

NATIONAL QUALITY FORUM

Moderator: Karen Johnson
June 4, 2012
3:00 p.m. ET

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

Suzanne Theberge: Good afternoon, everyone and welcome to the Neurology Endorsement Maintenance Workgroup One Conference Call. Thank you for joining us this afternoon. This is Suzanne Theberge at NQF. I'm joined by Karen Johnson, (Jessica) and (Reva).

And before we get started, we just like to have everybody do a quick roll call and let us know who's on the line and then we'll get started on the measure discussion.

OK, I think we have Gwen Buhr on the line.

Gwendolen Buhr: Yes.

Suzanne Theberge: OK. Salina Waddy?

Salina Waddy: Yes.

Suzanne Theberge: OK, Michael Kaplitt?

Michael Kaplitt: Yes.

Suzanne Theberge: Jocelyn Bautista?

Jocelyn Bautista: Yes.

Suzanne Theberge: Jack Scariano?

Jack Scariano: Yes.

Suzanne Theberge: Are there any other Steering Committee members on the line?

OK, and then we have (Karen) from the Joint Commission?

(Karen): Here.

Suzanne Theberge: OK and (Karen) from the American Academy of Neurology?

No. Sorry, was it Rebecca from AAN? At least somebody from AAN.

Rebecca Swain-Eng: Yes, there are three of us from AAN, Rebecca Swain-Eng, Sarah Tonn and Gina Gjorvad. Thank you.

Suzanne Theberge: OK, sorry. And then do we have anybody from AMA PCPI? All right, well hopefully, they'll join us shortly.

All right, I'm going to turn the call over to Karen to get us started on the measure discussion.

Karen Johnson: OK. Thanks, everybody for dialing in and joining our call. And thank you even more for taking the time to look at these measures in your workgroup and complete the preliminary evaluations.

So, what we're going to do on today's call is get us through six measures and we have pretty much about 15 minutes per measure, so not a lot of time, but hopefully the aggregated results that (Jessica) sent out or Suzanne sent out a little earlier will be helpful for our discussion today.

So, what we've asked each of you to do is (briefly) discuss it for one of the measures. So, as we discuss that, you will very quickly summarize the measure itself and also summarize the leading from the rationale and highlight the areas of concerns.

So, we don't really need you to highlight the places where everybody is in agreement. It's really the places where things are maybe either or not in agreement or things that are puzzling to you, that sort of thing.

We also ask you to focus on the must-have criteria for the most part. Again, that is because of our time limitations. And for the first one since it will be – the first one will be a little harder we'll definitely help you through that first one and kind of give you some little hints on how to go forward on that.

After the summary what we'll do in the different parts of the discussion is just to ask the Steering Committee workgroup members to discuss anything that they want to discuss and if you have questions that you would like to address to the developers, you can certainly do that. And the developers have been nice enough to join us on the call and they will be able to answer, I'm sure many other questions that you may have.

Again, we do have about 15 minutes per measure. So, it will go pretty fast. Our role here at NQF today is kind of threefold. One is to help. Formally, we need to clarify the criteria and the guidance for the evaluation. We're going to help you along with time.

So, we may have to interject from time if things are getting a little bit maybe too much of a tangent on something. And also, again, just to kind of keep you on track and help you do your summaries and that sort of thing. And we are very lucky today to have (Reva) here. (Reva) has done this many, many times and really have a good hand on how this workgroup call should go. So, I'm sure (Reva) will be helping us out very much on this and I'm very pleased that she could make the call with us today.

So, with that I think we'll go ahead and start with the first measure. The first measure that we have on our list today is 0434 it's the Joint Commission measure on VTE prophylaxis. And Dr. Bautista is – lead discussions on that.

So, if you don't mind, would you, on this one Dr. Bautista, go ahead and summarize your initial thoughts or first introduce the measure quickly and then let's start our discussion with your ideas, thoughts and the results from the preliminary evaluation around importance.

Jocelyn Bautista: OK. So, this is a measure that is capturing the percent of ischemic or hemorrhagic stroke patients who either receive prophylaxis for VTE or who have documentation why prophylaxis was not given by the day after hospital admission, so within those first two days. And it is a measure that is part of seven other measures addressing stroke care.

There are a number of exclusions. So, this is only for adults, only for patients who have a length of stay of more than two days and less than 120 days.

And it seeks to exclude patients who are on comfort care, who have been enrolled in clinical trials and who have been admitted for elective surgical intervention such as carotid surgery.

So, moving to review some importance to measure, I think there's four of us reviewed our submitted evaluations and we all thought it was at least moderate, three voted moderate – three voted high and one voted moderate as events of importance.

Stroke is common and VTE is estimated to affect about one percent of stroke patients. And for the performance gap, similarly two voted high, one moderate in terms of evidence or a performance gap. Current performance is about 90 percent.

I actually am the one outlier who said moderate for these two initial issues because while stroke is common, VTE really only does affect one percent of stroke patients and current performance is fairly high already at 90 percent.

So, in terms of evidence we all thought there was a great deal in terms of quantity with evidence. Quality wise, there is good evidence for pharmacological prophylaxis and effectiveness of that. There is rather limited evidence that non-pharmacological prophylaxis is equally as effective and consistency sort of mimics that three, two was rated at high, one moderate.

But I think for the most part, we all thought there was evidence for importance for measure and report.

Karen Johnson: OK, great, thank you. Does anybody else on the Steering Committee has anything to add in terms of what you were thinking about or what maybe jumped out of you and thinking about importance either impact or gap or evidence?

Michael Kaplitt: Well, this is Michael Kaplitt. I guess the only question I have when I was doing this, you know, I think I know the answer to this is, you know, I guess one of the issues with impact or important is not just how important the thing is but how much of an opportunity there is for improvement I guess is the key part of this process, at least that's my understanding of it.

Karen Johnson: Correct.

Michael Kaplitt: And the one thing that I guess I had a hard time with is understanding when kind of an opportunity for improvement is, you know, when that limit has reached. I mean some of these measures, there is clear evidence and some of these measures, you know, is evidence that you're reaching about 90 percent or so as she just said.

And I mean I guess it's just somewhat subjective thing. I mean I think that I personally gave my scores because I think this is important enough that, you know, we want to get as close to 100 percent as we can.

But, I mean, how do you know – how are we supposed to know where there's like a two percent disparity versus a 5 percent versus 50 percent is what really matters is that, you know – that's what I have a little bit of a hard time with.

(Reva Winkler): Sure. This is (Reva). In general, you're not alone. This is a common discussion point with Steering Committees and you're right, it is a certain amount of subjectivity here.

I think that if you kind of pull together your general experience and expertise is really what we're asking for. And as you said this is such an important process of care, perhaps even, you know, small percentage movement will impact significant enough numbers of people that maintaining the measure is worthwhile.

So, those are the kind of input we're asking from you. There is no – there are no absolute threshold. There are no absolute numbers. So, it really is a great deal of your subjective assessment of it.

Michael Kaplitt: OK.

(Lionet): And this is – this is (Lionet). I was the one that said no for (inaudible) importance largely because we are almost there and would you rather people spend additional time on measures where there can be a larger – where there is more of a need in terms of gathering all this information and having the physicians document as much.

(Reva Winkler): Again, I think this is – these are kinds of things that we're looking for you all to help us come to terms with. So, please factor in all of these different ideas as you're evaluating the measure.

(Lionet): So, I think I have a question largely about the overall process. Once we go through these, will we be prioritizing them?

(Reva Winkler): What you're going to do is this is the first patch review to help really identify main issues and get questions out to the measure developers. We're preparing for this in-person Steering Committee meeting later this month.

At that time, the discussion of each of these measures will include the entire members of the Steering Committee and you will vote on each of these measures independently.

(Lionet): OK.

(Reva Winkler): Anybody else have anything to add on the importance criteria? Do you feel that the summary of preliminary reviews pretty much reflects how you feel about the measure?

(Lionet): I did.

(Reva Winkler): OK, all right. If you don't have anything more to add, I'm out. Let's move on to scientific acceptability. Dr. Bautista, do you want to kind of summarize where you think we are on that?

Jocelyn Bautista: Sure, I think we were unanimous here, four voted yes and no nos. So, reliability, there were some questions regarding the exclusions that are not consistent with the evidence.

So, I am – I'm going to have to assume that they're referring to things like length of stay graded in 120 days and patients being excluded because they're admitted for like their (carotid) intervention.

My take on the exclusion though is that they seem reasonable even if there's no clear evidence for them. And the developers do make an argument that they since this one metric is part of a set, those eight metrics addressing stroke care, they've used the same exclusions for all of the metrics to keep them consistent. But there weren't any other concerns that I ...

(Lionet): Any other thoughts from other committee members in terms of reliability?

