NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
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Operator: Welcome everyone. The webcast is about to begin. Please note today's call is being recorded. Please stand by.

Wunmi Isijola: Thank you so much. Good afternoon all and thank you for joining and/or participating in our workgroup call for the surgery project. My name is Wunmi Isijola, the Project Manager here at NQF. Have here also Andrew Lyzenga, our Senior Project Manager; Melinda Murphy, our Senior Director. We also have our Project Analyst, Amaru Sanchez and we also have Karen Johnson who is another senior director here.

Before we get started we just want to do a roll call of those who are on the call. Mark Jarrett, are you on the line?

Mark Jarrett: Yes, I am.

Wunmi Isijola: Thank you. Richard Dutton, are you on the line? OK. Barry Markman, are you on the line?

Barry Markman: Yes, I am.

Wunmi Isijola: Great, thank you. Robert Sawin, are you on the call?

Robert Sawin: Yes, I am.

Wunmi Isijola: Thank you. (A.J. Yates)?

(A.J. Yates): I'm on.

Wunmi Isijola: Great, thank you. Allan Siperstein, are you on the call?

Allan Siperstein: Yes, I'm here.

Wunmi Isijola: Great. Do we have any of our other Committee members on the line?

Frederick Grover: Fred Grover.

Wunmi Isijola: Thank you, Fred.

Collette Pitzen: Colette Pitzen.

Wunmi Isijola: Collette, thank you for joining.

William Gunnar: Bill Gunnar.

Wunmi Isijola: Thank you, Bill. Is there any one else?

Larissa Temple: Larissa Temple.

Wunmi Isijola: Thank you, Larissa.

Richard Dutton: Richard Dutton.

Wunmi Isijola: Richard, thanks for joining.

Anthony Asher: Tony Asher.

Wunmi Isijola: Thank you, Tony.

Amy Moyer: Amy Moyer.

Wunmi Isijola: Thank you, Amy. Thanks for joining. Is there any one else?

John Handy: John Handy.

Wunmi Isijola: Thank you, John. OK. And we wanted to know if any of our developers are joining us as well.

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

Wunmi Isijola: Thank you, Jeff, for joining us.

Dave Hunt: Dave Hunt from STS as well.

Wunmi Isijola: Great. Thank you. Is there any one else? Is there any one else from CMS?

Carla Chronister: Yes, Carla Chronister from OFMQ.

Wunmi Isijola: Thank you, Carla. Is there any one from ASA?

Richard Dutton: This is Richard Dutton, I will also represent ASA.

Wunmi Isijola: OK. OK, so I just want to turn it over to Andrew. Do you have some words in terms of outlining the call today?

Andrew Lyzenga: Yes. So just a few words on how we'd like to proceed with this call. So far, what we've been doing with the workgroups – the workgroup calls and I think its been working pretty well is we've been trying to focus our discussion specifically around points of concern that you have about the measure – each measure that you're discussing at any point in time, questions that you have for the developer or areas of the measure that you find particular problematic or just have points of confusion about and that you think warrant further discussion by either the workgroup or the full Committee.

So I'm not walking through every specific aspect of the measure or every individual criterion although we would like you to base your discussion in the criteria to the extent you can.

But again, if possible, try to focus your discussion on any points of concern, questions for the developer, or things that you think really warrant further discussion from the full Committee. So we can just kind of keep it relatively short and concise. And we'll conduct further discussion about the measures at the in-person meeting. Any questions about that?

So we will ask each – our primary discussions to give just a very quick overview of the measure when we start this discussion and again to express

any particular concerns or questions you have for the developer. And then we will go to committee discussion and allow the developer to answer any questions you might have.

Without further ado, let's go ahead and get started with measures …

Melinda Murphy: Andrew?

Andrew Lyzenga: Oh yes, I'm sorry, Melinda. Melinda wanted to make a few comments before we started with the discussion of measures. Sorry, Melinda.

Melinda Murphy: That's fine. And I said I'd like to make a few comments to begin because I know it's going to very tight time to get through all of these measures in the time. So, these comments relate to some of the measures in this group, not all of them, but I just wanted to call out a few things. One is that every person who is in the workgroup and on the Committee is really asked to do a critical analysis of each of the measures in order to make the best decisions at the time of the Steering Committee.

So it's going to be important to you if you've not been here already to familiarize yourself with the algorithm that's included in the measure evaluation criteria guidance, so that as the decisions are made at Steering Committee meeting, you will be able to seek very clearly to why you evaluate something as being important and scientifically acceptable, feasible and usable. And with feasible and usable, you're going to say to what extent that is. So it's going to be important for you to use that criteria, use that algorithm and be familiar with it. There won't be time to do it in the workgroups, but I know you're ready for the time of the Steering Committee.

Along with that (inaudible) for information, if you do not see supporting data in this submission that you need to have in order for you to speak to how well measure meets criteria ask for that and its very important to ask for this as early as possible, for example today, when the developers are on, if there are things that you need to see at the time or before the time of the Steering Committee meeting, let the developers know that so that they can have it ready to be provided either before at the Steering Committee meeting.

In terms of the measure evaluations themselves which you've not done already again, look at the currency of the evidence and any updates that had been provided. If the evidence is the same as when it was last considered then you might want to know is that nothing has changed or is it simply that an update hasn't occurred. Because there are three (participation) database measures in this group, I wanted to just mention a few things about the participation in database.

You're looking at when the measures were first endorsed. Also look from there to when did reporting begin or when will reporting begin and you've got guidance in the documentation but says the expectation is within three years of endorsement. There will be some use of the measure reporting for used for accountability and within six years public reporting.

Look at the value of participation in the database as it relates to understanding outcomes and start as some of you already have done in asking about the transition to outcome measures beyond the structure measure of participating.

And another issue with the database is just to look at whether they are adequately specified to be able to be replicated by other database developers or users. In terms of the high performance in measures or tapped out measures, one of the questions to ask yourself is whether this would be a good candidate for placing in reserve status, endorsed, continued endorsement but placed in reserve status. So it could be pulled for reuse at some later date but not expected that it would be information would be collected in an ongoing manner.

And last but not the least related in competing measures do look at those. The developers who identified measures that are related in competing and ask the Steering Committee meeting, you'll be looking opportunities for harmonization, opportunities for combining opportunities to replace one with another measure if that is appropriate to do so

So with that, I'll stop there and I'll just say one last thing, Richard Dutton, he's got a hard line to walk today if you're going to try to do represent the

developer and participate in a neutral fashion in consideration of measures. Thanks, Andrew.

Andrew Lyzenga: Yes, thank you Melinda. And to Dr. Dutton, I might ask that you – well, you could answer technical questions about the measure but we would probably ask that you not serve as a representative of the ASA as a member of the Standing Committee. I should – maybe we could ask is there another representative of the ASA that's joined us on the call? It looks like none. We can always refer questions to the developers after the call and ask them to follow up before the in-person meeting. But again, Dr. Dutton, you're still welcome to answer any technical questions or, you know, clarifications about the measure that you're aware of. But we would ask that you not serve, you know, formally as a representative of the measure developer …

Richard Dutton: Got it.

Andrew Lyzenga: Got it, all right.

Richard Dutton: Thank you.

Andrew Lyzenga: No problem. All right, any questions or comments before we get started with the measure reviews? If not, let's go ahead and start with 0113. This is Participation in a Systematic Database for Cardiac Surgery. And I believe Dr. Jarrett is the primary discussant for this one. Could you give us just a quick overview of your thoughts about the measure?

Mark Jarrett: Sure, in being open I'll just – I'll be able to probably make it through of the meeting, but Joint Commission showed up at one of my hospitals this morning for their, you know, annual, (triennial) thing. So let me get taken off for a few minutes off-line. But I'll be OK, I think till at least 2:30, quarter to 3.

So this measure is a measure that's been around since original endorsement 2007. And basically it's a measure that just sees whether an institution, a facility is participating in a database for cardiac surgery. And it's simply a yes, no, nothing more than that. It's most last recent endorsement was back in December of 2011.

At this last heard it was about 90 percent of this cardiac surgery centers in the United States participate in this database. There's not a lot on disparity information on it really – that really applies. There is good evidence that people who use. I would say moderate evidence certainly at least who use the database for improvement to see how they're doing compared to others. Do find it useful and do show improvement.

The workgroup had looked at the importance issue and the evidence to support it. And, you know, that was felt to be pretty good. It's a highly, you know, it's a highly skilled procedures, you know, with potential severity and frequently done. So people therefore felt that it was important as well.

In terms of reliability and validity, there's an analysis by NQF but just is follow up again the workgroup looked at it and felt that it was, you know, that there was nothing really super remarkable. The lobbyist opened it up, you know, opened it up because there was questions about it. If you said yes was it the main database or perhaps it was to another database. That was one of the issues. Feasibility clearly has been going on so there's not even really an issue of its feasibility. And then finally usability the same type of thing.

