NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
May 8, 2014
2:00 p.m. ET

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

Wunmi Isijola: Thank you, (Bridgette). Good afternoon all and thank you for participating in the Surgery Project Workgroup Call Number Two. My name is Wunmi Isijola, Project Manager here in NQF. I also have here our Senior Project Manager Andrew Lyzenga. We also have Melinda Murphy, one of our senior directors as well as Karen Johnson.

But before we get started, I just want to take a roll call of those of the committee members that are on the line with us, if you can just state your name and we can proceed.

Amber Slichta: Amber Slichta.

Wunmi Isijola: Hi, Amber, thank you.

Ranjan Sudan: Ranjan Sudan with the Bariatric Society.

Wunmi Isijola: Thank you.

Barry Markman: Barry Markman with Aetna.

Wunmi Isijola: Thank you – thank you, Barry.

Barry Markman: Yes.

Kelsey McCarty: Kelsey McCarty with Mass General.

Wunmi Isijola: Thank you, Kelsey.

(Crosstalk)

Wunmi Isijola: I heard Collette, was there someone else?

Keith Olsen: Keith Olsen.

Wunmi Isijola: Hi, Keith, thank you for joining.

(Jennifer Wims): (Jennifer Wims).

Wunmi Isijola: Thank you, (Jennifer).

Is there anyone else on the committee who has joined us?

Clifford Ko: This is Clifford Ko.

Wunmi Isijola: Hi, Cliff, thanks for joining.

William Gunnar: It's William Gunnar.

Wunmi Isijola: Hi, Dr. Gunnar.

A.J. Yates, Jr.: A.J.

Wunmi Isijola: Thank you, A.J. Is there anyone else?

Bob Sawin: Bob Sawin from Seattle.

Wunmi Isijola: Thank you, Bob. Are there any other committee members before we go into our developers?

Amy Moyer: This is Amy Moyer. I just joined.

Wunmi Isijola: Thank you, Amy.

OK. Do we have any of our developers from the call?

Male: Who haven't already identify themselves.

Jeff Jacobs: Hi, this is Jeff Jacobs from the Society of Thoracic Surgeons.

Wunmi Isijola: Thank you, Jeff. And I think I heard (Pam).

Pam Owens: Yes, this is Pam Owens from the Agency for Healthcare Research and Quality.

Wunmi Isijola: Thank you Pam for joining.

Lisa Suter: This is Lisa Suter from Yale CORE.

Wunmi Isijola: Thank you, Lisa.

(Liyuan Han): This is (Liyuan Han) from CMS.

Wunmi Isijola: Thank you, (Liyuan).

Lee Fleisher: Hi, this is Lee Fleisher.

Fred Grover: And this is Fred Grover.

Wunmi Isijola: Thank you Dr. Grover and Dr. Fleisher.

(Liz Madigan): (Liz Madigan).

Wunmi Isijola: We do that one more time.

(Dave Sheehan): (Dave Sheehan), STS.

Wunmi Isijola: Thank you.

(Liz Madigan): (Liz Madigan), (case listing), one of the developers for the home health measure.

Wunmi Isijola: Thank you.

(Casia Koh): (Casia Koh) from (Agerman), also for the home health measure.

Wunmi Isijola: Thank you so much for joining.

(Crosstalk)

Wunmi Isijola: OK.

(David Heddle): (David Heddle), from University of Colorado also on the home health measure.

Wunmi Isijola: OK, thank you.

(Debra Dee): (Debra Dee) from (AP) Associates, also on the home health measure.

Wunmi Isijola: Thank you, (Debra), for joining.

(Sean O'Brien): This is (Sean O'Brien) from Duke University and one of the measure developers from the STS measures.

Wunmi Isijola: Great, thanks for joining.

OK. Was there anyone else before we get started?

OK, well, I'll turn it over to you, Andrew.

Andrew Lyzenga: Sure, so I'll just take a quick moment to start give an overview of what we'd like to accomplish during this call. We're going to walk through each of the measures on the agenda today. I don't – what we typically do in this workgroup call is not take a deep dive in each – into each of the criteria, although we do want to – want you to (ground) the discussion in the criteria.

So, keep your comments focused on those to the extent possible, but we probably don't have the time to walk through each criterion in detail. So what we would like you to do, if possible, is to highlight during the discussion any particular concern do you have, areas that maybe problematic in the measure or things that you think weren't greater discussion by both the workgroup and the greater committee at the in-person meeting.

So, highlighting issues of concern and then issues that you would like the developers to address, if you have questions for them or things that you'd like them to clarify about the measures either on this call or in advance to the in-person meeting. Those are the things we'd like to focus on during this call.

We still have each of the lead discussions – discussants give sort of a brief overview of each of the measures and to give their general impressions about it. But, again, then thereafter, we'd like you to focus your discussion as much as you can on any issues of concern about the measures, things that you would think weren't greater discussion either on the call or at the meeting, and then questions that you have for the developer or clarifications that you'd like them to provide before you get together for the in-person meeting.

Any questions about that?

Male: (No).

Wunmi Isijola: OK.

Male: Great.

Andrew Lyzenga: I think we can just go ahead and move into our review then.

Wunmi Isijola: And so our first measure is 0533 Postoperative Respiratory Failure Rate and, Dr. Ko, if you want to get us started.

Clifford Ko: Sure. I didn't make the first call so I don't know the format, how much time do you want me to describe this measure and then what specific item.

Andrew Lyzenga: Just a couple of minutes, just give us a very high level overview, you don't have to go into much detail.

Clifford Ko: Sure, OK. So this is NQF measure 0533, the measure title is Postoperative Respiratory Failure Rate, PSI 11. The measure steward is AHRQ. This is an administrative outcomes measure and it's basically a measure that really tries to address Postoperative Respiratory Failure at a secondary diagnosis, mechanical ventilation and reintubation and it's done as a rates per a thousand elective surgical discharges in adults, 18 years and older. There's a number of

exclusion criterion in terms of cases and I also think it's limited to elective surgery.

The rationale is that Postoperative Respiratory Failure is an important issue clinically and this is a way to address that. The numerator is done by – as I've said, it's an administrative data measure and so the numerator has a number of ICD-9 because there's four ICD-9 codes that address respiratory failure procedure code for reintubation, procedure codes for mechanical ventilation. And then, there's a number of denominator codes with a number of exclusions that a number of the comments address in terms of what's excluded and what's not excluded.

So, in a nutshell, that's what this measure is.

Wunmi Isijola: OK.

Andrew Lyzenga: Thanks, sir.

Wunmi Isijola: Dr. Fleisher, do you want to add anything?

Lee Fleisher: About the measure or the only concerns that I've heard about the measure?

Wunmi Isijola: You can – both if you'd like.

Andrew Lyzenga: If you don't – if you have nothing to add in terms of a summary or overview of the measure, you can go ahead and get into any concerns or questions do you have about it.

Lee Fleisher: So the only – and the way the measure is constructed and the measure allow somebody to – it does not necessarily define that this would be postoperative respiratory failure as a sort of primary event. It could easily be a secondary or even tertiary event within a cascade because it's anytime during the hospitalization, so that the timeframe really is during – unless I'm misinterpreting, is during consults. So somebody could be in the hospital for three weeks, have an event that led to a reintubation and prolonged mechanical ventilation. And those maybe unrelated to a secondary event.

So that's the one major concern that I preferred and could see based upon the construction of the event of the measure.

Andrew Lyzenga: OK, thanks, Dr. Fleisher. Any other comments, or questions, or thoughts from the rest of the workgroup?