One thing I was looking at and I'd appreciate your input in is when you look at the specifications and the numerator, you have sort of a combination of patients. You have patients who actually received the prophylaxis which is the desired action, but also the patients who had a – had a documentation that no prophylaxis was given.

How do you interpret a result like that when it's sort of a mixture?

Jocelyn Bautista: You have an interesting question. I mean I guess it all depends on what you're ultimately after. If you're just ultimately after a metric that gives you a percent of patients treated appropriately regardless of whether they actually received the prophylaxis or whether they were appropriately deemed to not to require the prophylaxis, then this gives it to you that way.

It obviously wouldn't be able to give you the two subsets, those patients who actually did receive prophylaxis versus those who were deemed not to require it.

I mean it also doesn't give you the reason, the various acceptable reasons, so people could just put in any reason why they're not giving prophylaxis.

Female: There is, I mean there is additional documentation not explicitly detailed in this document that gives the coders very specific guidelines of what's acceptable and what's not. I actually asked for that and I don't have it at the (inaudible) of my fingers, but there is a dated

dictionary that list what exclusions are acceptable or what reasons are acceptable. They allow patient refusal as an acceptable reason.

(Reva Winkler): Yes. Do you have any questions on the measure developers around any of these issues?

Michael Kaplitt: Well, the question I have about the numerator. I'm not so bothered by the documentation of the reason part because, you know, presumably the goal here, I assume, is to get most people to try to at least implement this as best as they can. So, if someone thought about it, thought that there was a good reason medically or whatever why they didn't want to do it in their medical judgment, I don't have a problem with that as long as they document it and didn't just ignore the subject.

I mean it's the same thing when we document for PQRI for example, you know, whether or not you use antibiotics. If someone comes in for surgery for an abscess, you don't give them antibiotics before surgery because you want to get a sample. You document why. So, there's a good reason and that's fine.

My question is more about the statement on to the prophylaxis section of the numerator where I don't understand the last part after eight, then it says, A, none of the above or not documented or unable to determine from medical record documentation. I didn't totally understand that.

Jocelyn Bautista: I'm sorry, where are you referring?

Michael Kaplitt: In the numerator detail which is I thought we were talking about?

Jocelyn Bautista: Do you have a page number?

Michael Kaplitt: Page 12.

(Lionet): The problem with that is, I mean, there are – there are certainly are good reasons, but then there are reasons that are sort of questionable. And I think that those are some of the ones that may need to be flushed out from.

So, for example if someone has the ischemic stroke and then this hemorrhagic conversation but it's a tiny amount and they have a VTE, some people would treat and some people wouldn't. So, I feel, you know, both would feel justified.

Michael Kaplitt: Right, I mean I guess it depends – OK, so, I mean, the problem is we could come up with a whole lot of complex scenarios, right, that, you know, ultimately the people on the ground they're going to have to make decisions.

I agree with you that some decisions are just bad decisions, are not justified by medical evidence and maybe – so it shouldn't be allowable as acceptable decisions.

(Lionet): Or at least – or perhaps for things like that, there should be a basic category so that we know why – specifically why people are not being treated.

Michael Kaplitt: Well, that's why I think that at least enforcing the documentation, you know – you know, not just documenting that they didn't get it, but why at least provide some, you know, something.

(Lionet): And I do agree with that. But I would kind of go one step further and perhaps have, you know, a few of the leading reasons one. And then you can always have other box, but just to be certain that you're ...

Michael Kaplitt: So, let's take – so, to take your example, you could – let's take the opposite situation, someone comes in, they have a very large hemorrhagic conversion and they need to go to surgery, they need to evacuate it.

So, until, you know, until things are stabilized there after surgery, let's say the next morning or something you're not going to start, you know, even low dose anticoagulation but if things are stable, you might start (something) or whatever. So, you'd say, well you could use venous blood pumps, right, which is suppose of us would do.

(Lionet): Right. Yes.

Michael Kaplitt: So, let's say, for some reason, let's say this patient had been, you know, bed bound, wheelchair bound, whatever and had a documented DVT and you don't have time to put in a filter or something because you have to take him to surgery. So, you're not going to do it. You're not going to do any anticoagulation because it's just – that's the way it is.

And then you'll do it later on, but you would document that, right? And most people would agree there's nothing wrong with that.

(Lionet): Right.

Michael Kaplitt: So, I guess my question was still – I mean unless I'm on the wrong one, one. We're on the (SPK) 01, right?

Jocelyn Bautista: Yes.

Michael Kaplitt: 434? So page 12 in that second bullet where it lists the types of VTE prophylaxis that are acceptable, that last sentence, I'm just confused.

Female: Is someone from the Joint Commission able to explain that?

(Reva Winkler): Sure. I'm looking, you said on page 12, what section are you looking at specifically?

(Lionet): Numerator details, 2A-1.3.

(Reva Winkler): OK. Let me just take a look exactly, my pages aren't numbered the same as yours, 2A-1.3 and you're looking at (inaudible) prophylaxis, correct?

Michael Kaplitt: Yes, the second bullet, correct, on that last sentence.

(Reva Winkler): Yes, how the measure works is that for the algorithm, the flow logic for the measure, we're looking for VTE prophylaxis to be administered within the first two days either the day of admission or the day after admission.

What's you're seeing are the allowable values which would allow you to be included in the numerator and they are as numbered. Number one, if you'd select at it with low dose and fractionated (inaudible) ...

Michael Kaplitt: So, I think – I think we will get the various – those various, I'm asking specifically about that last sentence.

(Reva Winkler): Yes.

Michael Kaplitt: After number eight which says none of the above or not documented or unable to determine for the medical record?

(Reva Winkler): Correct. That means that the patient did not receive any of those allowable values one through eight during that two-day period. If they received no prophylaxis, you would select A and then you would have to have a documented reason in order to be included in the numerator.

If you do not have a documented reason, then you would be in the denominator, but you would not be in the numerator. And as Dr. Bautista had mentioned, she reviewed the data element definition for reason for no VTE prophylaxis hospital admission, they provide – they have extracted with the details as to when they are allowed to select "Yes" for a reason data element.

If patient refused, you would be allowed to select "Yes." If there is a reason such as your hemorrhagic conversion where there was a reason for no pharmacological prophylaxis, we would require a reason for no mechanical prophylaxis to select "Yes" because the expectation would be that a pharmacological would contraindicate it. You would administer mechanical unless you documented a reason for no mechanical.

Or if the physician simply documented this in your surgery care, no VTE prophylaxis or whole VTE prophylaxis on the day of admission, let's say if the patient was going through surgery, that would also be an acceptable reason. But there is a very clear guidelines what would be acceptable reason documentation for inclusion in the numerator.

Does that answer your question?

Michael Kaplitt: Yes, that's totally fine. I just didn't know how A was being used because it wasn't clear to me from the subsequent pages. So, now I understand.

(Reva Winkler): All right, how does everybody feel in terms of the ratings for reliability and validity, the testing information that was provided to you, are there any issues you'd like to raise and discuss further? No.

All right. In the interest of time, why don't we ask Dr. Bautista to go ahead and summarize the thoughts on these remaining criteria of usability and feasibility?

Jocelyn Bautista: OK. So, on usability, again, out of the four of us, two rated this high and two medium. Again, the issue of exclusions and exceptions, I do think because so much of this relies on chart obstruction that it – that that limits the usability as opposed to, you know, discreet data elements.

Karen Johnson: Does anybody else have any thing to say on the usability or feasibility?

(Reva Winkler): Does anyone on the workgroup have experience with using this measure in your facility?

Jocelyn Bautista: Yes.

(Reva Winkler): OK. Any personal experience about it or issues you'd like to share?

Jocelyn Bautista: I think the documentation is probably the biggest issue not having the doctor's document why they're not using prophylaxis. There's not a common thing in practice. If something is so obvious to you, you don't automatically document why you're not doing something. So, that's an issue.

(Reva Winkler): Just to pick up on something that you mentioned in terms of the evidence. The measure allows for both pharmacologic and mechanical prophylaxis, is that consistent with the evidence?

Jocelyn Bautista: I'm sorry, ask the question one more time?

(Reva Winkler): The measure gives credit for either pharmacologic or mechanical prophylaxis. And is that consistent with the evidence that you felt was strong?

Jocelyn Bautista: Well there's strong evidence pharmacological. There's less strong evidence for mechanical. But mechanical is probably still better than nothing and that's the only thing we have when you can't use pharmacological, so.

(Reva Winkler): OK. Any other thoughts? So, any other concerns about how this measure meets the criteria that you'd like to further ask any questions about the developer – from the developer? If not, in the interest of time, we probably ought to move on to the next measure which looks a whole lot like the one we just were talking about which is measure 240.

Just to emphasize, the first measure that we were talking about from the Joint Commission is the level of analysis is at the hospital. This next measure, very, very similar, again, DVT prophylaxis for ischemic or intracranial hemorrhage stroke, this is for a clinician level, either individual or group level practice.