The only question that really can be brought up and it goes to something we said before, you know, participation in a database is that really been tight, you know, that's kind of like even before a process. That's not a process of care even type of measurement and really the question is, is this one that we want to keep measuring or do we want to really see something that evolves from this that really involves at least out, you know, intermediate outcomes.

So that's my summary and I will refer to the secondary discussant Dr. Dutton to see if he has anything else to add or from the group.

Andrew Lyzenga: OK, thank you.

Richard Dutton: Thank you, Dr. Jarrett, four quick things, first thanks to the STS for modeling registries for all of us. This is obviously been a tremendously successful project. And the fact that you are at 90 percent participation that it speaks to the validity of this process.

I would love to see in the supplies to many of the measures in this set, so for all of the developers a lot of data is presented about disparities including the table in this submission. It'd be great if that was accompanied by a summary statement that says we think there are no disparities or we think there is a tilt to the northeast or whatever you think the summary is. But often there is data but no interpretation. That would be helpful.

Second, I wonder if this might not be a candidate for harmonization for all specialties in medicine, all providers participation in a registry. And I know a generic measure has been around. It might perhaps work to make this a more generic measure for any specialty to some degree. CMS has already done this with the QCDR mechanism. And that might be one way to greatly simplify the amount the NQF is looking at.

Third, I'll echo what Dr. Jarrett said about, you know, what is the outcome of participating in the registry? STS is obviously documented enormous improvements in care. It's impossible to draw a cause and effect for participation in the registry. But I think there's a strong implication. And I think it would be harder to show an outcome at this point with no control group and nobody is not participating.

And then finally under the cost – the cost for direct participation in the registry is mentioned. I think it would also be useful at this time to have a cost for abstracting the data. In other words, how burdensome will it be for the hospital to provide the specific data requested. That's all I have. Thank you.

Andrew Lyzenga: Great, thanks, Dr. Dutton. With the – are there any other comments or questions from the rest of the workgroup?

(A.J. Yates): This is Yates, I have a question.

Andrew Lyzenga: Sure, go ahead.

(A.J. Yates): And it sort based to the comment but the question is the title of this measure and the next two is participation in A, systematic database. But in fact,

correct me if I'm wrong, the collection of that participation numerator is in fact the – the fact that they show up in the database as a participant with enough data to say that their participating highly. But is there actually a question asked in the STS database as to whether or not their in a database that's not STS. In other words is this just self – the title doesn't seem to match the fact that it's really about being in the STS cardiac surgery database.

Andrew Lyzenga: Thanks. So maybe it sound like we got a few questions and request for the developer. Could you maybe clarify whether participation in a different database or registry would qualify for meeting the measure.

Jeff Jacobs: Yes. Hi. This is Jeff Jacobs from STS. And I could address some of the comments that were made. The secondary review is summarized four points. Certainly we could add some restatements to our summary of the measure that summarize some of the data. I think we can work on that with an STS that would be non problematic.

The second item regarding harmonization of this across all subspecialties and just creating a generic measure that says participates in a subspecialty related database or something of those sorts. Well, that would be reasonable. I think certainly there's much more of an incentive to participate when this is directed at certain, specific, high profile, high impact specialties like cardiac surgery.

Regarding the fact that is a – not an outcome measure, I think it's a well known fact that this database is used as a tool to generate multiple other outcome measures that have been endorsed by NQF both individually and as components of composite measures. So this specific measure is not an outcome measure. Participation in this database is a tool for then participation and multiple other outcome measures.

And then we were asked about the cost for direct participation and the cost for abstracting data. The cost for participation in the database includes the feedback reports that are sent every three months from the National Analytic Center back to the sites which include data abstraction and comparison of individual programmatic outcomes the national aggregate data.

So therefore, participation cost include that level of abstracting. And in addition to that, if queries of the data are desired beyond the information contained in the feedback reports, those queries are also provided by STS as part of the participation fee.

And then finally Dr. Yates brought up the issue of the fact that this title – this measure's titled participation in a systematic database for cardiac surgery. And I think the reason this measure has that title is that this measure does not require participation in the STS database. It requires participation in a cardiac surgical database that allows benchmarking of ones own outcomes against national aggregate data. Clearly the most commonly used and popular tool that allows that level of benchmarking against national aggregate data is the society of thoracic surgeon database.

However, it was felt that the measure should have required use of a specific database, but instead should require participation in the database that allows benchmarking against national aggregate data. And I think that is that addressed all the questions that was raised. I'd be happy to answer any more questions.

(A.J. Yates): Well, just following up on that. I couldn't tell from the brief description of the measure that we're given that describes broad state, regional or national representation and the capturing of that participation. If you're not in the STS database, how does that get capture that you are reporting that you're in a database? And that part was lost on the in terms of the mechanics of the details of this and the other two measures. I'm not discounting the value of it. I'm talking about this is as an example of what might be other registries in the future that might be competing registries in other specialties. So I'm just trying to lay the ground mark here.

Jeff Jacobs: Yes, I think you're raising a very important point. And I would say, first of all, I get the measure itself, you're absolutely correct. It's met by participation in a multi-institutional outcomes based registry that allows the benchmarking against national, regional or statewide data. So that the fact.

I think that it is possible for another organization group or society to create a database that would meet those objectives. And I think that participation in that similar database could be track by that society as a tool to meet this measure. The STS is created one tool that meets this measure and tracks participation in the tool created by STS to meet this measure.

(A.J. Yates): All right. So it is in fact only measuring participation in STS?

Jeff Jacobs: No, the measure it's met by participation in any database that meets these criteria. STS measures participation in the STS database should another database exist to be created that would meet these criteria that database could also track participation in that database to meet this measure.

(A.J. Yates): OK.

Jeff Jacobs: So the measure itself does not require STS participation. However, the STS simply tracks participation in the STS database as a method of meeting the measure.

(A.J. Yates): OK. And within the question that send out to the group because we're reading and I don't mean to belabor this but this only going to be my comments for all three of the set. When someone is a participant, there's actually a question that says "Do you participating in this or another database or is it collective or is it a judge that someone's participating because they have been sending in data?"

Jeff Jacobs: Yes, I think I would answer that the same. If a site is participating – if a site is sending data to the STS database, that document, their programmatic outcomes, therefore, they're participating. That's how in participates.

(A.J. Yates): Right.

Jeff Jacobs: And STS as a measure developer and as a database developer tracks participation in a database developed by STS.

(A.J. Yates): Got you.

Jeff Jacobs: And another – should another organization choose to create a similar database there's nothing in this measure that says "That's not possible." In other words, this still not require participation in any given database. It requires participation in the database that allowed the benchmarking against statewide, regional or national aggregate data developer …

(A.J. Yates): And all I'm saying is that does exist or does become existent. It just needs to be addressed in terms of how it's collected so that it can be a judge. And I only say that's coming from say the perspective, I don't represent them. But instance, the Kaiser registry for a total joint replacement is a great registry. They may not choose to participate in a national registry.

I don't know what else exist out there at a near national level of system-wide medical centers that would like to be a judge, you know, looking at themselves. So, it would just be something to look into because it looks to me like the only way it's collected is this data sent in and you're participating which is sort of like circular argument it would be a (inaudible) was in escape clause.

Jeff Jacobs: No, I don't think it's a circular argument. I think that if one send data to a database, therefore one is participating in a database. That's a direct argument.

(A.J. Yates): In your database?

Male: To be more …

(A.J. Yates): (Inaudible) in the participation?

Male: That it would be interesting to know if the 10 percent who aren't reporting to STS are reporting to a different registry such as Northern New England cardiovascular registry or something like that or a Kaiser or VA or some other mechanism registry.

Jeff Jacobs: Sure. And in fact, we know from our own individual study that the overwhelming majority is the – actually less than 10 percent now of adult

cardiac sites that do not participate in STS are military hospitals, VA hospitals or Kaiser Hospitals, that's the top three groups.

Male: I just want to bring up one other thing on the cost because I think you want a different direction that I was headed. I was not asking about the cost of interpreting the data. I was asking about the cost of creating it, participation the STS, the last time I looked is was like 300 fields. Somebody has to get those fields out of the medical record and get them …

Jeff Jacobs: I understand.

Male: … into the registry. And that's a cost that is typically I think learned by the hospital but this is a increasingly question for any registry is how much does that cost, how much that can be automated, how much is the right electronic and how much requires a pair of eyeballs to do.

Jeff Jacobs: Yes. I think that's a great point that you're raising and I know we're running short on time so this measure – like have two minutes to address that point to the discussion that we applied to the next two measures in row. The way I would address that point is, first of all, I did go in different direction. I thought you were talking about the cost that takes that information back from the database once it's sent in and aggregated and that's (borne) by the STS instinct as part of the participation.

