: I guess I can read that. What he stated, Dr. (Hollander) made the point that some facilities may have a policy of doing an ECG on anyone who walks through the door with pain from the top of the abdomen.

I would agree that this may happen but would argue that this would represent an unintended consequence of measure implementation rather than a problem with the measure. The denominator for this measure as the time inspect is those patients with possible cardiac testing. It is left to the hospital to define those patients.

Female: Is there anyone else that might some other public comments, folks that have been listening?

OK. All right, Wunmi, I think we're good there.

Female: Yes.

Wunmi Isijola: OK. Well, thank you all again for participating and we look forward to speaking with you again.

Male: Thank you.

Female: Thank you, everybody.

Female: Bye-bye.

Male: Bye-bye. Thank you. Thank you. Bye.

Female: Thank you.

Male: Thanks.

Male: Thanks.

Operator: Thank you. This concludes today's conference call. You may now disconnect.

END