So, who's the ...

Karen Johnson: Dr. Scariano?

(Reva Winkler): Is Dr. Scariano with us?

Jack Scariano: Yes.

(Reva Winkler): Why don't you go ahead and just introduce the measure briefly and then give us your thoughts on the importance criteria.

Jack Scariano: So, now I'm going over the actual educational (area), you know, new aspect of it. And I think that the – that the pre (probe) area of education but also the actual post (probe) education. And I think that the post (probe) education is not being ...

Karen Johnson: I think he's discussing a different measure isn't he?

(Reva Winkler): Yes. The measure we really want to be talking about right now is ...

Jack Scariano: Oh, I thought I was talking about my measure.

(Reva Winkler): Well, I'm just looking at the assignments. Does someone else – who was assigned measure 240?

The piece of paper I have has status, has Dr. Scariano assigned to it. So, perhaps we had a miscommunication somewhere.

Jack Scariano: Let me check that again here. It didn't say 240, I don't think. It had me assigned to a 440.

(Reva Winkler): OK, all right. Does anybody in the workgroup feel that they could talk about measure 240 so we can keep rolling? All right, how about if I help out by sort of introducing the measure.

This is, again, a very similar measure on DVT prophylaxis or ischemic or hemorrhagic stroke. This is from a PCPI. This is for patients 18 years and older but again it is at the clinician level either the group or individual.

I think the primary difference is in this measure because we're talking about sort of the same process of care, the evidence should be the same. We'll be very specifically at the measure specification.

This is – the numerator I think is very similar to the previous one and patients who were administered prophylaxis by the end of the hospital day two. Denominator is patients with stroke, but the exclusions are two documentation medical reasons for not administering and documentation patient reason for not administering.

The (fees) are used as denominator exclusions rather than being included as numerator compliance kit. So, there is a significant difference in how this measure is calculated even though it's trying to measure essentially the same thing.

One of the workgroup members who want to talk about the discussion or the evaluations from the group?

Jocelyn Bautista: Sure, I can do that.

(Reva Winkler): Thank you.

Jack Scariano: Jocelyn Bautista. So, I've spent a lot of time reviewing this measure since it is so similar to 434. I think there are a couple of important differences in the exclusion that this measure 240 does not exclude patients admitted for elective surgical procedures like the carotid intervention.

And then I can't remember if it excludes clinical trial patients, but there were a few differences in the exclusion. But I think still, I mean as you said, the evidence is the same, so the important to measure criteria and the quantity and quality of the evidence is going to line up pretty similarly with the other measure.

I think you will get more information perhaps from this in terms of reasons because I think they capture the reasons a little bit better in terms of why a patient isn't given prophylaxis.

(Reva Winkler): In terms of scientific acceptability of this measure are – do you have any thoughts on the way the measure is testified and the testing for reliability and validity?

Karen Johnson: And this is Karen just to point out a couple of things about the intuitive guidelines and how you rate things. They tested this measure at a data element level, that's home page 11 through 12 of the measure. And they tell you the difference and they do numerator and denominator and they talk about their exceptions.

And they tested it all three of those and give you some CAPA specifics. And they're pretty good CAPA specifics. But what that is there is data element reliability testing. So, according to our guidance, they have tested at data element level but not at both element and measure score level.

So, for this measure moderate would be the highest rating that this measure would be eligible for on reliability. And then for validity, they tell you that they do face validity of the measure and they do a really nice job of telling you who is on their expert panel and how they did the systematic testing. And then they give you the actual question that they ask and the languages of what the different experts responded in terms of that.

They do give you details about that face validity. But then again according to NQF guidance, face validity is accepted, but to have gotten a high level of waiting for this measure they would need to show you testing at both the data element level and the measure score level in addition to this face validity.

So, again, this is a place where moderate would be the highest rating that this measure would be eligible for based on the information that they've provided in the submission.

So, does that make sense on how the ratings would go? No questions at all huh? All right, shall we go on to usability? Any questions or any discussion about usability or even feasibility of this measure?

I notice that someone on the final assessment for either to the (inaudible) endorsement, someone had said no on this one. Maybe if the person who said no is on the line, maybe could you just say why you thought maybe not?

Gwendolen Buhr: This is Gwen Buhr. I think I have said no on that one because I was thinking that as combining the non-pharmacologic and the pharmacologic and there isn't strong evidence for the non-pharmacologic.

And the way that the evidence was presented in this one, it didn't – it wasn't presented as well as the other one that's very similar. That's why I read the second one the one we talked about first, it was clear to me about the evidence. But just reading the evidence presented here, it didn't – it didn't seem all that strong of evidence.

Karen Johnson: OK, thank you.

(Reva Winkler): Any other thoughts about the individual measure? Now, one of the things we're not really talking about today, but will be a large part of the in-person meeting will be the fact that we've got two measures that are very, very similar.

If they're definitely related and that they're measuring the same process of care in the same patient population, so competing perhaps not so much because the level of analysis is one is a hospital and one is a clinician level of measure.

However, when you have two measures that are very – that are essentially alike like that at different levels of analysis, it's really essential that they're harmonized. And so the question I would ask to measure developers is to what degree what you harmonized these two majors realizing that the same patients in a given facility might be subjected to measurement under two different measures. And that's what sort of thing that drives folks out in the field completely nuts and are, you know, calling us and asking why are they different.

So, I really would like and encourage the measure developers to be addressing the harmonization question.

(Deidra): Hi, this is (Deidra) from the AMA PCPI? Can you hear me?

(Reva Winkler): Yes, thank you, (Deidra).

(Deidra): I just want to address your question about the harmonization. So, we actually have partially harmonized with the Joint Commission measure. We have a member of the Joint Commission actually is also a member of our workgroup and participated into the discussions regarding this measure.

The workgroup decided not to include the documentation of reasons why no DVT prophylaxis was administered by the end of day two as these patients will be captured in the exception. And the workgroup also thought that capturing this information, the exceptions allow for more straightforward measure focusing on whether or not the patient received the appropriate therapy.

So, that's pretty much the extend of the harmonization discussion, but the way the measures are currently constructed, we're capturing all of the same information, it's just construction differently because we're using the exception.

(Reva Winkler): All right thanks for that. We certainly want to make greater progress towards harmonization for measures that are so completely alike like this. We really – the expectation out in the field is to reduce their burden by, you know, maximum harmonization.

So, this will be an ongoing discussion I think and particularly an important one for this project. But in the interest of time, we really need to move on to the next measure which is?

Karen Johnson: The next measure is 0436, anticoagulation therapy for atrial fibrillation flutter from the Joint Commission. And for this measure, (Dr. Tolin) is our lead discussant. Unfortunately he had to be on an airplane right now.

So, what he's done is he sent us his introduction via e-mail. So, I'm just going to read his introduction for the measure.

Originally endorsed in 2008, this measure is one of the set used by the Joint Commission for hospital accreditation specifically the metric is to assess anticoagulation therapy at the time of discharge when the discharge diagnosis is ischemic stroke with documentation of either atrial fibrillation or atrial flutter.

The stroke can either be the single event or a current stroke. And I will go on and talk about his addressing the importance of the measure.

The medical evidence to support anticoagulation is not controversial. So, this means our positive and approximately 20 percent of stroke most commonly atrial fibrillation show great – had defined in A-fib patients in this being attributed to great anticoagulation needs.

He does have some more stuff that will come under the scientific acceptability. So I will leave that for just a minute and see if we want to – if there's any discussion on the importance of the measure, you know, impact, gap or adamant.

(Lionet): So this is why it's on IDS. I mean, I don't think that particularly we're looking at everyone's score and everybody agrees this is a really important measure. I think that one of the challenges is defining how people – and this maybe beyond the – beyond this measure.

But there's a lot of under diagnosis of atrial fibrillation either because hospitals are not using – they're either using, you know, just a simple EKG or they may not have telemetry. They may not have the tools really to give people either 24 or 48 hours of monitoring.

And actually more recently there are more and more papers showing that there actually may need to be longer term monitoring. And that was really my issue that we maybe missing a lot of the patients that may have atrial fibrillation in this accredited stroke patients that really should be mainly to be treated with anticoagulation.

(Reva Winkler): Thoughts from anyone else?