What you're talking about is perhaps the biggest cost of participating in any registry which is the cost of actually getting the data entered into the database, maintaining the salary of a data manager or other data entry personnel. And that perhaps is the largest cost of participating any multi-institution database and it's an important point to consider.

And the two issues related to that point that I would raise is number one, you're right that this is a (inaudible) usually but not always picked up the hospital. And this fact is an argument why these measures even if they have a high level of penetrance and a high level of participating should absolutely not be retired because big incentive for a hospital to put up the money to pay for the salary of the data entry personnel and the participation of database is compliance with this measure even if it's tapped out.

And it's quite common that surgical team, in this case, can meet with hospital administration and say that this is an NQF measure and we have to pay the salary even if it's cost so that we can comply with the measure and that's true even if the measure is tapped out at over 90 percent.

And second, we do realize the cost of data entry burdens and STS is currently in collaboration with leading electronic health record vendors to create a scenario where at least some of the data elements instead of being harvest by extensive data entry personnel can be directly imported from electronic health records, and although this system is not currently operational. We're working seriously to try to achieve that objective to try to minimize these costs that you're describing.

Male: Thank you.

Andrew Lyzenga: All right. Any other questions or comments from the Committee on this measure?

Amy Moyer: This is Amy Moyer. On this measure and then on the next one as well, it feels a little bit to me from looking from the purchaser perspective like they give me measurement areas. We've kind of evolved beyond using (foreign) accountability perspective. I understand that, you know, we want to keep participation but I feel like the business case these days is where you think outcome measures from these registries or public reporting as for pay-for-performance and centers of excellence program and those kinds of applications.

I could see earlier and then other areas of measurement. So for instance, in like a patient reported outcomes type area, we might want to be looking at – we just need to get everyone collecting that so that we can even start against that are using from measurement. But in this area, you know, we've evolved to the point where we have the data, we have the risk models and now we're at whole other level of using those outcome measures.

So when I – I looked what I would use from accountability perspective, you'll pay for performance program or public reporting. Those are the kinds of

measures I'll be looking at. And indeed the kind of measure to which I would have access related to the – so I struggled with the inclusion structural measures like this when they've kind of become the way of doing business that have been built into a business model in a different way.

Andrew Lyzenga: Thanks Amy.

Tony Asher: This is Tony Asher. I'm not in this workgroup. But may I ask a quick question, please?

Andrew Lyzenga: Yes.

Tony Asher: In hearing this conversation it seems to me in getting back to harmonization, I don't want to beat that too much but the, you know, the STS done such a fantastic job and I think you could argue than the context at least to ask surgery we really should be evolving beyond participation.

But I'm wondering if it was a more generic measure which is to say something that could be used by at least other procedural specialist, orthopedic surgeons, nurse surgeons, whatever they have to be who are just now starting to get into this area in a more national context if it wouldn't have much more value because I think for those groups is not accumulated the type of nationwide quality data that STS has. Participation alone would be extremely meaningful because obtain the data and getting that information allow them to build more advanced outcomes program that STS has, I think it would be a tremendous value.

Jeff Jacobs: This is Jeff Jacobs. I could briefly address the last one. First of all, the speaker who brought up that the ultimate goal of this is to be able to utilize information from databases for quality improvement and initiative such as pay-for-performance in public reporting. STS agrees with that 100 percent. We have one of the largest specialty public reporting initiatives that exist where data from the STS databases publically reported both on consumers report and on the STS website. So we agree completely with that point.

However, I think that we would not want to retire this measure because of the fact that there's outcome measures that exist because this very measure alone

that was said earlier is a tool that convinces hospital administrations to pay for personnel to maintain data for good database. And retirement of this tool would take away that theoretical weapon to convince hospital administration to pay those fees.

And the content of creating a more generic measure, I think the creation of a more generic measure to encourage other subspecialties to develop similar multi-institutional aggregate databases is a very good idea. But I wouldn't create some more generic measure and at the same time retire the specialty specific measures where quality national aggregate database is exists.

I think that it makes to me, maybe create more generic measure to encourage other specialty to create the databases that I would preserve the currently existing specialty specific measures that have been created where national aggregate database exist because these measures have tremendous value within those subspecialties.

Andrew Lyzenga: And the generic database already exists in the form in this group too which covers almost all the other specialties other than cardiac surgery. And that can be leverage in a similar way.

Any other thoughts or questions, comments from the workgroup?

Mark Jarrett: Again, this is Mark and I certainly see the utility of, you know, of pushing administration to say, well, you know, you have this measure, and therefore, we have to participate the database but I think it's something and I imagine that, you know, the society is doing this is to start parsing and finding out what important parts of that database to people need to be sending data to and if they've had to do that, that could – and that's going to be publically reported and it's going to be pay-for-performance, that will automatically force the issue that the data still have to be collected. And then eventually this measure of your structural measure can be a retired.

Melinda Murphy: It's Melinda. I want to say one thing. You've talked about the retiring the measure a few times the word retire has been mentioned. And when I looked

back what happened in last consideration at this measure, the notation it looks like in reserve status at that time.

So one of the things that we in NQF need to do is bring to the Steering Committee what that meant at that time and what it means for the measure at this time because does not appear that it has been considered in reserve. So we need to clarify that as a Steering Committee meeting.

The other is that in looking at the submissions for the three database measures, it's not clear that all of the information is there that will be look for at the time that the Committee is looking at evaluating against the criteria. So, I think what we need to do is provide some feedback to STS in that regard as well in advance to the Steering Committee meeting.

Allan Siperstein: Allan Siperstein here. I'm one of the guilty party that was on the former Committee three years ago and maybe I can speak for minute about the – also called reserve status. I think there was kind of philosophical push that adds our culture of safety to advances that we want the, you know, list of fully active measures to be the ones that are pushing the envelope forward, i.e. pushing more toward outcomes or composite measures.

And with many of the measures that – and we struggled with an adjective to describe them but if you use the term reserved or (emeritus), we are trying to come up with the reasonable term. The measures are absolutely perfectly valid and (votable) measures simply that, you know, number one, they have been tapped out in some ways. Or that the real value or where you should put your resources is towards the measures – as I said focusing more in outcomes. So not to disparate the measure at all but simply it was a flag to what indicate that had been, you know, successful, still valid, but we're moving to bigger and greater things.

Barry Markman: This is Barry Markman. I'm discussing the next measure and since we're kind of doing it collectively. The question is on the next measure what – I mean why are there only 244 participants when there's thousands of surgeons performing that the thoracic surgery doesn't seem to be as well robust as the cardiac registry.

The next question because we were talking from structure to outcome. There's another measure coming up 0458 pulmonary function test measure. And my question to the develop was the vast majority of the data used for that measure or to determine that measure, was that derived from participation of the thoracic surgeons in this registry because I like that measure. I like that pre-pulmonary function test measure.

So, have you're – already kind of use that data to do an outcome from your …

Jeff Jacobs: This is Jeff Jacobs from STS again. And I guess the discussion kind of moving out a little bit to the second measure it's on the list now which is thoracic measure. First of all, the overall discussion that need for structure of process measure that include participation in the database that we have for the first measure I think applies to this measure as well. What's unique about this measure, I just pointed out compared to the previous measure is the level of penetrance of the STS database specifically.

I think the reason for the differences in the level of penetrance is reflective of a difference in practice patterns of thoracic versus cardiac surgery. Cardiac surgery is essentially always performed by board certified cardiac or thoracic surgeon. And because cardiac surgery is always practiced by a board certified thoracic surgeons, essentially all members – our members of STS in participating has STS database.

Thoracic surgery on the other hand is a database – first, it's a subspecialty with participants come from multiple domains, most commonly either general surgery or thoracic surgery, and not all participants in the practice of thoracic surgery a board certified thoracic surgeon lobectomy, pneumonectomy are often times that by general surgeons, we don't have thoracic boards. Therefore, there's a different penetrance of the database. That being said, there's tremendous efforts within STS and outside of STS to expand the participation of the thoracic database to increase the penetrance and to welcome in programs that thoracic surgery that do not – that are not maintained by thoracic surgeons that are maintained by general surgeons.

So it's something STS is working on and STS is certainly welcoming the non-thoracic, non-board certified thoracic surgeons participate in the general thoracic database.

Barry Markman: So it's a 224, is that the entire database that you have in the registry for …

Jeff Jacobs: That's what I guess.

Barry Markman: … at this time.

Jeff Jacobs: Yes.

Barry Markman: The measure started in 2008 and I just wondered.

Jeff Jacobs: Right. So understood that none of the penetrance at this time which makes it the world's largest multi-institutional database for thoracic surgery and the world's largest multi-institutional database for lobectomy, pneumonectomy, and esophagectomy.

And to address your question where you're getting the PFTs and our use of the data from this database, multiple peer review publications and multiple quality improvement initiatives have been generated from the STS thoracic database, some of which are related to PFTs, some of which are related to outcome after lobectomy or pneumonectomy or esophagectomy.