Collette Pitzen: This is Collette Pitzen …

Andrew Lyzenga: Oh, yes, go ahead.

Collette Pitzen: … measurement. I just had a concern in reviewing the overall measure about the exclusion categories for MDC 4 and MDC 5. They're rather broad categories of patients to exclude from the measure that they maybe more likely to have postoperative respiratory failure. And within one of those MDCs, we would be excluding all cardiac surgery procedures.

So, I'm just curios about why that was included as an exclusion.

Andrew Lyzenga: OK, thanks.

If there are no other questions or comments from the committee, maybe we could ask Pam Owens, who's the steward of this measure to respond if she has a response, or if you don't, we can have – maybe you could give us some information before the meeting or.

Pam Owens: Yes, I think I'm going to have to defer to give the information before the meeting. I apologize. I actually was not – I am the scientific lead on our quality indicators, however, I was not around, working on their quality indicators when this was developed so in terms of a rationale regarding this exclusion category and excluding, you know, the MDC 4 and 5, I'll have to get back to you.

And in terms of – I will look specifically at the pass code in terms of the cascading events. I hear what you're saying and I will have a response for both of those.

Andrew Lyzenga: Thanks, Pam.

Any other questions or comments from the committee on this measure?

Clifford Ko: I think – this is Cliff. I think just one for a lot of the measures that are claims based measures or administrative code measures, it's just the validation piece of the administrative code for the clinical quality. That they do – they're in the whole long write-up, there's internal validation that's – that the administrative code was an administrative code and that the modeling using the administrative data is sound, which it looks like it is. But, you know, it's the question of, I think, what leaves off of getting to is that how well does the code for the numerator represent the care that's ongoing.

Andrew Lyzenga: OK.

Robert Sawin: Yes, and this is Robert, I would have the same question.

Collette Pitzen: This is Collette. Again, I just have just a general comment about the usability and the ability of this measure to identify opportunities for improvement. So as it's specified, it's a very, very low rate measure with very high rates of compliance. So, I think there are some concerns on that criteria as well.

Andrew Lyzenga: OK. Thanks, Collette.

Any other thoughts from the committee on this measure or from the workgroup?

Lee Fleisher: So we'll – given our concerns well by the time we get to the face to face while someone try to address those concerns in greater detail.

Andrew Lyzenga: Yes, we'll follow up with Pam Owens at AHRQ, and we'll work with her to get responses to you or during the advance of the committee meeting or at the committee meeting.

Lee Fleisher: Fantastic, thank you.

Andrew Lyzenga: OK, all right, well, if there are no other comments or questions on measure …

Melinda Murphy: Andrew?

Andrew Lyzenga: Yes, go ahead, Melinda.

Melinda Murphy: Sorry, it's Melinda.

Going back to what Collette just said in terms of high rate of compliance with a low rate in terms of cases to be measured. And I know there's one other comment that had been registered as that, this was a value for those reasons that it remains a value as a measure to be monitored but ask the question whether it would be valuable for accountability and public reporting. And would say that if that is an issue that persists, that should be discussed definitely at the steering committee meeting, because the steering committee may want to take a little different approach and action to a measure that they feel is good for internal reporting, but not useful for accountability and public reporting.

Andrew Lyzenga: Thanks, Melinda.

And just we – I should clarify that NQF endorsement does imply that the measure is suitable for both accountability and internal quality improvement. On the issue of a high rate of compliance, there is an option available to the steering committee to recommend measures for endorsement with reserve status, which is typically used for measures that have so – and so-called topped out that there are high rates of performance. But, where there are still potential concerns for removing endorsement of the measure in terms of whether there would be maybe some sort of slide back in performance if it were not being measured anymore.

We can describe that in more detail at the meeting and give you some more information on that option, but just to highlight that for you briefly.

So unless there are any other comments on this measure, let's go ahead and move to the next one. We have measure 0178, Improvement in status of surgical wounds.

Wunmi Isijola: Yes, and Amber, are you on the call?

Amber Slichta: I am.

Wunmi Isijola: Yes, great.

Amber Slichta: OK. So this measure looks at the number of health home episodes during which occasion who've demonstrates improvement in the condition of their surgical wound. Currently, the steward for the measure is CMS, been reported for quite some time. And the numerator includes all home health episodes where the patient shows improvement in status and the denominator are all eligible wounds that stand to be able to (inaudible) and improve.

There's significant evidence that there are many ways to impact this measure if there's room for improvement. There's significant evidence also with some morbidity and mortality associated with surgical site infection and complication.

There was one comment related to this criteria and, that the measure maybe approaching topped out status with the national average at 89 percent. And I did just want to point out there, you know, that 11, you know, 11 percent of people still not seeing improvements that seems relatively significant at least for me and in looking at potential disparities, the data attached to this measure shows almost a 3 percent difference between White and Black populations at a high and low, which I'm not a statistician, but that's likely statistically significant which would indicate this measure is still important, and may not have topped out.

And I apologize at the person who was going to present this, was unable to do so, so I'm tensioning a little bit. And …

Andrew Lyzenga: That's perfect, Amber.

Amber Slichta: And I think that's it. You know, as I've said before, this measure has been followed for a while. It certainly (went) itself to developing quality improvements. And those are my comments.

Andrew Lyzenga: Great, thank you. Any comments or questions from the rest of the workgroup?

Barry Markman: Yes, this is Barry Markman. You know, I can't get a good grasp from this measure of the kinds of wounds that they initially set the criteria for visitation, I mean, were these close wounds, were these postoperative infections. And, you know, that's a question for the developer. What were the types of wounds? And – I'm sorry.

And the second question is, are we going to get a good idea on the frequency and duration of the skilled nurse visits and how it correlated to wound improvement. Actually, one of the comments was, you know, it wasn't specific on how they determined how the wound improved. So, you know, those were my questions for the developer.

And the last question is, how are these skilled nurse visits integrated within the supervision and the office visits.

Andrew Lyzenga: Oh, if we have the developer on, maybe they could respond to that question.

(Debra Dee): (David), do you want to take or would you like me to, or?

(David): Yes, (Debra), I would defer into you, sorry.

(Debra Dee): OK. All right. So this is (Debra Dee) at (AP) Associates.

And so, this measure is derived from two different time points in the home health episode. At the beginning when the patient is admitted to home health or they've just returned from a hospital visit, there is a full assessment that they need to perform on the patient known as the OASIS data set. And that data set includes an item that asks, does the patient have a surgical wound. And then asks them to document what the status of those surgical wound is in terms of healing, whether it's fully granulating, or early partial granulating, not healing, or what the status is.

And then, at the end of the home health episode which, you know, is – it can be a variable links depending on the patient's need for home health. And when the patient is discharged, they also record the status of the patient's wound. And then, the measure is calculated based on whether or not there's been an improvement in that healing status.

Were there other – I'm trying to remember, I want to make sure I cover all those questions.

Barry Markman: Yes, I mean, the question is what – I mean, we require to see a close wound, just postoperative wound without an infection or how many had infections. I mean, I would submit to you that most wounds will heal, that, you know, if you ask most of surgeons' visit, you know, wounds heal. But I don't know when the skilled nurse go out, which close postoperative wound, you know, it's going to heal and then if it's an infection, it takes a certain (inaudible). I mean, I just didn't get a good feel before you breaking down those numbers. And maybe you can address it when we get to this.