- Jocelyn Bautista: My main concern was the gap and whether there really is a gap at this point. I think they estimated the average performance to be at 95 percent now. So, the question is how much better do we think we each can get.
- (Reva Winkler): Yes. It looks like one of you did a sort of back of the envelop calculation about how many patients that would be and came up with, you know, considerable number of potential prevention, strokes prevented, so.
- (Lionet): So, certainly are still gaps between groups. I mean the under diagnosis and under treatment in minority populations has been documented. And out of that – as for the minority population continues to grow, then this is going to become ever burdening problem.
- (Reva Winkler): One of the criteria around this gap is specifically addressing disparity. So data of no disparities within it is enough to identify a potential gap.
- (Lionet): All right, that's why I was bringing it up.
- Michael Kaplitt: Yes. I was the one who did the quick math because I was struggling with the same question because the percentage seems so low, but I said to myself, "Is it really worth pulling through all of this if most people are doing this fairly well.
- But then, you know, when I kind of did the quick math, it seemed to me like the numbers, you know, just – the absolute numbers justified that there's, you know, enough opportunity for improvement.
- (Reva Winkler): All right. So, we talked about the gap and the impact, how about let's about the evidence base for the use of anticoagulation therapies for patients with atrial fibrillation or flutter and patients who have a stroke?
- Is that a solid evidence base?
- (Lionet): Oh, one of the things that I really couldn't tell, I mean, largely the vast majority of people who have atrial fibrillation it's going to be fairly significant runs of A-fib, but there is not that much of a question as to whether or not to treat.
- But there are some patients that have these very brief episodes of A-fib that even the, you know, you bring in the cardiologist and the cardiologists are largely in disagreement with treating them with atrial – treating them with anticoagulation particularly if they come in with some other known cause or, you know, it appears to be a lacunar infarct with a lacunar syndrome. And, you know, they had five seconds of this burn.
- So, that was really the only thing that I couldn't tell from the information that was provided the specific definition. I think that there should be a definition for A-fib.
- (Karen): This is (Karen) at the Joint Commission. Here is from the data dictionary definition for atrial fibrillation or flutter and we do consider any episode of atrial fibrillation flutter documented

during the hospital stay as acceptable to select (just) as well as any documentation of a past history of atrial fibrillation or flutter.

And we do give inclusion terms, you know, obviously PAF and various inclusion terms that would be acceptable for yes as well as exclusion terms. So PACs would not be considered acceptable to acceptable to (accept yes).

So, I think that that level of detail is in the definition.

(Lionet): I'm sorry, what was the last part?

(Karen): That level of detail that you're looking for is in the data dictionary and the data element definition for atrial fibrillation flutter.

(Lionet): They're not – that's perfect.

Karen Johnson: This is Karen from NQF and what we may ask you to do is maybe we might open up the submission saying that you could just copy and paste this definition into a submission, that way everything will be together.

(Lionet): OK.

Karen Johnson: OK.

(Reva Winkler): All right any other thoughts around the importance criteria? Somebody made a comment that there were some controversy over when to initiate anticoagulant therapy after the stroke and over the benefits of one anticoagulant over another? If someone would want to expand on that a bit?

Jocelyn Bautista: Well, I think – I think that comes historically out of application, the developers wrote that themselves that there is some issue of how quickly after they had stroke to start anticoagulation especially if it's a large stroke and you're worried about hemorrhagic conversion.

(Reva Winkler): And what are your thoughts given that is the evidence with the measure?

Jocelyn Bautista: I don't think it is – I don't think it's incredibly significant. I think it's – I mean it's a limitation to the data and the evidence that we have. But I still think there is fair amount of evidence that anticoagulant should be done, we just need additional information on some of these additional details.

(Reva Winkler): OK. Any other thoughts from other workgroup member? All right, then why don't we move on to scientific acceptability to measure properties specifically the specifications and the reliability testing and the validity testing?

Karen Johnson: And this is Karen and I will read (Dr. Tolin)'s contribution to that part of the measure. He says the measure is specifically vague as to the anticoagulant use. Warfarin or Coumadin in

the past was the only agent available for oral use. Recently there have been several new agents introduced with differing mechanisms of action.

There are some advantages in the newer medications when compared to warfarin. And then he goes on to say the measure does not address continuation of therapy during the post discharge duration. There are also a series of exclusions listed limiting the metric to the target patient.

(Reva Winkler): I'm sorry, what was the last part?

Karen Johnson: He says, I'll read the last two sentences. The measure does not address continuation of therapy during the post discharge duration. There are also a series of exclusions listed limiting the metric to the target patient.

(Reva Winkler): Any other discussion from workgroup members?

I see here one of the comments that was submitted in the preliminary reviews that the agreement rate with some data elements is only 83 to 85 percent. Did you want to discuss that further whoever raised that?

Jocelyn Bautista: Yes, I have wrote that. I just want to bring that up to see if anyone else was concerned about that. There was therapy, reasons for not prescribing anticoagulation therapy at discharge, the reason was 82.6 percent and the data element anticoagulation therapy prescribed at discharge was agreement rate of 85 percent.

In which I suggest that there's some difficulty in obtaining this data.

(Reva Winkler): Thoughts from anyone else? Perhaps we can ask the Joint Commission if they've done any follow up on that to see what's happening as the measures been used.

(Lionet): Yes. I can address it. And it also goes back I think to the previous comment from one of the workgroup members or (Dr. Tolin) about the type of anticoagulant prescribed at discharged up until probably what, October 2010, warfarin was really the main agent being captured here in the numerator. And now, we have several new drug approvals for Dabigatran and for Rivaroxaban et cetera.

And unfortunately our specifications manual scheduled for revisions doesn't always correlate nicely with these new drug approvals. And until we add the medications to the drug tables we do not allow inclusion in the numerator.

So, there was about a let's see probably a nine-month period where we had many questions about using Dabigatran for anticoagulation therapy where it has been approved. It is an appropriate therapy, however it could not be captured in the numerator until we added it to the medication table for this measure which is table 8.3 in Appendix C of our specifications manual.

Dabigatran has been added per deck. Obviously the trade names and the generic names are always included so we pick up all the medications. And we have also added now Rivaroxaban and Xarelto, but that would not appear until the next version of our manual.

Female: But they are included in this measure, is that correct?

(Reva Winkler): They are now. They are now, but I think the part of the gap was that we were missing some of those patients in the numerator for a period of time because of the rapid extractions of those drugs and the usage of the drugs and we weren't able to capture them fully until we've changed the specifications.

And there is a lead time to change specifications nationally.

Jocelyn Bautista: Do you think that has affected agreement though on actually ...

(Lionet): Yes, I do because I think that directors nominated for A-fib and, you know, if they follow the guidelines exactly as they're written, they would be instructed to select no, but you still have gap directors making inferences. Well, they have approved and it's acceptable, so it should be yes.

So, I think that it had.

(Reva Winkler): Right, it sounds like there is a real potential from all sorts of audiences and it might be good if within the body of the specifications here, we were able to list out what is currently a part of the measure particularly if there's some lag going on in your specifications tables just so people are clear on what is and what isn't included in the measure. I think that would be particularly helpful.

Thoughts from the Steering Committee members?

Jack Scariano: Yes, this is Jack Scariano calling. I think one question though in management opposed to discharged with anticoagulation and I've headed (inaudible) that if you want to give this to someone an actual third medication, like the staff used to give, you know, (inaudible), would be the overall availability of that it's just wasn't there.

And then I don't know about the other availability of a new anticoagulant, but if it's that be recommended by the – by the actual quality forum that that people use these, you know, is it actually realistic that actually people could actually get them.

(Reva Winkler): In terms of what's allowable in the measure, I think that's certainly the decision that measure determine in specifications that it seems to me than in this particular measure there are alternatives that would allow you to be numerator compliant with any number of medication.

So, if there was just one, I certainly could see where that would be a problem. Thoughts from other workgroup members?

(Lionet): I mean, I agree with that last comment, but I – one of those issues that I wanted to feedback on is it's some this pretty simple – or the pretty simple decisions when you have patients who

are from the city that as you know one of the areas of help (inaudible) also care amongst rural populations which makes up a huge proportion of a number of people in the United States.

And even though someone a patient maybe interested in taking Coumadin, a physician maybe interested in prescribing Coumadin in order to really take the Coumadin levels under control, they may not have access to the appropriate turnout. And I'm going to talk a little bit about this in the discharge, they may not have access to the monitoring ability would certainly the newer medications will play a role in leaving some of those challenges, but there maybe other decisions that go in to not treating from one was Coumadin which is really – would be unfortunate.

(Reva Winkler): Do you think those sorts of issues are particularly problematic for use of this measure in real hospitals for instance?

(Lionet): So, even though (inaudible) I was at Emery and, you know, the patients became from the city, it was a pretty – you know, the discussions and then a decision was made. But unfortunately sometimes we would have to make, you know, we tell them that you need to find someone to be able to check your INR, then just on a regular basis. And that just wasn't feasible when they have to drive, you know.

A stroke patient would have to find somebody to drive them, you know, an hour to two hours away. And so, I don't know the impact and maybe someone from Joint Commission so could comment.

I don't have the answer to that. I can tell you that we haven't done a whole lot of – there hasn't been a whole lot of research or hardly any research done on rural care in stroke through at least the NIH and whether or not the CDC has done that, I don't know.