And although the penetrance is not as high as in the cardiac database and it's not as high as (we won't have at) one day, it's still the largest multi-institutional database in the world for patients undergoing these operations. So it's the best source of data available and has been used for these types of studies and whenever our goal is to increase the penetrance in the work and quite hard on that.

Barry Markman: Right. That was my comment is that, you know, the data collected is excellent and – if you can generate reports like this, that's, you know, I mean it's – it should be ongoing and move more towards an outcome measure to just structural measure if you are the largest database in the world.

Jeff Jacobs: Right. Yes. And from that database there are several outcome measures that have evolved including outcome after lobectomy, after pneumonectomy and we are in the process of developing some composite outcome measures as well. So we agree that what you're saying a 100 percent and what you're describing is really what is our ongoing work at this time.

Barry Markman: Yes.

Jeff Jacobs: Number one, to increase the penetrance of the data. Number two, to use the database to develop an increasing portfolio of outcome measures.

Barry Markman: Well, I have two other questions. I see this within each measure. It says that the database is limited to senior care. Is there – I mean does your data goes across the board …

Jeff Jacobs: Yes. No. The database spans the spectrum of all ages of patients undergoing thoracic surgery. It's not just lobectomy number 65 or 25-year old undergoing lobectomy would be in that database as well. But to the best of my knowledge, the only limitation that would relate to senior care is that one use the linkage of the STS database to Medicare data to track longitudinal outcomes or health care economic based on that linkage. But linkage would be limited to patients over the age of 65 or patients with renal failure because that's what is in the Medicare data. But the STS General Thoracic Database in of itself is happy to accept data, outpatients of any age.

Barry Markman: OK. And there is public reporting on it? I saw some (inaudible).

Jeff Jacobs: Correct. So, at this time, the STS database it's used to publically report, adult cardiac surgery. The public reporting model of isolated lobectomy outcomes has been developed by STS and it will be rolled out in 2015. So the budget is in place to do that and …

Barry Markman: Right.

Jeff Jacobs: … the measures in place to do that and this will be publically reported in 2015.

Andrew Lyzenga: Great. That's my comment. We can move to the next one if you want the (inaudible). Dr. Sawin, you want to make a comment? I'm sorry. You're the second …

Robert Sawin: No. I thought – I think the discussion is remained to the pediatric one as well. This is congenital heart and pediatric cardiac surgery is a new measure proposal. And all the discussion which is said applies to that.

The one question I had one is at one point it says that it is not risks stratified but my understanding of the STS pediatric heart database is that isn't in fact stratified by RACHS and Aristotle scores?

Jeff Jacobs: Yes, you're absolutely correct. The STS Congenital Heart Surgery Database is risk stratified. We've used the RACHS and Aristotle tools for close to a decade now. And over the last few years, we've developed a new tool that is based more on objective data and less on expert opinion subject to probability which is called the (STS-EACTS) categories standing for Society of Thoracic Surgeon, European Association for Cardio-Thoracic Surgery. And that's risk stratification model that we've developed by an analysis of over 75,000 pediatric operations, the largest such analysis ever done. So the last – an upgrade in our methodology of risk stratification from being based in a large part on expert opinion to being now specifically related to actual data in the database.

So the (sure) answer is that the congenital heart surgery database is absolutely risk stratified and the methodology that risk stratification are improving on a yearly basis.

Robert Sawin: OK. And I had no other question.

Jeff Jacobs: You know what, I think that the other thing I just realized is that it might be that that code about risk stratification is simply related to the fact that variable of participation in the database is not risk stratification, it's not risk stratified …

Robert Sawin: Yes.

Jeff Jacobs: … but the database itself and all outcomes are risk stratified. So maybe I give you a really long (wait and) answered to the fact that actually it's just the participation and of itself is a risk stratified but data and the outcomes are.

Robert Sawin: OK, all right that makes sense, so. Because that's one of my biggest concerns about people's confidence in reporting data to the registry is if it's not risk stratified to …

Jeff Jacobs: (Moved out).

Robert Sawin: … about disparity.

Jeff Jacobs: We agree completely and especially in the STS pediatric heart surgery database …

Robert Sawin: Right.

Jeff Jacobs: … with this tremendous variation and case mix from program to program, rigorous risk adjustment is essential. And I think the most advanced pediatric heart surgery risk adjustment in the world is now done by the STS general heart surgery database.

Robert Sawin: OK, I have no other questions or concerns.

Wunmi Isijola: Any other comments?

Jeff Jacobs: No.

Wunmi Isijola: OK. So then we can move forward with – Karen, you want to start?

Karen Johnson: Yes, this is Karen from the NQF. I just wanted to make sure that everybody is comfortable in thinking about the validity testing that was or possibly was not done for these measures. I know the developers know that in at least one and probably I'll show you these measures and we'll talk about how they do audits and make sure that the data in the various databases are accurate data and that sort of thing.

But, again, when you're thinking about validity testing particularly for this yes-no measures, participation yes-no, that really didn't matter. You're just interested in, you know, the data element that you're interested in is whether or not participation happened.

So we are thinking about validity and I think this was mentioned early on. What you'd really like to see is you would like to know that the facility for the clinician to participate in these registries actually have that are outcomes than the ones who do not.

So, I would ask the developer and maybe this is something that can provide later on, I did not see it in the submissions right now.

This have that kind of information to show that the facilities that participate do have better outcomes, that might be a little harder now with the first measure because penetration is so high. But for the other measures, it would be really interesting to know that.

Jeff Jacobs: Yes, this is Jeff Jacobs again. We do have some published peer review data in the congenital database that addresses that issue as well as in the adult cardiac database. And we can share those references with the National Quality Forum what topic is next discussed.

Karen Johnson: OK. And just to point out, it's not quite, you know, with our volunteers being so busy and just giving them the references and having them go look it up – look up the information is probably not optimal. So if you could just summarize those through for our committee members, that would be much appreciated.

Jeff Jacobs: Absolutely, we would be happy to do that.

Karen Johnson: Thank you.

Andrew Lyzenga: OK. Thanks.

So, are there any other comments or questions on the three database issues – measures we've just been discussing? I guess we can sort of just pass that those are the group.

Before I start, are there any other comments, or thoughts, or questions?

Male: No.

Andrew Lyzenga: All right, hearing none, let's go ahead and move on to 0126, the Selection of Antibiotic Prophylaxis for Cardiac Surgery Patient. And Dr. Dutton, I think you're the primary discussant on this one.

Richard Dutton: Yes. And as already noted, I am probably conflicted since the ASA with our workforce is the next measure which is very similar. But perhaps the STS folks (inaudible) answer the questions around this one.

This is a very straightforward measure that's been around for a long time, specifically it is if there an order present for the correct antibiotic (before) cardiac surgery case.

And it has appropriate inclusions and exclusions that's been very well worked out over the years. The definitions of the correct antibiotic and the inclusions for the measure are consistently skipped which applies across all a surgical cases.

So, this measure is in harmony with others. I really only have a couple of points for the developers to put on their list for the meeting. Once again, it'd be great if not just (inaudible) in the data but your interpretation of that. This shows no disparities or this shows a concern in this part of the country or this kind of patient, et cetera.

I think two questions that are likely to come up with the meeting. One is, this measure is the numerator is order for the appropriate antibiotic. And my question would be, are we testing whether we chose the right antibiotic or whether we wrote an order for an antibiotic. And if it's the latter, with a better (SRB) was the (inaudible) but did we write an order for it, one that actually asks, "Did we give it?"

And I'm sure there's a reason for that, I know this measure has been around for a long time and has been discussed many times.

So, I suspect there was a reason but I suspect (you'll be) asked the question.

And then the other question to consider is around the broad topic of harmonization as already said, these recommendations are exactly consistent with SCIP recommendations. (In) general is cardiac surgery population (inaudible) the different measure or would a more generic general surgery measure be appropriate as well.

There are some populations I know where exclusions maybe relevant, for instance, in obstetrics, there maybe a concern about giving antibiotics before the baby is delivered in some cases. And that leaves to special consideration. But is that kind of thing (through) on cardiac surgery or would this work just as well as the same measure for collect, the major hip replacements or other surgeries.

That's all I have.

Andrew Lyzenga: Thanks, Dr. Dutton. Dr. Yates, do you have any an additional comments or question?

(A.J. Yates): Yes, I fixed the feedback loop. I agree with the other two just said. You know, the question comes up about the feeling and how if this is a readily med measure to the point of being questioned in terms of it value. And I would say that it is so critical, the impact is so high in terms of patients with mediastinitis, the external ones. It's just can't be – it can't be let go. And I would say the same for other critical antibiotic administrative measures.