Fred Grover: This is Fred Grover, let me just follow up too with that. Obviously, there's a certain amount of subjectivity when you're – for all of us when we're evaluating the wound and people can come out with different – maybe different assessments. How much standardization is there among your visiting or home care folks, and how they evaluate these wounds? And have you ever done any sample auditing to see if there's consistency across centers in how they interpret the status of wounds.

Amber Slichta: We give a good deal of training and there is a manual that provides the – we follow the WOCN guidelines for wound healing and the descriptions. And we have done reliability testing on the item, this item has been in used for over 10 years.

So, reliability has been very good on this item.

(Liz), did you want to add anything?

(Liz Madigan): A little bit, you know, a part of it is they see all kinds of wounds. So they see some patients who have wounds but they really think for heart failure or some other reason, but because they have a wound they need to note it. So you have a patient around, you know, a hip replacement done and – but the real reason nurse is there is for heart failure treatment and evaluation in pieces because of stability. So, they're certainly monitoring the wound and they would expect it to heal. So that is exactly right.

In other cases, they're going to see, you know, the hips abdominal (limbs) that are going to require long term kinds of care as you all know. So it really runs the gamut in terms of the kinds of surgical wounds to see these nurses see.

Collette Pitzen: This is Collette, I'm just going to adding onto the discussion. I just want to understand the data a little bit better. Is the data element that the measure is being calculated from a simple yes-no question, is the wound healed, yes, no, or is there more detail in the OASIS system than that? Thanks.

Amber Slichta: What is recorded is the healing status based on the WOCN criteria. And that, as I've said, would be fully granulating or early partial granulation or not healing.

Collette Pitzen: OK, great, thanks, that helps.

Amber Slichta: Sure.

Andrew Lyzenga: Any other questions or comments from the workgroup on this measure?

Melinda Murphy: Andrew, it's Melinda again. I have a question. In the denominator statement, it leads to episodes in which the patient was eligible to improve in the status of their most problematic surgical wound. And that suggests that there could be more than one and that someone makes a choice about which one they're going to look at. Is there criteria for that as well to determine the most problematic?

Amber Slichta: Yes, we – again, in the instructions that accompany the OASIS and the manual that agency clinicians use, there is a lot of instruction in terms of determining how you would select the most problematic wound.

Barry Markman: This is Barry again, now, do you have anymore data on how the nurse – on the nurse interventions of these wounds of what, you know, I mean, is there a direct correlations of the nurse healing the wound, I mean, what are the wound treatments, and are different treatments better than others, or? I mean, the contribution of the skilled nurse to the healing on the wound and their intervention.

Amber Slichta: (Liz), is that something you want to address and …

(Liz Madigan): Well, I can, so a part of what happens is, of course, they're following physician order. So, the nurses are pretty good advocates especially nurses where the agencies are focused on this, or they're advocating for the optimal wound care practices. But they have to follow the physician's orders for the treatment.

So, you know, they don't make independent decisions in terms of what kinds of treatments they're getting. But they are and then surveying the wound as well. So they're watching these wounds and then contacting the physician when they have concerns.

They may advocate for certain kinds of things based on their experience and their, you know, their expertise. But – and some agencies also have WOCN nurses they can call in for consults if they need them. So, it really runs the gamut in terms of the variety of resources available.

Barry Markman: Yes, I was also, I mean, I have one last question.

Are there any comments about caregiver status, why our nurse needs to come in, versus having a caregiver, or number or, you know, or the patient changing their own wound dressings?

Amber Slichta: So there is an OASIS side and it talks about caregiver availability and what the caregiver can do. So it's a separate item in the OASIS data instrument. So that – what happens in some cases is that the caregivers are taught to change the dressings if they can. In another cases, the caregiver is either aren't willing or aren't able, or there's no caregiver.

Barry Markman: OK, OK. And …

Amber Slichta: And I think that the quality, you know, measure that we're looking for is that if there is a problem during the episode, the home health clinician does something to ensure that healing proceeds at the rate that is possible.

Andrew Lyzenga: And this is Andrew, and just to clarify and certainly not to suggest that, yes, these questions are not relevant, but as an outcome measure, we don't require there to be any scientific evidence around and around the processes that one might use to improve care or improve the status of surgical wounds, or, you know, we don't ask the developers to give specific information around that.

The only thing we asks for an outcome measure like this is a credible rationale showing that there is at least one process or intervention, or structure that – and contribute to an improved outcome (inaudible). Did that make sense?

Barry Markman: Yes.

Andrew Lyzenga: I'd also ask if somebody is – had us on mute, if you could – or on hold, if you could take us off hold, we're hearing some background (inaudible).

Female: Well I guess we know who it is.

Male: (Inaudible) give away.

Andrew Lyzenga: All right, any additional comments or questions on measure 0178?

Hearing none, let's go ahead and move onto measure 05 – sorry, 0454, Perioperative Temperature Management.

And I think our primary discussant on this is Dr. Olsen. You on the call?

Keith Olsen: Yes, I am.

Andrew Lyzenga: Hi, great, just want to give us just a brief high level overview of the measure and any thoughts or questions you have on it.

Keith Olsen: OK. And this is number 0454, Perioperative Temperature Management. In brief, it's measurement of our detection of a normothermia with a temperature measure greater than 35.5 degree Celsius within 30 minutes of in-time of anesthesia or 15 minutes post in-time.

It's pretty straightforward, there are some – a few exclusion criteria primarily cardiopulmonary bypass surgery, regional nerve block, and surgeries less than 60 minutes that are unlikely to develop hypothermia.

Strong justification in the number of supportive publications, that very few publications is non-supportive. I would think this would probably be a standard acceptance with the anesthesia. NACOR which is a reporting group of anesthesiologists, the National Anesthesia Clinical Outcomes Registry, has kept track of this although they only have about a 25 percent reporting rate. In that, those that do report around and greater than 95 percent compliance.

The question, I guess, would be out there would just be the standard and it's already close to topping out. We don't know about some – a lot of those hospitals without electronic healthcare records to be able to forward the data as well as smaller institutions.

But, that's kind of in a short version.

Collette Pitzen: This is Collette Pitzen, I have just a couple of secondary comments to add if that's OK?

Male: Yes, sure, thank you.

Collette Pitzen: Just a couple of technical suggestions, I would suggest that the numerator be stated a little bit differently, it gives the impression that you really look just the outcome of temperature. But further into the measure and please correct me if I'm wrong, you are also accepting warming devices as meeting that criteria so that's warming device or normothermic temperature.

And then the second comment I have is, again, Dr. Olsen had alluded to this, it's registry participation in terms of assessing, you know, the performance rate for the measure and what processes are in placed to ensure that all eligible patients are submitted. And that's a very general comment I have (about all) registered based measures.

But – and then the developer had noted that they're making some changes on the CPT II code use. There is a little bit of inconsistency between how the

numerator is stated and the actual CPT II quality improvement codes, but I understand that they're working on that. Thanks.

Andrew Lyzenga: All right, thank you.

Any other comments or questions from the rest of the workgroup?

Wunmi Isijola: So I have a question for Collette, you're making the assumption they're working on that, are you looking to hear and update at the steering committee meeting …

Collette Pitzen: That would be great. And in fact, there was indications further in the documentation that they're talking about propose and exchange for that, but the CPT codes listed in the way the numerator has stated, they are different temperatures that are being expressed.

Wunmi Isijola: OK, so.

Collette Pitzen: Thank you.

Male: (I'm on mute).

Andrew Lyzenga: So did we – do the developers care to comment on that at this time, or would you like to take a look and return with some additional information at the in-person meeting?