Michael Kaplitt: You know, I totally agree with – agree with that limitation who I have, I'd say half are in rural areas. You know, they just can't get transported because as we get the auto-blood drawn and, you know, even to their primary care doctor with the price of the gasses and the inability to try to get, you know, transportation. It's been a real problem and also in other medication level.

(Lionet): And certainly with the newer medication, I mean that's helpful with the new medications. But, you know, some people are a bit hesitant in patients who have stroke because there hasn't been a lot of study regarding that. But I think it could impact your measure. It would be very interesting to be able to capture if that was one of the reasons why.

Suzanne Theberge: Yes. Maybe the Joint Commission have any experience or thoughts with this issue?

(Karen): You know, this is (Karen) from the Joint Commission. I can't give you numbers on, you know, patients in rural areas on what's the usage of the various anticoagulant medication is. But all I can say is that from the time that these new agents are approved, we are just stormed with questions from the field about their use.

And as I said, it does take time. We're on a schedule for updating specifications, so it takes us time to adjust the specifications to reflect this new drug approval. And it seems that most

certainly, at least from the questions that we received that they were being widely adopted but exactly what the breakdown is in rural and urban areas we do not collect that data.

Suzanne Theberge: All right. So, in terms of this host or level measure, are there anymore thoughts on – from the committee on scientific reliability and validity. If not, how about usability, feasibility of the measure? None of the drugs. Any issues or concerns?

Dr. Bautista I think was used – you've used these measures.

Jocelyn Bautista: I don't think we've had an issue with this particular measure.

Suzanne Theberge: OK.

Jocelyn Bautista: And I hadn't thought about this when I was reviewing it. But the whole issue of new anticoagulants coming out does raise an issue because you're going to have to be changing the metric every single time, a new substance comes out.

I would think that would impact the usability and – usability of the metric.

Suzanne Theberge: OK. Thoughts from anyone else?

All right. We've got a similar measure next, measure 2.41, which is essentially the clinician level version of this measure from PCPI percentage of patients 18 years and older with a diagnosis of ischemic stroke or transient of ischemic attack with document permanent versus general practice of atrial fibrillation who are prescribed in anticoagulant discharge.

So, whose measure is this?

Salina Waddy: Salina Waddy. Hi.

Suzanne Theberge: Great. Hi there.

Salina Waddy: So, yes, (Sigma) is very similar to the previous measure. The only question since you said it that way, I was not entirely clear if this was a measure to – for the physician citation, left the hospital or as they were leaving the hospital.

So, they then discharged. So, are you measuring it as a hospital or once they actually leave?

Jocelyn Bautista: At the moment of discharge?

Salina Waddy: I'm sorry?

Jocelyn Bautista: The way I read it is at the moment of discharge. It's really the same measure.

Salina Waddy: Right. I mean, that's what I thought. But then what she just said was it was at the level of ...

Jocelyn Bautista: Yes, they just collate it at the level of the physician but it's still the same data.

(Lionet): So, from PCPI, does everybody – do we have that right?

(Reva Winkler): Yes, that's correct. It's supposed to be collected at the moment of discharge before the patient is leaving the hospital.

(Lionet): OK. That's what I – that's what I thought. And then looking back at it, you also said that level analysis was practice and the group of the practice. I just want to be sure based on what was said. Anyway, I'll move on.

So, there are obviously a lot of similarities with the measure that was just evaluated. What I was really surprised about is there was quite a bit of disagreement. It was about half the group thinking that this was high, the other high level of evidence, high level of importance. But about half the group really didn't – or didn't think there was enough evidence.

And so, I was wondering if the hospice didn't think there was enough evidence we could ...

Jocelyn Bautista: So, I think I wrote insufficient. And I was really just judging the application, not that there isn't in the world evidence but the application really did not do a very good job I thought of describing evidence.

(Lionet): So, you thought that they should be a little bit more elite?

Jocelyn Bautista: Yes. I mean, I was – you know, maybe I didn't judge that appropriately. But that was – it was more of a rating of the application.

(Lionet): OK.

(Reva Winkler): This is really just to clarify. We really are asking you to use the information in the application to make your ratings. It's always difficult when you're an expert in the field and you know what the evidence is. And so, we kind of leave it to you to factor that in as you will. But really, what we're asking you for is to assess the information provided.

(Lionet): Well, based on that, it seems like there's a split in the group. So, I don't really know how you want me to handle that in terms of the discussion.

(Reva Winkler): Well, I think the question is, is it going to make you feel that the measure does not need criteria. Are you going to appeal that your knowledge, either from reading the other measures of information and from your own expertise? Are you going to kind of fill in the blank for the information that you feel might be missing in this and still feel that the evidence is sufficient?

(Lionet): Well, I mean, at the end of the day – and I'm just going to get to those in, I mean, everyone did agree that this was a suitable measure that met the criteria. So, our test probably didn't reach the level of really putting the brakes on things.

(Reva Winkler): OK.

Jocelyn Bautista: Yes, and I would agree with that. So, you know, even though I said insufficient information submitted, I do think we know enough about atrial fibrillation and its impact to stroke to say this is a significant measure.

(Reva Winkler): Yes, this is great feedback to the developers. Ultimately, when we do the final evaluation, please realize that your ratings will be sort of – there's an algorithm for how they get to put together in terms of whether it passes the overall criteria of importance, an insufficient of low-rating will not allow it go forward.

So, you'll have to kind of come to terms with that. So, it sounds like you're comfortable enough with the evidence that exist, perhaps not on the piece of paper but in the world. Do you have any issues around the data for the opportunity for improvement?

Jocelyn Bautista: Yes. They actually seem to sight a bigger gap than the other application. They rated to current performance of 79 percent. I think the other – and again, that's probably because of the difference in terms of physician level versus hospital level perhaps.

But I'm OK with the information about the gap.

(Reva Winkler): OK. Any other issues around importance to measure for this particular measure? OK. Let's move on to the scientific acceptability. And we can start with, you know, the specification, do they align with the evidence for construct validity and then the testing for reliability and the testing for validity.

Whose measure is this?

Salina Waddy: Mine. Salina Waddy. So, largely, I mean there was – it's kind of mix path once again of – a mixture of kinds of mediums. At least my question regarding the definition, the one that I raised, I didn't realize that that definition was the data dictionary, so I feel definitely more confident regarding at ...

(Reva Winkler): The answer on the data dictionary was for the other measure.

Salina Waddy: Oh, I'm sorry.

(Reva Winkler): So for this particular measure, your question was how was NQF defined that? Perhaps the folks from PCPI could clarify that?

Female: Hi. So, we actually have included the nominator definition for the different type of atrial fibrillation but has not included a definition for NQF.

(Reva Winkler): Oh, OK. So, I guess I asked in the wrong place then. So I do think that it'll be helpful to have something that really defines the atrial – defined atrial fibrillation not just how we test it.

Gwendolen Buhr: Similar to this, this is Gwen that I think that I would like to see what the exceptions are. And there's probably somewhere else in addition – as well. But there were some 46 percent exception rate at the same time. But ...

(Reva Winkler): I'm sorry, where are you seeing on 46 percent exception rate?

Gwendolen Buhr: I don't know, somewhere in that. Let me see.

Karen Johnson: Page 13 of the submission, and that is in Section 2B3.3

(Reva Winkler): At the bottom of page 13. So, that was the exception rate for the testing project. That was significantly model sample size. If you look at the data we provided actually for the PQRS data, the exception rate was much lower. It was 15.05 percent in the PQRS program.

Gwendolen Buhr: OK.

Karen Johnson: And sorry, what section was the 15.05 percent?

(Reva Winkler): It's in the performance gap data section.

Karen Johnson: Oh, here it is. OK.

(Reva Winkler): Any other thoughts on reliability and validity information? Do you feel that the testing was adequate and demonstrated reliability and validity of this measure?

(Lionet): And it seems, like, largely, I don't know if you agree, but there was. But there was some smaller issues that needs to be – that should be addressed.

(Reva Winkler): Can you be more specific? Such as?

(Lionet): No, no, no, just of the information that's presented.

(Reva): OK. Just information in it.

(Lionet): Nothing new to add.

(Reva Winkler): OK. Anybody else from the work group? And when I was looking at this measure, one of the things that came up was I notice that on this measure, they don't – you don't include atrial flutter, and that was included on the other measure.

Is there an explanation for that?

Risha Gidwani: This is Risha. I'm not recalling a discussion of inclusion of atrial flutter in the measure. That's something that we can certainly propose to the workgroup.

(Reva Winkler): Yes. I think again this are very – this is a very similar pair of measures that are measuring the same thing for patients hospitalized with stroke. And so, we do have significant harmonization questions. And that was certainly be one of them.

Gwendolen Buhr: Another one, if I could bring up, this measure includes TIA whereas the other measure does not.