And I would consider something like this as being important to keep as an active measure in the sense of it being a watchdog, your house might not have been broken in and you may not have much crime in your neighborhood. But when you leave the house, you feel better that there's a watchdog there, and I think this is or leave behind that just sort of just keep on leaving behind so that it does what it's supposed to do and make people not forget that it's important.

Andrew Lyzenga: Oh, thanks, Dr. Yates.

Any other comments or questions from the workgroup?

John Handy: Yes, John Handy here. And so, I'm confuse because it is a recurring theme as for Dr. Dutton's comment is that we're measuring whether an order with place versus whether the patient actually receive antibiotics. So that kind – and because it's so prevalent and all these antibiotic measures, if there's some methodologic reason why that is the case, because we really care about whether the patient got it now, whether it was ordered.

Andrew Lyzenga: OK. The developer have any comments on the – those question …

Jeff Jacobs: Yes, hi, yes, this is Jeff Jacobs again. And first of all, I would say that I agree with essentially everything that was said thus far. What's important on whether or not an antibiotic is given not whether or not it was order, you know, I think we would certainly agree with that. We also agree how are – what the importance of harmonization and harmonizing measures across inspection whatever possible.

And I think for what I understand right now, most of the NQF-endorsed antibiotic measures are about when the order is given rather than – whether or not the order was given rather than whether or not the antibiotic was given. And I think because of the goals of harmonization, we've tried to remain harmonized with these other measures. With that being said, I personally agree it was important to pick the antibiotics during patient's names, and not that there's a incoming order path.

Now, I – the other thing I would say is I would strongly agree with what was said by the last speaker regarding the importance and unique aspects of infections after cardiac surgery.

Mediastinitis is an extremely big deal. It's one of the most major life-threatening infections that exist. And not only is a major life-threatening infection, but active caring for a patient with mediastinitis whether they live or die as tremendously labor intense as an expenses.

And I think because of the magnitude of how bad mediastinitis after heart surgery is. It clearly does in and of itself measures special significance out of special measure because it's a very big deal for all those reasons.

So, I think the principles that I would apply to answering all of these questions is first of all, we agree with the previous speaker said, we're supporters of harmonization. We agree that the important factors whether antibiotics are given rather than the orders written, but we need to be harmonized with other antibiotic measures endorsed by NQF.

And we think that individual measure for antibiotics after heart surgery is tremendous merit because of the severity of magnitude of a post-cardiac surgical infection. And we can certainly be prepared to discuss any or all of these elements in more detail at the face-to-face meeting.

Allan Siperstein: Allan Siperstein here. Just wanted to comment just, you know, historically, a lot of these measures are seven, eight years old. And my understanding is just from a logistic point of view, it's easier to go to paper charts and find an order and much more tedious and error prone to go to the medication administration record and find out what and when things have actually been given. And now that we're moving more to an electronic system, you know, the question is, should all of this be held to the higher standard of actual administration.

Jeff Jacobs: And the timing of the administration relative to the beginning of the operation.

Amy Moyer: And this is Amy Moyer. I would argue, what we're actually looking to these harmonized – how many patients having an infection. That's what we want to know. And that's what measure that's available out of the STS registry.

So, for accountability purposes, it would seem we would want to move towards that outcome measure, keeping those, you know, certainly useful for quality improvement purposes. But that's not what we're – what we're looking to endorse here, I believe.

Jeff Jacobs: This is Jeff Jacobs from STS again, I'll briefly address that point. I agree that it's really important as whether or not a patient gets mediastinitis. And that's

another variable that's track quite close in the STS database and it has an element of other outcome measures that have been endorsed by NQF including our composite measures of outcomes after coronary bypass grafting and outcomes after isolated aortic valve replacements. So we do track mediastinitis and it is an outcome measure that's a component of other NQF-endorsed measures.

That being said, multiple process measures exist across NQF but that's the administration around antibiotics. And because of that and because of the previously discussed magnitude of mediastinitis, I think justification exist to have this present, not only as an outcome measure, but also the process measure.

And another justification for that is that mediastinitis is really, really rare even in a good – even in a center with a relatively high mediastinitis rate. The incidence of mediastinitis is still really, really rare. So because it's so rare, the overall quality of care delivers the (overruling) majority of patients might just be tracked, not by whether or not they get mediastinitis, but also by whether or not their antibiotics were given appropriately.

(A.J. Yates): So, this is Yates. Correct me if I'm wrong. But I'm – as I read this, the numerator statement states that it's not just a documentation of an order, but also the documentation that it is actually given preoperatively.

And that's also the guide – that's also the criteria for how we're measuring SCIP at our hospital, is that whether or not it's actually given within a certain time period. So I think this measure does, in fact, capture the administration of the antibiotic in addition to the ordering.

Jeff Jacob: I agree completely. Yes, I agree completely. If I misled when I answered my question, I'm sorry. What I was trying to say was that our goal with the way this is worded regarding orders given and antibiotics given, it's basically to maintain harmonization with the SCIP measures and other similar measures. So I agree with exactly what you just said.

Richard Dutton: This is Rick again. They should be harmonized. That, I think, is probably the first priority. Looking at what's – I don't know if they can scroll back to the

top of the measure on the screen, but looking at it, the definition here, who have an order or received antibiotics. And it really should be probably (properly received) antibiotics. They are just – and that's just the brief description of the measure. So, if I misled, I apologize.

Andrew Lyzenga: So is the – did the developer clarified that it is received preoperative antibiotics, or is it an order for antibiotics fulfill the measure, so I just wanted to clarify.

Jeff Jacobs: I think the wording here is worded that it matches exactly what's ordered in the SCIP measure. And I think that probably the best way to handle this discussion moving forward so that I can prepare a better dialogue about this topic that I can share with the group at the face to face meeting, and I'll just come prepared to discuss the distinction between ordered given an antibiotic administered and how one qualifies or did not qualify based on those two.

Andrew Lyzenga: Thanks. Any other questions or comments from the workgroup?

OK. Hearing none, let's move on to 528.

Male: I have one more question.

Andrew Lyzenga: OK, go ahead.

Male: I had mute on. Some of these – some measures carry historical overtones and just for – in specific, the use of clindamycin as an alternative drug for cardiac surgery as opposed to vancomycin in the patient that has a documented true allergy risk with a cephalosporin.

In orthopedics, we're moving away from because of biograms and knowing that it's a static drug. We're moving usually to vancomycin as our secondary drug of choice. Is that the same in cardiac and is this – is it possible that there's a shadow from past usage that's making it stay in this particular measure, or is clindamycin acceptable?

Jeff Jacobs: Right. So, I think that – this measure is currently constructed, although often in some measures still is a 100 percent consistent with the latest published peer review data about choice of antibiotics for adult cardiac surgery.

And there's a number of published papers, look at this topic on a multi-institutional basis. And I think that the antibiotics described within this measure are 100 percent consistent with which those most recent manuscripts. In other words, I don't think it needs to be – I don't think that there's any reason at this point in time to change text about the choice of antibiotics.

Male: Thank you.

Jeff Jacobs: Yes.

Andrew Lyzenga: All right, any other questions?

OK, let's go to 528, Prophylactic Antibiotic Selection for Surgical Patients. And Dr. Markman, you're the primary discussant on this one.

Barry Markman: Right. Coming back from the cardiac surgical measures, this is – I mean, not to belittle the cardiac but this is a one of the well – best well-written measures I've ever seen. And, it's been around since 2009 and it's based upon some evidence article and the – it's important to actually read the numerator because a lot of the comments made prior and it's the number of surgical patients who receive – who received prophylactic antibiotics recommended for their specific surgical procedure. And they actually list out the procedures. They table which antibiotics.

And as an aside, when you look at the actual procedures, there are several hundred thousand (cavities) mentioned as procedure. So, one of the questions I have for the developer in terms of harmonization, since your data collection and you confirm if this is correct, is more robust. It's not just based upon the order and receive, but there's a lot of exclusions. If you look at them, if the timing is not right or if it's a previous infections, there's about 20 of them. How does that compare or have you ever compared this to the (inaudible) to cardiac measure.

In terms of everything else of the measures, it's gold standard, if you look at the number of patients collected in one year between January 1st in 2012, they started with about a million and a half cases. And then, through sampling and validity, they went ahead and use 4,600 of these cases. There's 3,500 hospitals participating as part of the mandatory reporting and accreditation and financial incentives. This is a great measure and even though the performance gap is very, very low, I would like to reiterate what the other comment it was made that this is – that this one should continue as a watchdog.

And the last question, the third question is, what are the outcome measures that had been precipitated from your data?

Dale Bratzler: So this is Dale Bratzler, can you hear me?

Male: Sure.

Andrew Lyzenga: Yes, we can.

Dale Bratzler: OK. So, I'll try to address your issue. So, this performance measure does focus on administration of the antibiotics to patients who were hospitalized having surgery, it's very procedure specific. It's updated continuously based on published guidelines whenever they're updated. So we try to keep the antibiotics selection was up to date for the procedures that are done.