Or we will reach out to the developers and make sure they are aware of the – our committee questions and ask them to be prepared with a response at the in-person meeting. And – oh, yes, go ahead.

Wunmi Isijola: Yes, along that line, were there some questions also or some additional information (desired) regarding testing?

Karen Johnson: Yes, this is Karen. I know that with the testing results that they've seem to provide seems to be more just showing results overtime, which doesn't really quite hit what we mean by reliability testing. So, I think we would ask them if they have other kinds of testing either at the score level or of a data element.

Andrew Lyzenga: All right, thanks, Karen.

Wunmi Isijola: So at the in-person meeting, we'd be looking for additional information in that regard.

Andrew Lyzenga: Any other thoughts or questions from the workgroup on this measure?

All right, hearing none, let's go ahead and move onto the next. Next we have measure 0119, Risk-Adjusted Operative Mortality for CABG. Lee Fleisher …

Male: Sure.

Andrew Lyzenga: … you are our primary discussant.

Lee Fleisher: Yes, did you just say that I am (Lee)?

Andrew Lyzenga: Yes, Dr. Fleisher …

Lee Fleisher: Yes, yes, OK, sorry.

Andrew Lyzenga: Yes, 0119, no problem.

Lee Fleisher: So this is well-utilized measure by STS, the Society of Thoracic Surgeons in utilizing their database, which is utilized in about 95 percent of all cardiac surgery. And it's patients age 18 or older undergoing isolated CABG who die including both hospitalization in which CABG was performed even after 30 days or does occurring after discharge from the hospital was in 30 days.

And this is essentially a risk-adjusted measure that is updated with – by the Society of Thoracic Surgeons as far as the risk-adjustments overtime. There's a lot of validation much of it in the published literature. There's well-described variation and naturally risk-adjusted outcomes, as well as differences and shown with disparities, with regard to both race and gender, which I know that at least just economic status is being debated at CSAC in the future. And how that'll affect the measures unclear.

But otherwise, this is a pretty well-defined measure that's been – but the key is really being part of the STS database.

Andrew Lyzenga: All right, thank you, Dr. Fleisher.

I believe we have Dr. Ko as the secondary discussant, do you have any additional thoughts or comments, Dr. Ko?

Clifford Ko: Oh, nothing for me.

Andrew Lyzenga: OK, thanks. How about the rest of the workgroup? Any thoughts from you on this measure?

Amy Moyer: This is Amy Moyer at The Alliance, and I just had a question about the levels of analysis. There are other measures that are in PQRS that kind of get at different practices, but it just seems like mortality is really a key outcome measure. And I'm curious why this doesn't go all the way down to the individual clinician level.

Andrew Lyzenga: OK. Do we have the developers online for this measure? I think I heard somebody – yes, yes.

Jeff Jacobs: Yes, we do this multiple numbers at the Society of Thoracic Surgeons (clinical). This is Jeff Jacobs.

Andrew Lyzenga: OK, hi, Jeff.

Jeff Jacobs: And, you know, good afternoon. I think the only question I've heard so far relates to the question of individual provider evaluation versus problematic evaluation. And up until now, the STS strictly publicly reported hospital based outcomes or program based outcomes, based on the belief that outcomes after cardiac surgery are reflective of the performance of the entire team.

That being said, STS is very well aware of a strong desire for multiple shareholders to move forward with individual provider performance measure. And consequently, STS is in the process of developing now similar measures for individual providers. The development of measures is complicated by the fact that the sample sizes are clearly smaller than the sample size for an entire program, but that's not going to prevent the development of those measures.

So I guess the short answer for the question is, our current measures are problematic level or hospital level, because of our belief that outcomes are related to the performance of the team. However, we are in the process of also developing measures for individual providers which we – and to release relatively soon.

(Dave Sheehan): And I would just add from – this is (Dave Sheehan) from STS that really a sample size issue is very concerning when you're looking at a single procedure and a typical surgeon's volume. Even though CABG is one of the most frequently performed major procedures, it still has sample sizes at the surgeon level which are typically inadequate to get meaningful differentiation or performance in a one-year sample. You can extend out to multiple years but the further away you get in the data you're using for the measure, the less relevant those (were) more remote data points become.

So, that's another major reason that we have tended to stick to the program level in addition to the team issue that Jeff phrased, the composite individual surgeon measure that we're developing encompasses multiple procedures and that sort of makes up for the sample size issue with CABG alone. But CABG remains such a central part of the armamentaria and of any surgical program and cardiac surgery that we think we should continue to have this measure.

Collette Pitzen: This is the Collette from the workgroup. I have a couple of comments if that's OK?

Andrew Lyzenga: Sure, go ahead, go ahead.

Collette Pitzen: I just want to talk a little bit about the performance gap and I'm not implying that this isn't an important measure because it is. But in terms of public reporting and providing opportunity for improvement, the STS website, every single practice that is listed is given a two star rating. So it's not demonstrating the ability to differentiate provider groups from one another.

Some other just general comments, again, registry participation and a way to ensure that all eligible patients are included. And then just a comment on feasibility. The data elements that are collected for the STS registry are pretty

intensive looking. I would venture that some groups are able to collect all of this information electronically, but that many do need to abstract (inaudible). So I just wanted to comment on the feasibility and the data collection burden.

Andrew Lyzenga: Thank you, Collette.

Jeff Jacobs: This is Jeff Jacobs, I think I should address all three of those points.

Collette Pitzen: Great.

Jeff Jacobs: First, I would comment on the issue about our ability to discriminate program using the mortality measure, and having your one star, versus two star, versus three star. And my answer to this is going to have two parts. The first part would be that the mortality measures and isolated quality measure but is also was a component of our overall CABG composite score, which is a multi-domain composite that includes mortality, morbidity and processes of care.

And when doctor gets to the composite, we differentiate programs by the star ratings with consistently year after year about 75 percent two star and 12.5 percent one star, and three star.

Now, if we talk about the individual mortality component alone, or this particular measure, what I can tell you is that in 2013, for example, there was 1,046 sites in the STS database that performed an isolated CABG. 870 of those performed 50 or more. And the different mortality across those sites range from 0 percent to 12.1 percent.

So, although, the overwhelming majority of CABG participants or database participants achieve excellent results of isolated CABG, there are still some that have higher mortality. The star rating system – and I reflect back because of confidence interval issues. However, public reporting site at the STS plus the public reporting site, our consumer's report, allowed not only visualization of the star rating, but the associated numeric mortality numbers with those star ratings date, simply right clicking on the stars.

So, I think there is differentiation between programs by drilling down beyond the stars to the numbers.

Second question is related to our ability to capture all patients in the database. And I can tell you that between 90 percent and 95 percent of cardiac surgical programs in the United States currently participate in the STS adult cardiac surgical database and report isolated CABG. And of the few programs that don't – most our programs involved with the VA on military hospitals, so all those penetrants are not a 100 percent, it's pretty close to a 100 percent, and therefore, we're capturing almost all patients in the United States undergoing isolated CABG.

And finally, regarding to the ability to capture all of the data elements, I think there's a couple of pieces of information to share related to this. First of all, the high penetrants shows that most programs do have the ability to participate and capture these data elements.

Second of all, the quality of the capture of those data elements is audited aggressively with, perhaps, the most aggressive audit of any clinical database in the country right now with multiple sites having site visits and audits every year.

And finally, we do realize the concern of data entry burden and we're currently in the process of collaborating with leading genders of electronic health records to potentially develop methodologies that at least some of the data elements can be imported directly from the electronic health record of the STS database. And although we don't have the ability to do that now, we anticipate being able to do that in the future in an effort to minimize data entry burden.