(Reva Winkler): Is the evidence for the anticoagulation therapy for atrial fibrillation sort of exist independent of the stroke and the TIA? But the fact that TIA patients are included in its measure. Is that – is the evidence still solid for both of those?

(Lionet): I think it really is going to depend on in terms – I think it will be helpful for TIA if you, like, had – if you just didn't take all commerce, but those with ABC higher, ABC scores or something like that, which you defined as a little bit more rigorous than all commerce.

And then you're just going to get into a really big mess once you add TIA, or else exclude TIA from the measure. It's just a really big problem. Does anyone else want to comment on that?

Jocelyn Bautista: Yes, I agree it introduces a lot of problems to include TIA. And this measure also has that same issue with validity that they only had face validity. I don't remember what other measures they're talking about that.

(Theodore Schwartz): This (Theodore) from the EMA and PCPI. I just wanted to add with regards to the TIA question. The reason why I was included is because there are guideline recommendations from the American college of American College of Chest Physicians and American Stroke Association that address patients with TIA, with pursuits of paroxysmal or permanent atrial fibrillation. So, it's supported by the evidence, that's why it was included in the metrics.

(Reva Winkler): So, can you repeat that – the first part of what you just said?

(Theodore Schwartz): The guidelines from the American College of Chest Physician and the American Stroke Association include recommendations for patients with TIA and a-fibrillation. So, that's why they – this patient population was also included in the measure.

(Reva Winkler): Do you hold on how they design TIA?

(Theodore Schwartz): In the guidelines?

(Reva Winkler): Yes.

(Theodore Schwartz): I do not.

(Lionet): So, I mean, I think what we can say – I mean, certainly, if you think that they have TIA and the cause of – both TIA was atrial fibrillation. It absolutely make sense 100 percent.

But I think that when you're going to use – and if you're going to use this within an academic hospital, I think that that would be very, you know, a very simple – a relatively simple exercise to do. But if this – since this is going to be more global and the quality of the detection of TIA, that can really – you could be including a lot of things that are just spelled or transient events and it's not nearly as clear.

(Reva Winkler): All right. Any other thoughts from anybody else? Is this is a serious problem for this measure? Is this is a significant threat to the validity of the measure?

- Karen Johnson: Following a line from the 436 application, they mentioned that Joint Commission testing indicated that the TIA population could not be reliably identified which is why they remove TIA from their measure.
- They don't give, you know, numbers or data for that testing. But I think this is different.
- (Reva Winkler): Yes. So, as of PCPI, have you tested the reliability of the TIA part of the measure? OK. I think that would be – oh, I'm sorry, Risha?
- Risha Gidwani: I'm sorry, I'm just looking through the testing data here. I'm not sure if you can give me another minute to look at it or to be able to answer your question. Yes.
- (Reva Winkler): Yes. Well, I think these are important questions that would be helpful to get clarified before those committee meets. So perhaps you can, you know, not feel under the guns here. But I do think this is an important question post to you that we'll be looking for additional information when the entire committee gets together.
- Risha Gidwani: OK.
- (Lionet): Are you going to be – so I just want just really quickly. So, are there notes regarding this discussion?
- (Reva Winkler): They'll have the transcript in a day or two.
- (Lionet): OK. Great.
- Risha Gidwani: This is Risha. I just wanted to add that the measure was tested with the TIA population included.
- (Reva Winkler): OK.
- Jocelyn Bautista: So we're specifically asking about the reliability of identifying TIA patient.
- (Reva Winkler): All right. Anything else on scientific susceptibility? I am kind of mindful of time here. How about usability or feasibility for this measure? Anything?
- Salina Waddy: It looks like there were – so this is Salina again. Once again there was, you know, half and half regarding the usability, and I was wondering what the two that put medium or moderate? Do you have any suggestions regarding to the – how useful – or is it related to those previous definitions or questions or there are new comments?
- (Reva Winkler): Don't be shy.
- Salina Waddy: From either Michael or Jocelyn or ...?
- Jocelyn Bautista: Yes, I'm trying to remember. I'm sorry. I think my – I think the main thing I was reflecting on was the data extraction issue in terms of all the reasons, you know.

Salina Waddy: Yes.

Jocelyn Bautista: It's just it's very difficult to – it's very time intensive going to the medical chart in identifying those reasons. I think that's the main thing I downgraded for.

(Reva Winkler): OK. Any other thoughts from the committee before we move on to the next measure? The only other thing I'd like to point out is, again, we've got two very, very similar measures. Yes, there are different levels of analysis, but they do address the same patient population with the same process of care.

So, we will be looking for, you know, very, very good alignment and harmonization. So, I would ask both of developers to be prepared for that at the in-person meeting. In addition, I would just mention to PCPI that – NQF has endorsed measure 1525, which is again anticoagulation of patients with atrial fibrillation that's an outpatient measure for not exclusively for stroke patients.

But, again, once the patient leaves the hospital, they're going to be, you know, captured in measures in the outpatient world. So, they really should be measured similarly.

And I would really point to the needs for harmonization across those measures and that direction as well. So, given that we've got two more measures to do, why don't we move on?

The next measure is 243 stroke and stroke rehab, screening for dysphasia.

Suzanne Theberge: And that's Dr. Kaplitt's measure.

Michael Kaplitt: Right. So, this is a measure for something here. So, this is a measure to identify a percent of patient, of adult patients, patients 18 years and older, whereas either ischemic or hemorrhagic stroke who was seen of any type of feeding – anything by mouth essentially whom dysphasia screening was performed prior to oral intake using a, you know, a variety of dysphasia screening tools that are allowable in the measure.

And the goal of the measure I guess is to identify – is to determine percent through patients that are being screened to try to prevent aspiration and eventual pneumonia, which is a major problem in stroke.

Now, in terms of the impact, I think that there's fairly good evidence that swallowing difficulties can be under-recognized. I think there were several cited in some others that I found to suggest that's still in the general community, you know, probably more so on the general community than stroke centers but probably, you know, overall that there are still wide disparities, and even the reported dysphasia rates.

And that probably relates not just to reporting problems, but also diagnostic problems because the measures have different level of sensitivity. There's also obviously varied rates of dysphasia depending on the type of stroke.

One of the things this measure does is it does not discriminate between types of stroke in general. As far as I can tell, it's all inclusive. And, you know, there's data in – of the citations and elsewhere that – which is not surprising that different types of stroke or different dysphasia rate, such as atmospheric stroke has a lower dysphasia rate than, say, a brainstem stroke which makes sense to all of us.

So, I think there's a wide variability in the reported dysphasia rate based on a type of stroke. And that's the only rationale that I would say, well, maybe, you know, there should be more evidence presented before creating an outcome measure that includes all types of stroke because it was particularly low in a specific type of stroke, we could all imagine what that might be, you know, some focal impart that doesn't really affect swallowing it all. And maybe it would be less useful measure in those patients.

But that type of stroke is not the only reason for the disparity. It's also the nature of the type of screening that's done. And so, I think that the argument that there is, you know, potential for high impact in terms of reducing the number of aspirations, obviously, the correlation between aspirations in this case are dysphasia and atrial pneumonia was not perfect because there was – there's lower rates of pneumonia than there is of atrial aspiration, et etcetera, in this study, you know, in this formalized study.

But nonetheless, the numbers are – the percentage is a pretty high and the variability is pretty high. It's like the impact is perfectly fine and I think the citations in that regard were OK. But I think that there is obviously – there's, you know, reasonable evidence of a performance gap at least based on the reporting system, biases they say that only, you know, some of this data is based on the PQRS performance system.

Their recording – reporting program which is voluntary and which only about a quarter of people, you know, have participated in. So, that could represent a selection bias. My personal bias is that that probably represents a selection bias in favor of the measurement. And again, I make the assumption that the people that the people that are voluntarily reporting are probably the ones that are doing this kind of thing the most and reporting on it the most so the numbers are probably worse than anything. It might be rather than better because of this.

So, overall, I thought that the – you know, that the evidence impact was good. My only personal issue with this was that the vast majority – and I have to admit that I reviewed this first because I knew this was going to be my main measure and then I reviewed the others.

And I will say that the Joint Commission measures overall. And I think this has been the sense of product base on the discussions. It seems to be a lot – have a lot more detail and a lot that are justified than some of the EMA or AHA1s rather, sorry.

So, in this case, for example, a lot of the data that's presented and one comes from a single paper, which was a very good review. It was like a meta-analysis that eventually identified 24 studies that were used for inclusion of supported disc. And that's fine.

But much of what's in here was lifted verbatim from that one paper, so it's hard for me to tell how much came from the expert review of these papers by the American Heart Stroke

council. And they list all the members many from my known, many from experts. But it's hard for me to tell how much came from their assessment versus how much from this one paper because of the fact that so much of this was lifted verbatim from that paper.