The performance measure does exclude those patients who have infections or other reasons to alter the choice of antibiotic. And we currently, now, have revised the measure that we only look at the antibiotics administered before the operation or up to closure of the wound. In other words, giving antibiotics after when closure is not likely to be useful.

The outcome measures – I mean – so your two questions, have we compared this to the STS measure, I think is you question. And …

Jeff Jacobs: Right.

Dale Bratzler: … we have. But I think it's important to recognize that the data sources for the metrics are very, very different. I mean, this particular measure requires hospital medical record abstraction or electronic evaluation of actual administration both the timing and selection of the antibiotic versus the STS, which is a registry based measure.

And the subsequent one that hasn't been discussed yet, the physician – the PCPI measure that focuses on actual ordering the antibiotic which is based on physician claim. So they all have different data sources.

So I don't think we've done a direct comparison. I suspect the results are probably quite similar because, you know, there is nearly a universe of the cardiac surgeries in the country that you open this database.

The second question about what outcome measures have been precipitated. as you probably are aware, CMS now has use of the National Healthcare Safety Network, the CDC's network for reporting of surgical site infections for a limited group of operations right now, colorectal surgery and hysterectomy. I think CMS in the process of the – excuse me, of evaluating other operations for possible use of actual surgical infection rates, but I can't speak for CMS, specifically on that.

Andrew Lyzenga: All right, this is an excellent measure. Any comments from the second discussant?

I think it was Dr. (Gerald), if you're on. I think he have to drop off.

(Inaudible) from the rest of the workgroup?

Richard Dutton: This is Rick Dutton again. And although this isn't our measure, it's obviously highly similar to our measure and we'd be happy to be in harmony with the – from the anesthesia side.

In terms of the data capture process, it's actually simpler in reality perhaps (the lab) abstractor or in many cases, a practice management abstractor can look in a single place on the anesthesia record and discover when the antibiotics were given relative to the start of the surgery in most cases now.

And what antibiotic was given. So, it's become easier as this has been a measure now for many years, it's become much easier to capture the data.

Andrew Lyzenga: OK, thank you.

And Dr. Bratzler, I actually had a clarification from the staff. We noticed that in the last time, the measure was given endorsement maintenance. There were a few changes noted, some inclusions were added, endometritis, free air in abdomen, perforation of bowel, and a couple of exclusions added as well.

We couldn't actually find where those relocated in the measure. And we just wanted to get some clarification on whether those changes were, in fact, made and if they are (did) in the submission?

Dale Bratzler: Yes, so those – all those changes are made, those are actually exclusion, so anything that would suggest infection, so free air in the abdomen, the abscess in the abdomen, endometritis, any of those would be considered infections prior to anesthesia and would exclude the case from the performance measure.

So, I'm suspecting, I don't have the document in front of me, but there are tables in the manual that list those diagnoses that would be excluded. But any of those …

Andrew Lyzenga: But those are included in the code sets?

Dale Bratzler: Yes, I don't know if (Wanda) or (Carla) on line, if they could clarify that. But, yes, we have added those as exclusions.

Andrew Lyzenga: OK, thank you.

Male: Of the subject matter expert there for the rest of the committee, those would be excluded because of one or two possibilities. First, if the patient comes to the ER with an infection, they're probably in – on the antibiotics already and stocking of those with vancomycin. On the top of the reason, those vancomycin would be a bad idea, that's one reason to exclude those.

And the other is, many times, the surgery is exploratory and with (inaudible) before giving antibiotics because if we give the antibiotics first, we will kill

the culture and then not find out what the problem was. So that's why those would be excluded.

Andrew Lyzenga: OK, thank you for the clarification.

Any other questions or comments on this measure?

Hearing none …

Female: I have a question. And Dr. Bratzler may know the answer to this. At the last review of the 528 and 268, there was a recommendation made that they be combined into a single measure. Are you aware whether or not there's been a discussion about doing that?

Dale Bratzler: Not that I'm aware of discussion mainly because – so the 268 is the ASA, the – a major on actual selection of the antibiotic, first generation, second generation self explore. I think there's been conversation about the choices of the antibiotics but, again, the data sources are very, very different.

So one, you know, 268 is a major that focuses on the ordering physician, what's under their control and they are frequently reporting these measures, the claims data. You know, as electronic specifications before that I think there is interest in harmonizing, but as long as the two processes recollecting the data are completely separate, it would be difficult to do at this time.

Female: Thank you.

Richard Dutton: Hi, this is Rick again. Actually, I have a question for the NQF staff about this. 268 is not ours as far as I know. I think ours is 269. And I think it's in a different workgroup. So I know you asked if ASA was on the phone but this – I'm not sure we're actually the stewards of any measures in this particular workgroup.

Male: 268 is the AMA-PCPI …

Female: Right. And that …

Richard Dutton: OK. And I think that one may still be with AMA-PCPI.

Female: OK.

Male: And it is.

Richard Dutton: OK. Thank you. That makes me feel better. I'm not actually as conflicted as I thought I was. The one that we took over from PCPI is in a different workgroup which has to do with the timing of administration.

Male: OK.

Female: So that's it?

(Sam Kearney): Yes. Excuse me, can I make a comment? This is (Sam Kearney) with the PCPI.

Andrew Lyzenga: Yes, absolutely, hi, (Sam).

(Sam Kearney): Thank you, just to clarify. Yes, so 268 still remains a PCPI measure. We are working in conjunction with the American College of Surgeons to support this measure through the NQF endorsement process.

Just wanted to clarify and I wanted to add to Dr. Bratzler's point earlier about the difficulty in combining the measures, you know, the measures were designed for very different purposes. And the 268 does focus on the performance of individual physicians.

And, additionally, the design was crafted in different ways and I'll ask my colleague, (Tony), if she could just speak for that.

(Tony): Sure.

(Sam Kearney): (Inaudible) some nuances there.

(Tony): So with the measure as we move into 268, it really – you'll see that it focuses on cephalosporins with the intention of including as many procedures as possible within the measure. Whereas facility level measure and Dr. Bratzler, you can correct me on this if my interpretation is wrong, it seems it focus –

you have a list of procedures and then you include a wider variety of antibiotics.

So they kind of one started with the antibiotic to include as many measures and the other ones are in – as many procedures – excuse me. And the other started with procedures to include as many antibiotics as possible. So those are just kind of new onsets within the measures that I'd like to highlight as well.

Female: OK, thank you. And just to finish the thought, at the time this was discussed with the last group, they'd look at the question, are the steering committee – with the question of having them combined into a single measure from which the data for (P6) that could be extracted and reported.

So, if you've provided the information, I think it will be potentially discussed at the steering committee. Thanks.

So then, you're ready, Andrew, for 268?

Andrew Lyzenga: Yes, I think we can move on to 268. Dr. (Cullen), I believe you're the primary discussant.

(Dr. Cullen): Right, so we've touched on this already. It's looking at the percentage of patients over 18 who get a first or second generation cephalosporin, that's an expansion of the numerator from the 2008 endorse measure where they look just to – as I understand that first generation cephalosporins, and the denominator is defined by CPT codes that were developed from by a list of various surgical specialty organizations. And the denominator list was also – there were more exclusions created for or exceptions created for the denominator.

Otherwise, it sounds as though the measure hasn't changed significantly since 2008. It is as mentioned from administrative data and is at the provider, or a group provider level, and goes to ultimately report this publicly, I don't know that it's currently being publicly reported other than through the PQRI which shows that about – that the compliance with the standards is about 95 – 96 percent but that's a very selected group of participants in the PQRI. And a

larger study that was referenced in 2013 from a SCIP study show that, you know, the non-compliance of the antibiotic administration that approaches 11 percent or even higher if you look at some element of the processes that are set as many as 75 percent of the preferred practices are not complied with.

So, that's still a significant problem and I think as mentioned there are differences in how the data is gathered here compared to the others.

So I don't have any other concerns other than what we've already mentioned, the overlap with the different antibiotic measures.

Andrew Lyzenga: OK, thank you. Anything to add back there, Siperstein?

Allan Siperstein: Oh, well presented. Just a couple of details in that as we discuss what the other measure that in order to meet your requirement, you need either an order or documentation that the drug is actually been a receive so either one is acceptable.

Andrew Lyzenga: OK.

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

Male: I have one comment.

The exclusion criteria for the denominator include the broad category of documenting the medical reasons and then the measure has parenthetically a series of different things. And it maybe appropriate to include within the parenthesis or separate from medical reasons, the possibility that the patient has a documented allergy to cephalosporin.

And the second thing that's more subtle but it is now widely recommended, is that there is a certain amount of MRSA screening done now for – in our profession, total joints. And the MRSA screening has become widely done enough that there maybe – it maybe that the patient gets a vancomycin for a process that isn't seen as a medical reason, so to speak, and it's expected to be captured but it maybe inappropriately not captured.