I think I got all three questions.

Collette Pitzen: This is Collette again, can I respond, thank you very much. I completely agree that the measure within a composite is very valuable. And I was just making my comments on evaluating the measure as a standalone that's coming to us (to review).

My second question about – I didn't doubt the wide penetration use of STS, but at the individual site, is there any assurance that a participating site is

including all of their patients? That was what that comment was really (add to). And …

(David Sheehan): Collette, this is (Dave Sheehan), I can just respond to that …

Collette Pitzen: OK.

(David Sheehan): … to follow up and just comment the audit which this year will encompass 10 percent of all STS participant programs, includes an audit of the hospital's OR logs. So, we look at the cases that have been submitted to STS and we compare it against the cases in the hospital operative logs to make sure that there's a 100 percent collection of those data.

Collette Pitzen: Perfect, that's exactly what I needed to hear. Thank you.

(David Sheehan): Yes.

Andrew Lyzenga: Great, thank you.

Any other thoughts or questions from the workgroup on this measure?

Well, hearing none, let's go ahead and move onto the next. Next up, we have measure number 2558, Hospital 30-Day All-Cause Risk-Standardized Mortality Rate Following CABG.

And …

Kelsey McCarty: I think …

Andrew Lyzenga: Yes, sorry, go ahead.

Kelsey McCarty: Sure, this is Kelsey, presenting measure 2558. The steward for this is the Centers for Medicare & Medicaid Services. And I have to thank Dr. Fleisher for his introduction of the previous measure as the description is almost identical.

CMS even states in their description that they sought to harmonize with the STS (committee) metric, and therefore, maintained a much similarity as they could in this admission.

The primary differences (or at) the STS metric speaks to look at mortality within the hospital stay, even if it exceeds a 30-day mark, as well as an all-cause 30-day mortality. This metric only looks at the all-cause 30-day metric, so they're not – it's not evaluating in hospital beyond 30 days.

The other differences that they cite is the difference in patient population given that this is (pulling) from the Medicare database, as well as the fact that it's – the isolated CABG as one exception or exclusionary criteria regarding (epicardial main) procedures in the STS metric that this one does not include.

Other than that, the two metrics are very similar. My only concern is leading through this was visit, this was enough to justify a second metric on this topic and maybe understand more about the advantage of CMS in proposing this over the current STS metric.

Andrew Lyzenga: OK, thanks, Kelsey.

So, any other thoughts or comments from the rest of the workgroup?

Otherwise, we might – I think we – we'll have to have some discussion at the committee meeting or following the committee meeting, or we will likely have some discussion around related and competing measure issues and harmonization issues.

We will have to get to the point where we – and we – well, we won't address those issues typically until we have made endorsement recommendation on each of the measure at which point. If we have – if the committee has recommended two measures that are deemed to be competing, we will ask you to have some discussion around whether it would be appropriate to choose one of those measures, the best in class. Or whether there is a credible rationale or justification for having both measures, in which case, we would also ask you to have some discussion around harmonization of the two measures. And if

we are not already harmonized, how the developers might best be able to do that.

Any questions about that?

Collette Pitzen: This is Collette. I have a question now when I'm thinking about both of these measures together.

Male: (Sure).

Collette Pitzen: The second measure, 2558, pulls in the vital statistic records as a piece of assurance of capturing 30 day mortality and I'm – know I'm curious about the STS measures, and if there are some connection with (inaudible).

Jeff Jacobs: Yes. This is Jeff Jacobs. And I can answer that question.

First of all, I think the background is that STS would at least view these two measures of complementary, because they fill gaps what the others can't address. We think that the clinical measure provides enhanced ability to do risk-adjustment to define a more pure cohort of patients undergoing isolated CABG.

The administrative measure provides method for non-participants in the STS database were less than 10 percent of the country to be able to report mortality. But I think that, the specific question related to our ability to track longitudinally mortality, which there's two pieces in (play) that we have. As Dr. (Sheehan) described, we have a vigorous audit program.

And in the STS database documentation of vital status, 30 days after the operation is required through a number of measures either seeing the patient in the office or confirming that the patient is alive from a referring cardiologist. So that documentation is all the component of the database and that (deal) is audited aggressively.

Secondly, we are – we have successfully linked the STS database to the Social Security Death Master File. And we're also working on linking at STS database with the National Death Index as well.

But I think our primary method of verifying 30-day survival through a clear clinical documentation and clear audit is quite precise and accurate.

And finally, I would just briefly add that one advantage on the STS side is that many patients die after 30 days while still in the hospital and those are only captured with a death on postoperative 31 would only be captured with a clinical measure.

Collette Pitzen: Great, thank you for the clarifications.

Andrew Lyzenga: Thanks, Dr. Jacobs.

Any other questions or comments from the committee on measure 2558?

Melinda Murphy: So Andrew, I have a question for the reviewers in terms of 2558 and the all-cause …

Andrew Lyzenga: OK.

Melinda Murphy: … whether or not they feel comfortable in understanding whether the all-cause in conjunction with the following CABG surgery obscures anything with respect to CABG mortality, or did I see that as being controlled in a way that is valid.

And then I had another question about the denominator exclusions when it speaks to other unreliable data to know whether or not that's defined or handled in some way definitively in an extraction algorithm.

So the first question is to the group, did they see that? And the second question would be for the developers coming to the meeting.

Andrew Lyzenga: Thank you, Melinda.

Kelsey McCarty: So this is Kelsey again on measure 2558. We wanted to think that I'd appreciated about this submission is that the developers did look at socioeconomic status along the Medicaid population in different death files of the population, as well as in African-American population in terms of that had

any difference in terms of mortality rate. And what they found that in those two factors that there wasn't any statistical difference of notes.

I think to your point, one of the concerns I have is that those are two socioeconomic factors that could drive mortality. I think there are many others that were not presented in at that effect. So, I'm not a statistician, but I would share the curiosity and wondering if there are other socioeconomic factors that could impact that.

(Crosstalk)

Andrew Lyzenga: … just to interject for a moment. I should note that the issue of adjusting outcome measures force factors – for sociodemographic factors is actually something that we have been thinking about a lot at NQF, and actually have a committee, a special panel looking at that issue right now. We're viewing it and trying to determine whether we will recommend that outcomes measures can or should be adjusted for sociodemographic factors.

At the moment, NQF's current policy or guidance for measure developers is that outcome measure should in fact not be adjusted for sociodemographic factors.

The reason for that is that, it could – or just a way – problems and quality between different facilities. And actually masked disparities based on sociodemographic factors in terms of the quality of care being provided, that may change based on – depending on the recommendations of the socioeconomic status panel.

But at the moment, our current recommendation which we kind of have to go by until the expert panel's recommendations are finalized.

And we have to go by our current policy which is that developers should not address measures for sociodemographic factors. Is that clear? Or any questions about that or comments?

Collette Pitzen: This is Collette. I have an additional question about exclusions for 2558.

Andrew Lyzenga: Sure.

Collette Pitzen: Just a more curiosity, but it looks like that if a patient have a repeat coronary bypass procedure during the measurement period that that patient is not really excluded but they're not counted as the index visit. And I'm just – I'm curious on the development side how that's impacting the measure rates.

Lisa Suter: This is Lisa Suter from Yale CORE. I'd like to respond to some of the questions that I heard, if that's all right with the committee?

Andrew Lyzenga: Sure.