So, that was, you know, one small concern I had in terms of the, you know, the level of review that this subjected. So, the other thing which I'm not sure whether this matters, and then I'll shut up and let others comment. But the only other thing – and I'm not sure that this matters is in section 1C16 where it has to quote verbatim, a specific guideline recommendation that's relevant to this says, "A smallest screen should be performed in the first 24 hours after stroke preferably by speech language pathologist."

And that cites some more recent article in stroke that's sort of a comprehensive overview of the recommendations for stroke management. And it's just not clear to me, I mean, the performance measure here doesn't say anything about 24 hours even though that's the guideline recommendation.

So, if 24 hours isn't part of this, then I guess it doesn't really matter. But if the 24-hour does matter, I couldn't find a whole lot of evidence to support why it's got to be 24 hours. I think that this support for the idea that you shouldn't feed somebody before they have a dysphasia screening, I thought it was good evidence for that. And that's the overall gist of the measure.

But this 24-hour thing, I didn't know what to make of that because I didn't know whether that's relevant or not here. So, that was really my only sort of confusion in that first part. But otherwise, I thought the evidence is pretty good for it.

(Reva Winkler): Do you want to say if the measure developers have any thoughts in relation to ...?

Michael Kaplitt: Oh, I just – I do. I do. But before I ask the measure developers, maybe you guys from NQF can tell us what the purpose of one of the question in 1C16 is.

(Reva Winkler): Oh.

Michael Kaplitt: That might help.

(Reva Winkler): 1C16 is the guideline recommendation because we know so many people are major developers based on guidelines. We want to see exactly what it says.

However, if you notice, the evaluation criteria isn't based on what the guideline say but is based on the evidence that should be underlying those guidelines. So, the fact that the guidelines have the 24 hours in there, if you feel that the measure doesn't address that and the evidence doesn't address that, then it really isn't in play for us right here.

Michael Kaplitt: Right. So, that was my sense of it, was that I thought it was pretty irrelevant. I just want to ask what the purpose of there was because as far as I can tell, the measure doesn't really include any others statement in there 24 hours and there's very little evidence that's presented or that's in the paper that we've decided to support.

But if the measure is not really using that as far as I can tell, then it probably is irrelevant. I just want to ask about it.

(Reva Winkler): Sure.

Michael Kaplitt: OK. So, that's really all I have to say about that.

(Reva Winkler): All right. Any other thoughts from other steering community members in terms of the importance criteria, the impact – the opportunity for improvement and the evidence? Are there any questions or concerns about any of those criteria? Somebody is – in terms of the evidence, somebody's comment was the studies are not randomized but there are a lot of them and they show consistent results.

Does that pretty much summarize things for folks?

Michael Kaplitt: Yes, I think that's right. I mean, most people voted it moderate, I think probably for that reason.

(Reva Winkler): Sure. Moderate still passes. But ...

Michael Kaplitt: Right.

(Reva Winkler): But that may be the reality of the circumstances.

OK. In the interest of time, why don't we move down to scientific susceptibility and your thoughts on reliability and validity?

Michael Kaplitt: Yes, I mean I thought – if I'm understanding the methodology right, and I may not be, but if I'm understanding the methodology right, I thought that the evidence was pretty good for reliability and validity based on the, you know, the testing results which showed pretty – almost perfect reliability.

(Reva Winkler): OK.

Michael Kaplitt: And I thought that the numerator and denominator were – OK. There's only one thing again, which was really vague to me, where was it? And the denominator exclusion, hold on, this one thing – oh, here. And the denominator exclusions which is on our page nine, which is 2A1.8 denominator exclusions.

(Reva Winkler): All right.

Michael Kaplitt: Under the exception are the patient reasons, I understand, patient leaves, whatever. That is what it is, although they refused to, you know. I guess if they're waking up and enable to speak to refuse, there probably not that much trouble anyway.

But hundred documentation reasons are now performing dysphasia screening. It says, example patient without any focal findings and thought of stroke would initially evaluate it.

And then it says other medical reasons. Now, as we've asked about in other measures here, those other medical reasons to find somewhere that I missed.

(Reva Winkler): So this is the agenda of EMA, they are not defined. These are not exclusions; they're exceptions. And we only list ...

Michael Kaplitt: Oh, exceptions. Sorry.

(Reva Winkler): And we list examples just to – they are just examples who are not meant to be an all-inclusive list for the exceptions. And the exceptions allow for clinical judgment by the clinician. That's why we include them.

Michael Kaplitt: So maybe – maybe you can define for me the difference between an exception and exclusion?

(Reva Winkler): Sure. An exclusion is absolute. Those patients should never be included in the actual measure population. With the exceptions, however, the exceptions are actually used to remove patients from the denominator of the measure when the patient doesn't receive that they're be your service and it would not be appropriate for the patients to receive that they're be your service for a specific reason.

Michael Kaplitt: OK.

(Reva Winkler): It allows for the physician to use their judgment in cases where, you know, there are some medical reason why the patient – maybe there's a constant indications of medication, maybe there's an allergy, you know, things like that were – it would be appropriate for the patients to receive the service or therapy.

Michael Kaplitt: That sounds fine. But as we discussed some of the earlier measures, so that means that it's entirely up to the discretion of the physician to define what their medical judgment is, which is fine, except it leaves it open.

But without any type of sort of restriction on that, for example, things that can't be – you know, as an example, things that cannot be used as an exclusion or a restriction. Basically, every physician could just come out with any random reason from what I can see here. And that would be excluded and you'd always have 100 percent performance or agreement, or whatever.

(Carrie): This is (Carrie) from the EMA. I work with the testing and the implementation group. And we have done many testing projects on measures including this one as well as many measure like it. And we have found extremely high rise of agreement for the vast majority of our measures, including this one, when we are looking at the exceptions that are documented in the medical record and comparing them to a list of medical exceptions that has been adjudicated by an expert panel.

So, we have done that research and we have done very, very good of the rates or medical exceptions in a couple of published papers as well as on non-published work.

Michael Kaplitt: Well, that would be – I mean, that's fine. I mean, that would be nice to provide because I have, you know – I mean as we've heard earlier, we're supposed to judge the document in front of us, right?

(Reva Winkler): Correct.

Michael Kaplitt: So, you know, I don't have that. But I mean it wasn't enough for me to, you know, sort of object it based on this, I'm just saying it's, you know, in retrospect when I read some of the others and I thought about this we're, you know, it just seems a little broad and vague without, you know, supporting justification to say why this doesn't just give everybody sort of a free pass, essentially.

(Reva Winkler): OK.

Salina Waddy: So, this is methodology that we use with the many of our measures. And it's also a methodology that is used with a large majority of the measures and the PQRS program. So, it is something that definitely we have monitored very closely. And the amount, of course, since they are using it in their PQRS program, let's watch that as well, though we can't provide any results from ...

Michael Kaplitt: Well, no, that's fine. And don't get me wrong, I'm a big believer in physician, you know, autonomy to a reasonable degree. But on the other hand, the whole purpose of this exercise is to provide some oversight guidance, you know. Otherwise, if we all have pure autonomy there would be no need for things like this, right?

So, that's the reason why I'm saying it is that I don't disagree with giving flexibility and option, et cetera. It's just there was really no data provided they say to me whether other medical reasons is a valid exclusion criteria or not, or exception, whatever.

Salina Waddy: And I agree with that comment, I agree with that comment on mouthful of the measures. The only thing I question is you said that the rule is to provide oversight new guidance. I was thinking that it was to identify what people were really doing.

Michael Kaplitt: Well, no, but I mean in the broader term. I'm not talking about the specific measure. I mean the whole process of having outcome measures and reporting this stuff, et cetera, is ultimately to come up with best practices and guidance, right?

I'm talking in the big picture sense, not the specific thing. And so, all I meant was that if that's the case, then there should be some limit to autonomy. I mean, you know, other medical – another medical reason that it's completely invalid medical reason. It shouldn't necessarily be allowable just because the physician document did it.

Now, I agree. It sounds like there's good evidence to support if that kind of thing isn't happening. But I just wasn't given that. That's all.

Salina Waddy: I completely agree with that statement.

(Reva Winkler): OK. All right. So, I think we do need to kind of move things along a little bit. So, any additional comments about the specifications or the reliability or validity of this measure? How about usability or feasibility?

Michael Kaplitt: Yes, I thought that was fine. I mean, this is – compared to what we were talking about earlier, this is actually a pretty easy measure to implement because it doesn't require a whole lot of searching and chartering in terms to figure out whether this is being done or not. You're not looking for a whole bunch of additional measures.

And I think the data provide and suggest that it's pretty straightforward to use.

(Reva Winkler): Right. Any comments from any other committee members? OK. Since we're rapidly approaching our time limit, let's move on to our last measure, which is 440 stroke education. Who's got that measure?

Gwendolen Buhr: That's me, Gwen Buhr.

(Reva): OK, Gwen. Why don't you go ahead?