So I just throw it out to the developers that for allergies and for the purposes of MRSA screening, it maybe that people do not use cephalosporin.

Male: Yes, those are good comments and actually you did bring up one of the potential weaknesses here. Since it is administrative data, I'm not confident that clinicians are always going to document the reason why they didn't give the first generation or second generation cephalosporin. So, there's some vulnerability there, but I think it's a relatively minor issue.

Allan Siperstein: Well I think, you know, I mean, that's an important point but that exclusion does allow them to do subtle so …

Andrew Lyzenga: Right.

(Tony): And this is (Tony) from the PCPI. We just want to mention that the examples that you gave are certainly valid ones and the ones we have in our parenthetical list are certainly not exhaustive.

And so I just wanted to make that point that those would be valid or could be potentially valid reasons as well.

Male: Right, and that my point is that it just, at some point, you have to make sure that there is reliable capture of those exclusion criteria and that there's not a systematic bias against people that are using MRSA screening or have extra caution in terms of potential allergy implications.

There are some people that for a penicillin allergy would just (hives), may not give a couple of (spurn) which I would disagree with. But I don't think they should be castigated for having done that and not captured. And so, the validity of capturing that would be important, the reliability, I mean.

Male: Yes, agree.

Male: Thank you.

Andrew Lyzenga: All right, any other questions or comments on this measure?

Hearing none, let's go ahead and move on to 0129, this is Risk-Adjusted Prolonged Intubation, an outcome measure. And Dr. Yates, I think you're our primary discussant on this.

(A.J. Yates): Yes, I am. This is a maintenance measure first endorsed in 2007, re-endorsed in 2011. The numerator is the number of patients older than 18 undergoing isolated CABG that require ventilation for greater than 24 hours after leaving the OR. And that numerator includes those patients who are reintubated and those numbers, that time period is added back into that particular numerator.

The denominator is the number of patients undergoing isolated coronary artery bypass. It's important to realize that there is a risk adjustment that has been carefully worked out that utilizes the composite score from the STS have selected risk factors that were picked by expert panel and later through regression analysis looked out and given weight. And I believe it appears to be a good risk adjustment model.

In terms of the importance of the measure, the stated evidence from the storage is that there's strong evidence that more adverse health outcomes are expected in patients with prolonged intubation.

I would agree that there would be prolonged ICU stays and prolonged hospitalization for prolonged intubation. There is, however, a recent literature from Cochrane and I'm only mentioning it because it is the Cochrane database. And their 2013 review of early intubation or extubation programs and they looks specifically at low dose – lower dose narcotic and anesthesia, and they also look at rapid extubation programs.

And what they've found was they couldn't show a correlation between the shorter intubation periods and or versus longer intubation periods and any difference in terms of adverse outcomes, and specifically some of the ones that are mentioned in this measure.

Now, it maybe semantics because they're talking about an early extubation program and this is late in the two maybe far enough apart that they're not saying the same thing. But I would just throw out to the developers that given

the fact that the Cochrane database came out with this, it would be probably good to address that one question.

Nonetheless, I would still say that it's an important measure regardless of whether there's adverse health outcomes and that the time in the ICU and the time in the hospital are both prolonged regardless.

The performance gap is reasonably high between 4 percent and 16 percent. I don't think there's any question about there being high impact frequency and cost.

I believe that the reliability has been proven to be high and that there's reasonable validity. The one thing is that they do capture the reintubation time period as a penalty, if you will, for (has) and perhaps extubated too soon.

The one thing they don't do is capture the rate of reintubation. And I would see that as a potential adverse outcome that'll build the time as captured, the actual event of being reintubated is traumatic and has risks. And so it might be at some point worthwhile to have that somehow captured.

The feasibility has been proven high. The reported validity is already been demonstrated. And that would be – and it's a unique measure with no obvious competitor. So going through the checklist, those would be my comments and my editorialization.

Andrew Lyzenga: Great, thanks, Dr. Yates. Anything to add, Dr. Siperstein?

Allan Siperstein: No, I think that was outstanding presentation. I think one of the other important aspects in this measure is that it really encourages a multidisciplinary approach using best practices to manage this.

So if anything as opposed to, you know, giving the antibiotics which is little more unit dimensional that this really encourage as a team approach to optimizing the management of these patients.

Andrew Lyzenga: OK, thank you.

Any additional comments or questions from the workgroup? Any comments or responses from the developer?

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

Andrew Lyzenga: Yes.

Jeff Jacobs: I would first compliment the two previous speakers, I agree with everything that they've said. And I think that it was a nice summary of this measure.

But regarding the Cochrane database and the concept of early extubation, I think at the end of the discussion on that topic, it was noted that this particular measure did not focus on early extubation. It focuses on the percentage of patients who are intubated for more than 24 hours postoperatively.

So, early extubation protocols are protocols that are often implemented after cardiac surgery with the goal of either extubating somebody in the operating theater or in the immediate few hours after surgery.

And I think the Cochrane data showed that it may not be so beneficial to try to extubate somebody in the operating theater or immediately after surgery with these early extubation protocols. And it is correct that that is not what this measure is looking at, this measure is looking at the percentage of patients on – who are intubated for more than 24 hours.

But interestingly enough, within STS, we did do a study that we published in September of 2013, where we looked quite closely at the percentage of patients who are extubated at different lengths of time within 24 hours after cardiac surgery.

And we looked at variation across hospitals when patients could extubated during those first 24 hours. And in that analysis, we were really unable to find any meaningful data that would be useful to shape the development of a metric looking at the cohort extubated within 24 hours.

That's what – although the Cochrane study this, I don't it really relates to this particular measure which is looking at a later time interval.

And the second question about looking at greater reintubation, that's something that's a variable within our database that we could certainly look at and incorporate into a future measure.

Andrew Lyzenga: OK, thanks, Dr. Jacobs.

Any other questions or comments from the workgroup? Hearing none, let's go ahead and move on to 0458, Pulmonary Function Tests Before Major Anatomic Lung Resection. And Dr. Siperstein, we have you as our primary discussant.

Allan Siperstein: Great. This is another STS measure. It is a process measure and what it looks at is the number of thoracic patient age 18 or older who undergo at least one pulmonary function test within 12 months prior to undergoing a major anatomic lung resection and the list of those CPT codes and specific procedures are specified.

This is a fairly mature measure that was recently endorsed in 2008. And the value of this, obviously, is encouraging proper and full preoperative assessment before patients undergo lung resection.

The compliance with this measure have been high initially about 91 percent in 2008 and increased about 94 percent in the 2010 to 2013 timeframe. It is generally considered part of standard of care in order to both assess resectability and preoperative risk in these patients.

One of the questions that I, you know, have regarding this specifically has to do with the, you know, population of patients who did not have a pulmonary function testing. And I would be interested in seeing some data in terms of what the outcomes or in that group of patients who did not have testing. And actually what those patients were, were they certain, you know, lower risk CPT codes or low risk patients who, for whatever reason, the clinicians decided that they did warrant testing.

All in all, I think it's a well written, well (road) tested measure.

Richard Dutton: Hi, this is Rick Dutton, I'm the secondary discussant and I'll (plus) in a couple of things. I'm also interested in the – how the outcome data actually looks around this measure. I will point out that this is asymmetrical outcome if you got the PFTs and you didn't need them. It's a small expense, but no big deal. Whereas, if you resect too much long and wind up with a pulmonary cripple, it's now been later dependent for life or needs a transplant, that's a very big deal.

So, the potential adverse outcome here is way worst than the simple cost of doing the task.

That said, now I do have a question of whether routine testing is still considered necessary in patients who are low risk ASA 1 or 2 patient or patient with a normal exercise tolerance coming for a single lobectomy or segmentectomy both with new or surgical techniques and imaging that's advance to – I think the key data. And support of this measure was from 2003. The standards and guidelines updated in 2013.

But one of the things that's happened since then is the resolution of CT MRI ultrasound is all increased to 100 fold. And one wonders if we – if this – if full PFTs are still needed for every patient having a lung resection.

And I just want to put that question out for the developers.

Jeff Jacobs: This is Jeff Jacobs again from the Society of Thoracic Surgeons. I'm not sure, but one of our thoracic surgical colleagues also maybe on the call, if not, I'll be happy to address the question.

All right, maybe he's muted or maybe had to leave and go to the operating room himself.

I can address this question from two points of view. First of all, I agree that this is a very asymmetrical outcome where it's a very low cost cast while cost didn't – not doing this test in resecting too much long is tremendous both from the healthcare perspective and also from an economic perspective.

So, I think that – I like the terms describing an asymmetrical outcome. And I think the cost of doing the test is so minimal that it's – and the risk of doing the test is so minimal. And it's probably justifiable to do this test to prevent potentially horrible outcome of resecting too much long.