Lisa Suter: The first question was regarding the stipulation for excluding unreliable data elements and a request of whether or not there's a formal algorithm.

Yes, there's a formal algorithm. These kinds of data elements are very rare but they are things like age 130 or those kinds of things that are outside parameters. And we would be happy to provide details of our algorithm for unreliable data if the committee would like to see that in the in-person meeting.

The second discussion was discussing the issue of the all-cause mortality, and I'm not sure that there's a lot of controversy about that. But just informing the committee that we feel that using claims data, it's very challenging to distinguish related and unrelated events and there is a – because of the nature of CABG surgery, our clinical experts were comfortable with using an all-cause mortality definition as a reliable – more reliable outcome measure related to the care that the patients receive at the time of the CABG surgery.

In regards to the exclusion of the CABGs that occur following the index CABG and how that impacts the measure score. We have not investigated that specifically, although we can do so if the committee would like us to provide that information. It is a challenge in mortality measures because, obviously, you have a different risk of death, knowing that there is a follow-up admission to an initial admission.

So, often times with mortality measures, they randomly select index admissions to try and offset this unequal risk of mortality. With CABG, we have a challenge in trying to coordinate our readmission in mortality measures. So we have eliminated downstream procedures in terms of being additional index admissions in this measure, but we do correct for the history of an index – a prior CABG procedure.

So the additional risk for someone under going a redo CABG that might be outside of the window. So you're seeing the redo procedure later in the measurement timeframe is captured by the risk adjustment.

And I guess on the last point regarding socioeconomic status, if there are very – if there are specific analyses that the committee would like our group to bring back for the in-person meeting, we would be happy to try and accomplish that, in addition to the other analysis that we've already provided.

Thank you.

Andrew Lyzenga: OK, thanks. Melinda did you get your questions answered?

Melinda Murphy: Yes. Thank you.

Andrew Lyzenga: OK.

Any other comments, or questions, or thoughts from the workgroup on this measure?

I hear none, so let's go head to our last measure. We're making good time.

(Crosstalk)

Andrew Lyzenga: Yes, OK. Go ahead.

Ranjan Sudan: Thank you. This is Ranjan Sudan and I'm the Chair of the Research Committee for the ASMBS, and I'm presenting this on behalf of the ASMBS and my words of disclosure. Dr. (Martin) was to discuss this but he's unavailable so I'm sort of pinch hitting for him.

So the measure is 2556 and this is looking at Yearly Surgical Case Volume of Primary Stapled Bariatric Procedures and setting …

(Crosstalk)

Female: And I thought I was (inaudible) this. Is that incorrect?

(Crosstalk)

Andrew Lyzenga: Yes. I should have been sort of cut in here. For the workgroup calls, we actually would ask our workgroup members to introduce the measures …

Male: Oh, sure.

Female: Oh, OK.

Andrew Lyzenga: … at the in-person meetings, we do ask our developers to do a brief introduction of their measures. But on the workgroup calls, we'll just ask you to respond to questions or comments from the committee. So, but we do appreciate that.

Amber, do you want to give a quick overview of the measure?

Amber Slichta: Sure.

This is being (the host) of the new measure and I think we've already covered that. So, thank you. And the measure would look at the yearly case volume of the primary stapled bariatric procedures performed on people 18 and older, meeting the NIH consensus conference guidelines for this type of surgery.

The rationale for this measure includes that it's easily quantifiable and the proposed there are also indicated that it's a proxy for the experience expertise and institutional commitment to this type of surgery and a proxy for patient choice as well.

There are two potentially proposed numerators for this measure. One would look at the actual cases reported. The other potential proposed numerator

would be discharges based on a variety of codes for bariatric surgical procedures and a diagnosis code for morbid obesity.

And then again, the denominator would include all hospitals performing the surgery and, again, there's a variety of codes that would be included in the denominator.

There is certainly ample evidence that this could potentially be a high priority measure given the high prevalence of morbid obesity and that it's increasing. The evidence for measuring volume is, however, mixed. There are some evidence that indicates volume at the surgeon and institutional level, decreases morbidity and mortality. However, there is other evidence tying decreased morbidity and mortality to accreditations rather than only surgeon and or institutional volume.

The feasibility to – for looking at this measure, there is a cost associated with accessing the (MDS AQIT) database. The data can also be collected discretely as prescribed by the proposer from a number of different sources which may or may not create a burden depending on the hospital that needs to collect it. There don't appear to be any – and there don't appear to be any competing measure.

So I think my overall comments are certainly there's an increasing need for the measures in particular that might lend themselves to patients making a good choice about where to have this type of surgery. I'm not the (evidence here) does seem to be mixed as to whether or not volume is a reliable indicator of whether or not morbidity and mortality will be decreased. So I will stop there.

Andrew Lyzenga: Thank you, Ms. Amber.

Any other comments or questions from the workgroup before we turn to the developer for a response?

Fred Grover: You know, let me – this is Fred. Let me (drill) with just a follow up on that a little bit. It seems like that the thing in the area I'm involved with volume, if you look across the board, volume is correlated with outcomes. But there are many exceptions to that rule, there are some high volume centers that don't

perform as well. And there are some low volume centers that perform surprisingly well, when you analyze, their mortality, morbidity, and various other outcomes. I guess my question is, why don't you go to the cracks of it and measure mortality and morbidity.

Kelsey McCarty: This is Kelsey. I've always seen studies that suggest that volume in terms of outcome is also very closely tied to the individual performing this procedure. So I'm curious to learn from the developers why this is gone, why it's only looking at the organizational level and not at the individual level.

Andrew Lyzenga: OK, great, thank you both.

Now at this point, does the developer have any responses or thoughts on the committee's comments to this point?

Male: Sure.

Ranjan Sudan: Dr. (Martin) is available, so maybe he can start then I can add if need be.

(John Martin): Hi, this is (John Martin). And first of all, I appreciate the committee taking time to have a thoughtful review of the measure, I'm happy to answer any of the questions.

I'm the (president elect) of the society and we've put forward this measure because we do believe the preponderance of the evidence supports that there's improved outcomes with the volume standards (inaudible) to respond in one of the questions about the potential burden, the reporting measure. It's not required to have this through the accreditation body. That should be a safe (inaudible) the accounts of the number of dates is actually easily (inaudible) or any local hospital level with the measure being in placed.

The other, I think, question that came up is why not examine mortality and morbidity. We do think that those are important things to measure. But we do think that the process of the volume is one that's important that affects those outcomes and it's one step forward beyond that.

Final point I'll make is that bariatric surgery at least in its current iteration is relatively new accreditation for the procedures that's only been around for about the past seven years. So we view this measure as being important towards the continued growth and integration of bariatric surgery into the medical community.

Final thing, I guess, was around the surgeon versus the hospital. There are not a lot of data to distinguish between hospital and surgeon volume. Most of the data are really around hospital volume. And I do – we do believe that this measure looking at strictly stapled cases in a hospital level will help ensure starting level quality for patient seeking bariatric surgery.

So, thank you again for the opportunity.

Andrew Lyzenga: OK, thank you.

Melinda Murphy: So Andrew, this is Melinda, if I can make a comment or two.

As the steering committee considers this measure, I think one of the questions that will come, again, at this group has alluded to is, that this is identified from backing up a little bit as a process measure. In fact, it would probably be considered a structure measure. And that most often, steering committees are going to ask, is there a companion outcome measure, when you're putting forth a new measure that looks only at volume.