Gwendolen Buhr: OK. Sure. So, this measure is talking about the proportion of ischemic or hemorrhagic stroke patient who have documented that they or their caregivers were given stroke education material and it's part of that set of measures from the Joint Commission.

The stuff education material have to include five things; activation of the medical emergency medical system, need for follow-up after discharge, medication and prescribed discharge and risk factors. And they have the same exclusions as the other Joint Commission measures that we've already looked at.

In terms of the gap, there – the document said that there was either 10 percent gap or a 30 percent gap depending on which thing that you looked at. In terms of the disparity that talks about the disparities in stroke, but it doesn't talk about the disparities in stroke education, which is really what the measure is about as giving stroke education.

Indirectly, you may impact stroke. But I think directly you're measuring stroke education and it doesn't given us much data about stroke education. It talks a lot about stroke. So, people who are in the steering committee who looked at this, there were three people who rated as high impact into as moderate impact, and two of a high performance gap, and two as a moderate.

(Reva Winkler): Like I said, it's something about this measure. I just want to really – I have a real issue with this measure, not – I completely agree that it's important for people to receive education. I completely agree that it's important that we want our patient informed. But to provide education doesn't necessarily mean that the person is going to either understand it or be able to act on it or have some type of behavior change which you would really like.

And so, there's a lot of limitations with the stroke education studies that are currently being done. Very few of them actually studied behavior change.

Gwendolen Buhr: Yes, that was my main issue with the data presented and with, I guess, the data that's available in general, is that it doesn't talk about clinical outcome measures. It talks about giving stroke education materials.

And there was one study that they talked about which said that they increase compliance with medications and decrease depression. But when I looked at that study, it said that it was not at a clinically significant level of decreasing depression, so.

(Reva Winkler): And also one that was listed is actually an intervention that I'm in-charge of at the institute and it hasn't been completed. So, they're actually studying with behavior change part right now. So, I really did have an issue with this one.

Gwendolen Buhr: So, you are probably the one that voted no.

(Reva Winkler): Yes, I was.

Gwendolen Buhr: And your rationale for that is the lack of evidence for the education process of care in terms of ...

(Reva Winkler): The lack of evidence doesn't mean anything.

Gwendolen Buhr: OK.

(Reva Winkler): The lack of evidence that it actually leads to either incompliant with the medication patient being able to really tell you what a stroke is, you know, 60 days to a year later or better understanding what hypertension is.

The whole point of – so it's kind of like if you took a person that's – who will receive all this education for 12 years and at the end of the day they still can't read, they can't write, they can't do anything, you know, are you proud of yourself because you gave all this education but it didn't mean anything?

Gwendolen Buhr: OK.

(Reva Winkler): Thoughts from anyone else?

Michael Kaplitt: Yes. I mean, you know, I had – I forgot, I thought I had given this like a moderate thing, I believe, I don't recall my exact score. But, you know, I will say that, you know, I had some similar concerns when there's an enormous amount about stroke itself. But for example I had actually written some notes under 1B1 where it says briefly explain the benefit. And they cite – they give some citations about the need for mass education about patients, you know, not getting to the emergency room in time, et cetera.

But I wrote – but the measure is about educating patients who already had a stroke. And I didn't find that relevant to patients that already had a stroke because this is talking about the general population of people in the world.

So, this isn't about stroke education in the general population. It's not the value of stroke education among those who already have a stroke. And while – I'm sorry?

Gwendolen Buhr: So, I guess – and I was thinking about that as well. And speaking to the people who are going to have a recurrent stroke or it is trying to affect outcomes like compliance of medication or depression or disability, things like that. But there isn't new evidence presented that the stroke education help those things.

(Lionet): So, there are three points that I want to make. And hopefully I will remember what they are. First, is directly to your point that was just discussed about people who had a stroke and educating them for – in order to get them to the hospital either within the TPA window or for them to – well, for the TPA window for subsequent stroke.

And there is one study called SWIFT that was actually for behavior change. It hasn't been completed. It's an IDS funded. But the final result has not been published yet.

The second issue is who exactly are we educating because at least within the hospital while the patient is in the hospital, there are several studies that has – are now shown there is more of a cognitive impact than what we initially thought. And so, it's maybe more important to educate a family member than the specific stroke patient who may have other problem.

Michael Kaplitt: And how does that relate to whether or not it's important in terms of actually changing anything for these patients after they've had the stroke? I mean, you cite one study that's not in here and that you're saying the data isn't really fully available on yet?

(Lionet): Yes, it's not fully available yet. That's the only ...

Michael Kaplitt: But in here, in this document it doesn't seem like there is much in the way of support for the idea that education for patients who already have a stroke is important. I'm not saying it's not it's just where ...

(Lionet): I agree with you. I agree with you.

Michael Kaplitt: OK. I mean, there's another thing that I know that the end of 1B4, for example, there's a paragraph that says the importance of stroke education cannot be overemphasized, which is, you know, "OK, fine." But it's not an attribute of statement ...

(Lionet): I mean it's nice thing to say. But how good (inaudible) actually ...

Michael Kaplitt: But that's not my issue. What's interesting is there's only – for example, if there's only 20 to 40 percent of the general population is capable of recognizing warning signs and symptoms, going to need to immediately call 911.

But that's the general population. I could make an argument that once someone has a stroke, how do we know that it's only 24 – 20 to 40 percent of patients who already experience the symptoms and know they had a stroke. It might be much higher and – I mean, I'm not saying educating them has no value, I'm sure you can make arguments. But that data to me is not relevant to the population that's being addressed to you.

Gwendolen Buhr: I agree.

(Reva Winkler): So it sounds like there are some significant concerns on the – whether this measure and the evidence for stroke education is related to outcome. We're kind of getting towards the end of our timeframe. Do you briefly want to talk anything about the other criteria on scientific acceptability, usability and feasibility?

(Lionet): I think it's very messy. I mean, there is a mixture of different populations. But I think you're going to have to tease those two parts, the general population versus certain population. I completely agree with the previous comment.

(Salina Waddy): Yes. So the measure specifically is measuring the stroke population.

Female: Correct.

(Salina Waddy): And it was a really big mixture of how we rigged it. Two said high, two said moderate ones and blow in reliability.

(Lionet): Well, at least as well for me a big – a big issue is even if you're taking stroke patients which – is it the patient that should be educated or the patient and the family, and how much is actually retained? I mean, that's a big – really big issue.

Gwendolen Buhr: And I guess if the patient or the caregiver were educated, then that counts in this measure.

Female: Yes.

(Reva Winkler): OK. Given that we're down to our last couple of minutes, are there any other major issues you'd like to share with each other about this measure and – that you haven't already talked about?

OK. I realized that we will be discussing these measures fully at the in-person meeting on June 20th and 21st. But this is a chance for the committee members to share their initial thoughts and discuss some of these issues and perhaps get some clarifications from the measure developers. And so, we do thank everybody for being on the call.

Operator, I don't know if we have anyone on the listening mode. Could we see if anybody has any questions or comments before we close?

Operator: Ladies and gentlemen, to ask a question, press star one on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.

At this time, there are no questions.

(Reva Winkler): Thank you very much.

(Lionet): Can I just say one thing?

(Reva Winkler): Please do.

(Lionet): So, I mean, I do think that – I mean, I think we speak for all of us that we really try to give our, you know, our honest opinions about these measures and everything, but I think we should also underscore the people that put these measures together to provide all the information really did a terrific job of summarizing a whole lot of information for us. And it's appreciated.

(Reva Winkler): Great. Any other comments? I'm going to let Suzanne tell you what we do next.

Suzanne Theberge: Thanks everybody for your time this afternoon. We will have the transcript of this call available in the next couple of days, and I'll post that on SharePoint and let all you know that it's there.

For the rest of this week, we have the other three work group calls the next three afternoons. Feel free to join and listen in if you're interested. And then in a couple of weeks we will have the in-person meeting here in D.C. And we'll be discussing all of the measures at that meeting if you'll need to read and review all the measures before then. However, you don't need to complete the surveys that you completed for this because we'll be doing the voting at the in-person meeting.

If you have any questions or follow-up comments that you want to share with the workgroup or the staff or the full committee, just send me an e-mail and we'll get that out. And if you have any questions, just let me know.

(Lionet): Should we be responsible for presenting or leading a discussion at the workgroup or – I'm sorry, at the in-person meeting or how is that going to work?

Suzanne Theberge: Yes, we will ask you to present the same measure that you presented today. And a similar summary of the introduction to the measure and then summarize the discussion that we have here today.

(Lionet): OK.

(Reva Winkler): Any other questions? All right then, we're at our time. And so, for everyone, thank you very, very much for joining us today and we look forward to seeing you all in D.C. in a couple of weeks.

Operator: Ladies and gentlemen, this does concludes today's conference call. You may now disconnect.

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