In fact, I think steering committees, to uniformly over an entire set of measures, has identified that they've – were comfortable endorsing a volume measure only when it was accompanied and reported with an outcome measure. So I just offer that as the developers think toward the steering committee meeting and as the work members think toward it.

This maybe a larger question that's raised. And the developer would need to think about that carefully, I believe.

(John Martin): May I respond or.

Female: Sure.

Male: Sure.

(John Martin): So I really do appreciate that comment. I think that that's perfectly consistent with, you know, our efforts to have volume as a reported measure, which certainly would consider to be a companion piece with morbidity and mortality. We just thought this was the best one forward. And we'd certainly would be mindful of whatever the overall policy might be for this kind of procedures.

Regarding, you know, whether (you're) not be considered volume structural process I think has allude to some degree interpretive. The volume is how the care is rendered. And a lot of the things actually go in for volume as mentioned in the measure. There is, of course, the outcome measure part of it. But, physician patient satisfaction goes into (that) as well. But, I fully understand where you're coming from. And we would be open and welcome to having this as part of the companion piece if that's what's needed or required.

Karen Johnson: And this is Karen. I have a couple of questions for the developer. One is, I noticed or I didn't see any testing for reliability or validity. Can you tell me if I just missed it or if you, perhaps, have not done that kind of testing?

And then secondly, I'm curious about opportunity for improvement. I'm viewed that this kind of structural measure. So, I'm just curious what you would – if how you would expect – is it that increasing volume would fix the gap? I'm just a little bit confuse about opportunity for improvement.

(John Martin): I think that's a really good question. I think the first part about opportunity for improvement is that there's quite have been a variety around the volume that's out there that's been offered by different organizations or by different (inaudible) payers. And this is the – this particular standard is one that's endorsed by the evidence. And it allows more participation for centers.

There are still quite a few centers that do not perform at that level of volume. When we'd look at probably our best kind of national measure for this is the National Inpatient Sample. There are still quite a few hospitals perhaps on the

order of about 20 percent that don't meet that standard. And there's demonstrable negative outcomes for them.

In regards to the reliability part of it, we haven't specifically tested that. When we got it, it's relied upon what's been published around the area, when looking at volume and outcomes. And it's been pretty consistent. It's been measured both on a hospital level, a state level, and national level. So it does appear to be, you know, fairly easy (festival) type of measure.

Andrew Lyzenga: OK, thank you.

Any additional comments or questions from the workgroup?

Well, hearing none, we'll move onto the next one. I was in error in saying that was the last one, there actually is one (more) measure. This is 2557, Hospital-level, 30-day all-cause readmission rate after elective primary bariatric surgery procedures.

And Collette, I think you're the primary on this one.

Collette Pitzen: Yes, great, thanks. Yes, measure 2557, a 30 day all-cause readmission measure following elective bariatric surgery procedures. Four defined procedures are included in that. And the readmission is for any cause within 30 days after the discharge date.

I'm just going to intersperse comments as I'm reviewing the measure, too. I hope that's OK. The developer state does not have a traditional numerator and denominator, but actually it does. So the numerator for this measure would be the patients that have the event of 30-day all-cause readmission. The denominator is stated as all hospitals performing bariatric surgery, but I would – or suggest maybe that the intent was the denominator is all patients undergoing that particular procedure.

Although there was no data, or a testing, or analysis, performed on this measure, I think it's important to measure and can impact, again, the national epidemic of obesity and the number of patients that are having this procedure.

There was literature provided that did demonstrate some potential opportunity for improvement. Citing the readmission rates of laparoscopic bypass, 6.5 percent for open, 9.4 percent for sleeve gastrectomy, 5.4, and adjustable gastric banding, 1.7. So grant to these readmission rates aren't as high as some of the chronic conditions like heart failure, COPD, and cardiovascular disease that have readmission rates on the 18 percent to 22 percent range. But many surgical procedures have much lower readmission rates. So I think there's potential opportunity for this measure.

Again, my concern about a registry based system, the developer indicated that patients are being lost to follow up. That – it would be a rare instance or not a concern, however, studies of the Medicare population have demonstrated their readmission to another facility could be as high as 22 percent from the same data. It could be an issue with this measure.

Let's see, what else. Oh, the exclusion for this measure, the intent is to exclude malignant neoplasms of or gastric cancer. And the codes listed are ICD-9 150 series which is malignant neoplasm of the esophagus. But I'm wondering if the developer considered the next range of codes which is (151X), the malignant neoplasm of the stomach, and if that would be an important exclusion to include.

And I'm just wondering – again, we have no data to demonstrate any opportunity for improvement and I'm wondering if the developer has the opportunity to look at some of the data within their system, and to provide some of that information for us.

Andrew Lyzenga: All right, thank you.

Any comments or responses from the developer at the moment?

(John Martin): Sure. This is (John Martin) again and thank you for the comments.

In response to opportunity, one of the reason this is particular measure was chosen was because some of the other outcomes post-surgical such as mortality, small balance instruction, (EVP), bleeding, (we found) and review

of national registry data were quite low mortalities about 0.1 percent and those other complications on the order of less than 1 percent.

And we chose readmissions because there's still opportunity for improvement there, where you have a higher prevalence of the outcome, which is roughly about 6 percent to 8 percent depending on which registry you're looking at.

So that's where the readmissions was chosen and it is a place where there can be opportunity for improvement and lots more opportunity for coordination of care that lends itself to bariatric surgery where we do employ a lot of different multidisciplinary teams including nutrition psychology and everyone else.

I'm sorry if I missed what the other comment was.

Collette Pitzen: This is Collette. Let me try to back up. Just one of – that comment was just related to, we have no data with your submission that allows us to evaluate that potential opportunity. So I don't know if you have the opportunity to actually provide us with some readmission rates for these patients, that would be helpful.

An additional comment – I just had some technical things about the numerator – how the numerator and denominator was stated that it's actually a proportionate rate measure. And that it could be impacted by the same data in terms of readmission.

And then, the second comment was related to the exclusion codes, perhaps the consideration of the 151, but I'm not a cancer expert. So, just a suggestion.

(John Martin): Yes, thank you. And just a couple on exclusion part. The type of procedures are sometimes – and not just for a (residue) but for cancer. And the intent was that the exclusion was going to be for the listed codes that were malignancy and it was meant to be listed as (151X). So any sort of (subjects) associated with those first few numbers then exclusion. So, thank you for demonstrating that.

Collette Pitzen: Great.

(John Martin): The other thing about the actual readmission rates, we do have a date available to one of the registries and the concern would be provided to the committee. And I think the other point was around missing data, which I think is very valuable point.

Some of these readmissions may not occur at the index hospital. If there's participation in one of the registries, there is opportunity to actually get the missing data with 30-day follow up. And I would offer that one of the registries is – can be a (inaudible) very good follow up rates at 30 days, it's in the 90 percent range.

But that is something that, I think, many of the readmission measures have as a problem potentially where you aren't able to pick up on that data. But that's our current thought around that is the reliability about having the 30-day follow up in particular registry.

Collette Pitzen: OK. So this is Collette again. I just – for clarification. So with the registry, there is an attempt to reach out beyond the index facility?

(Crosstalk)

(John Martin): Yes. So, the way it would work is that there's usually a letter that goes directly to the patient and find out if that patient was readmitted at a different facility, and then that information is relayed back to the index hospital.

Collette Pitzen: Great. Thank you.

Ranjan Sudan: Yes. Can I jump in and just add one comment that would have clarified that point further? As a criteria for participating in (MDS AQIT), that is a requirement. And we require in a very high participation and attempts to be able to get that data from phone calls, of course, to primary care doctors, et cetera. And so we are aiming for about 95 percent follow up at that 30-day point.

Collette Pitzen: Great, thank you.

Andrew Lyzenga: Thank you.

Any other comments or questions on this measure?

(Crosstalk)

Female: Sorry, please go ahead.

Female: Hi. I just – I had a couple of questions, again, for the developer. As you know, our NQF measures are deemed to be useful for both QI and accountability. But you state that while you're working on doing a risk adjustment method for this measure, you don't have one developed yet. So this measure currently is not risk-adjusted.

So, I guess I'd like share a little bit more about that. And do you think that is, you know, not being risk-adjusted and stating that you think that risk adjustment would be useful? Is this an appropriate measure for accountability purposes?

And then second, like the last measure, I did not see any information on reliability or validity testing. So, I'm just wondering, is it – did I just miss it or did you not provide that?

Thank you.

(John Martin): Thanks for the comments. In regards to the first part which is – I'm sorry, what was that first part again? I was thinking about your second part.

Female: About risk adjustment.

(John Martin): Oh, risk adjustment. Thank you.

So we – the risk adjustment in bariatric surgery is still involving field but it's getting closer. The main problem is that a lot of the risk adjustment that has been done to date is relied on administrative data that lacks a key component of risk adjustment, namely the (DMI). So that generally has not been available.

That being said, a lot of the newer clinical registries are able to capture that where they have the (DMI).

The issue prior has been having enough sort of a substrate or research substrate to figure out the risk adjustment.

One of the registries is able to do that now, the (MDS AQIT) that has roughly about 200,000 cases. The anticipation is that the risk adjustment model will be completed this summer. So that model will be available.

That being said, the approach we took with this particular measure or our risk adjustment is what I would call risk stratification. And the idea was to exclude the revision cases that we know carry a higher readmission rate.

In addition, obviously excluding those cancer cases. And really speaking to the index procedures, and we think that that would give us a more (homogenous) model population and allow us to have a better direct comparison. So that was our first approach is risk stratification, but we anticipate that the risk adjustment will be available later this summer.

With the reliability issue, again, we're relying on what's published data out there around the readmission, so what has been offered has been what's been in the public's literature.

Andrew Lyzenga: OK. Thank you.

Additional thoughts or questions?

All right, hearing none, we can go ahead and move onto our next agenda item, which is bit of discussion about the role of the – our discussion leaders at the in-person meeting.

I'll just say a few words about that. We have actually developed what we're calling a script for each of our lead discussants. We will provide that to you, our committee members, in advance of the meeting. And that will actually walk through each of the evaluation criteria with a few key points and key questions that we'd like you to address in your introduction of the measure as well as for, again, each criterion as we walk through that.

The process will be during this in-person meeting is that we'll have the developer give a short introduction of their measure. We'll have the lead discussant give another brief overview of their thoughts and reflections on the measure as a whole.

And then we will walk in through the criteria one by one. We'll first discuss importance and each of the sub-criteria within importance and then we'll take a vote on importance to get the committee's rating. Then we'll – we'll then move onto scientific acceptability, hold some discussion around that issue. And, again, vote on the scientific acceptability criteria and move on in that fashion through each of the criteria.

This is a bit of a departure from previous committees where we've just held discussion and then voted on all of the criteria one by one at the end of that discussion. We think that helps us focus the discussion a little bit more directly on each of the criteria and helps us to address those criteria specifically one by one and get a little bit more sort of coherence to the discussion.

So, again, we'll be distributing those lead discussant scripts in advance of the meeting. I think that's about it on that, unless you have anything to add, Wunmi.

Wunmi Isijola: And also the script that Andrew was speaking to, that's actually posted on the SharePoint site so you can reference that. It's under the general document section. And just so we don't get out of the way. Do we have any of the NQF member in public who may want to comment on any of the measures being discussed today?

Andrew Lyzenga: Yes. Operator, could you open the lines for public comment now?

Operator: And all lines are open.

Andrew Lyzenga: So we would welcome any comments from the public if you're on the call.

Wunmi Isijola: OK. All right.

Andrew Lyzenga: Hearing none, I guess we can go ahead and move on.

Do you want to give us some info on the next steps, Wunmi?

Wunmi Isijola: OK.

So our next step is, essentially, we have our next workgroup call and that is on May 13th. We do ask for the committee members who are on the call today to submit your survey responses by May 9th which is tomorrow. And then we will convene again. And with that being said, Melinda, did you want to add anything?

Melinda Murphy: No, thank you.

Wunmi Isijola: OK.

Andrew Lyzenga: And just to clarify for the members of this workgroup, you don't – you're not required to attend the subsequent workgroup call, but you're, of course, perfectly welcome to listen in if you think it would be helpful and enlightening, that you sort of done your duty with this workgroup call in terms of your workgroup responsibilities. Although, we will ask you to review all of the measures that have been submitted under the project before the steering committee meeting. So, you do have a little bit of homework yet to do.

Any questions or comments from our workgroup, or developers, or the members of the public before we sign off?

A.J. Yates, Jr.: Yes, this is A.J. Yates, Jr. from Pittsburgh. I have a quick question.

Andrew Lyzenga: Sure. Go ahead.

A.J. Yates, Jr.: For this particular workgroup call, we had a compilation of the preliminary comments.

Andrew Lyzenga: Yes.

A.J. Yates, Jr.: And on the last one, I don't remember the compilation of commentary being sent out ahead of time, the summary comments. And when I go in on the

SharePoint, I don't see anywhere where I can look at the compilation from either workgroup one or workgroup two. This is things to think about when we come to the in-person meeting.

Wunmi Isijola: OK. If you go in the SharePoint site, you are correct and we compiled the workgroup as a survey responses and it should be up for workgroup two. We can, in fact, upload the one for workgroup one. But also just as an FYI within each measure, we have also uploaded each individual measure with these corresponding survey responses. But to your point, we'll definitely make sure that that is provided for your review.

Andrew Lyzenga: Yes, just to clarify what Wunmi just mentioned. For the in-person meeting, we'll have in each of the measures document sets. Or as part of the measure submission document, we'll actually have sort of at the top of the document both any public comments that have been submitted on that measure and also the workgroup comments that were submitted prior to the workgroup as well as a brief summary of the workgroup's discussion on that measure.

So all of that will be collected in a document of the measure submission for you to be able to access pretty easily.

A.J. Yates, Jr.: Just to be clear, so are the comments that have been put into the summary – the preliminary comments are going over to be incorporated to each of the measures as we move forward?

Andrew Lyzenga: Yes.

Wunmi Isijola: Correct.

A.J. Yates, Jr.: And just a point of clarification one more time, I'm on the SharePoint right now looking at it and all I can see is group one, and I see the number of response is zero. And I can't click on anything to show me what that compilation looks like.

Wunmi Isijola: OK. So, A.J., if you go to the general page so you're not going to click survey, you're going to scroll down to the very bottom of the home landing page.

A.J. Yates, Jr.: Right.

Wunmi Isijola: Where the meeting material for each individual call.

A.J. Yates, Jr.: Got you. OK, so it's in there.

Wunmi Isijola: Correct.

A.J. Yates, Jr.: OK, thank you very much.

Wunmi Isijola: No problem.

Are there any other questions? OK.

Andrew Lyzenga: All right. Well, thanks everybody. We appreciate you taking the time to join us on this call. Please do feel free to reach out to us with any (inaudible).

END