And there's no clear agreed upon evidence that exists that a subset of patients are low risk and do not need pulmonary function test, because their pulmonary function test – because their pulmonary function status can be clearly evaluated with an alternative and most expensive modality.

So, I think it's an important question asked and important concept to examine. I think pulmonary function testing still plays a major role in all patients who are undergoing in lung resecting.

Allan Siperstein: And Allan Siperstein here. You know, the comment I was trying to make obviously is that, you know, the gaps in compliance with this, it would be useful to examine. You know, why there is that continued gap and an attempt to make efforts to close it if indicated.

Jeff Jacobs: Yes, I would agree completely. And that I also agree that it would be interesting to examine the outcomes of patients we have undergone lung resection with and without documentation of pulmonary function prior to the lung resection. I'm not sure with such a study would show, but I think it would certainly be interesting to look at that study as well. So I agree with exactly what you're saying.

Andrew Lyzenga: OK. Any other comments or question from this measure?

John Handy: This is John Handy. I'm a little confused by the wording, so the percentage of thoracic surgery patients is always how – what is the percentage that we're considering. Is it a 100 percent? Is it 80 percent?

So the wording of the measure says percentage of thoracic surgery patients undergoing at least one pulmonary function testing within 12 months prior to anatomic lung resection.

Allan Siperstein: It (inaudible) the result is a numerator and denominator, the final answer – the final result is at percent.

John Handy: Right.

Jeff Jacobs: Right, the numerator of the – the numerator is the number of patients who undergo PFTs, the denominator is the number of patients who undergo major anatomic lung resection. And that leads to the calculation of a percentage of patients comply with the measure.

Andrew Lyzenga: OK. Thank you.

Any other comments or question?

Hearing none, let's go ahead and move on to the next one. Another outcome measure here, this is 0114, Risk-Adjusted Postoperative Renal Failure. And I think we have – you again Dr. Siperstein.

Allan Siperstein: I must (have that) again. So, this is another STS measure. This is a real outcome measure or very well risk adjusted. Again, well, that a measure originally endorsed in 2007, re-endorsed in 2011. And what this measure looks at are the percent of patients who develop renal failure after undergoing isolated coronary bypass surgery.

And the definition of renal failure is interesting and that it is like creatinine greater than four, or if your creatinine increases three fold over baseline. So if you start at one go to three, you hit the metric or, obviously, if you need new dialysis.

Interestingly, they include in this metric people who have had prior transplant and go into their cardiac surgery with normal renal function. I think that group is appropriately included.

There was a very elaborate risk adjustment that is done and as would be expected, patients that are walking in the door with increasing degrees of mild renal insufficiency or at greater risk for hitting one of the barriers, or the

triggers in this – the group that's at particular risk, or people with very advanced state greater than 80 in diabetes.

And so the – just the back-of-the-envelope, look at the risk adjustment, looks at totally appropriate for this measure.

One of the areas where I think additional data would be helpful. In many ways, I kind of regard re-endorsement of these measures kind of as a grant re-approval. And that it helps to show that there has been improvement.

I think this data may not have been presented as cleanly as it could have been, data was presented in categories with low, mid and high performance sites. And, obviously, the performance on this measure varied from 0.3 percent in the highest performance, about 2 percent in the mid, and 6.7 in the low performance. And there was some data given to indicate that if you start out in one of those categories, you tend to stay in one of those categories.

But what I would be interested in, there's a little bit more granular data in terms of whether either raw or adjusted percentages seem to improve overtime, you know, in those sites that we're participating.

Obviously, one of the challenges, I guess positive issues with STS is that the compliance is so high that you can't cleanly compare non-participating groups to participating groups. But, obviously, my question is for those that have been following this measure overtime have they gotten together and improve this metric.

The – and just to wrap up, I think the, you know, clinical importance obviously is it by maintaining good perfusion throughout the preoperative process which is, obviously, again a team sport. It'll help to optimize this outcome.

Andrew Lyzenga: OK, thank you. Anything to add, Dr. Yates?

(A.J. Yates): Yes, I was just going to follow up on the last comment. It's – again I had talked to the STS for their measures and for their registry, last opportunity to

say this on this phone call, but I think they've done a remarkable job over the last 20 years.

But the one thing about this measure as referred to in the last comment which is team, it's a team approach and so this is the outcome out of what might be a black box. And it may not be just the perfusion pressures, it maybe attention to nephrotoxic drugs, it maybe attention to preoperative risk factors, it maybe a number of things that – it maybe the postoperative pressure maintenance.

And so, it's not just the surgeon, it maybe the anesthesiologist, it maybe the cardiologist or the surgeon in the postoperative period, or the intensivist. And so, to measure this at the clinician level, strikes me as being somewhat arbitrary when it really ought to be at a facility level.

And my question to the developers when this is reported, is it reported at the clinician level. And, obviously, the captain of the ship is the surgeon and may affect that. But is it appropriate to sort of risk adjust for the facility that the surgeon is working in when it's reported. In other words, if the facility has a bad track record, not that you want to give the surgeon a pass, but you ameliorate the reporting on him or her, or she or he for that reason. That's my only point.

Andrew Lyzenga: OK. Thank you. Any response from the developer on that point or any other …

Jeff Jacobs: Yes, sure. This is Jeff Jacobs. On the last call as a group, we discussed strategy for reporting outcomes based on programmatic assessment versus the assessment of the performance of individual surgeons. And STS have always have the physician that outcomes after cardiac surgery are reflective of the performance of the entire team in terms of currently up until now, we've always reported the outcomes based on either the hospital or the cardiac surgical program or both.

That being said, we're now in the process of developing a platform for reporting the outcomes of the individual cardiac surgical providers in addition to those of cardiac surgical programs in hospitals. And our rationale for reporting these outcomes stratified by individual surgical outcomes is to meet

the tremendous desire and need of the public to be able to have access to this information.

The creation of this individual surgical outcomes is somewhat challenging because of the problems with sample size and achieving inadequate sample size to document performance when we're looking at the number of cases done by an individual provider. Nevertheless, I think we would agree that there's a substantial movement towards reporting the outcomes stratified for the individual surgeon. STS is in the process of developing methodologies to be able to achieve this objective.

Allan Siperstein: Allan Siperstein here. I just want to – I want to throw the question back to the developer just in terms of, is there any cleaner data on whether there has been improvement in this overtime.

Jeff Jacobs: That's something we'd have to go back to the database and look at. But I think we know clearly, there's been improvement in overall survival and outcomes after coronary bypass grafting overtime. And so that's a fact that we've documented and published.

I'm not sure about the answer to the question that it has the same improvement and documented specifically for the domain of postoperative renal failure …

Allan Siperstein: And just to comment too, this is part of the CABG composite score as well, so it feeds into that overall metric.

Jeff Jacobs: Yes, I've also just received the text that my colleague, Dr. (Shaheen) is on the phone as well. But his line is muted. And if we unmute (Dave), he might be able to add his dialogue of it.

Female: Operator, could you make sure all the lines are open?

Operator: One moment.

All lines are open.

(Dave Shaheen): Hi, it's (Dave Shaheen), can you hear me?

Jeff Jacobs: Yes.

(Dave Shaheen): Thanks. I was trying to comment before number of occasions but my line was muted. Jeff, I think you've answered this exactly correctly.

We have documentation, there's paper by (LBARDC) that we can show you in terms of the decrease in incidents of renal failure. But, in order to look at individual programs overtime, we would have to go back and query the database which we can certainly do.

And Jeff is absolutely correct as was the reviewer that this is a team support. And the prevention of renal failure is something that really we attribute to the entire program. It is part of the composite. And we are moving towards individual surgeon level of reporting in the future, but it'll be a composite of composites.

So this will be one small part of it that I, you know, I think the cardiac surgical team as a whole is responsible for the outcome and anybody that touches that patient or has anything to do with the management whether it's a intensivist or an anesthesiologist, whomever is involved in the care plays a part in whether or not that patient gets renal failure, even the person that may choose the wrong antibiotic. So, it is a team support and we attribute it right now to the program level.

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

Sounds like none. Any other questions or comments from the committee in general on any of the measures we've just discussed?

All right, well, let's take a moment to open up the line for public comment.

Operator, can you prompt the public to make comments if there are some inclined?

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

And there are no public comments at this time.

Andrew Lyzenga: OK. So, then, just to say a few quick words about the in-person meeting that is approaching. We'll ask, you know, I'd maybe just describe quickly the process for reviewing the measures at the meeting.

What we'll do is we'll have each of the developers give a brief overview of the measure, give a description of what the measure is and making key points that they would like to. Then we'll have the primary discussant who will be the same person who is assigned for the workgroup discussion.

The primary discussant or the secondary discussant, you guys can work that out amongst yourselves if you like.

We'll ask you to walk through the measure criterion by criterion. We'll have a – we actually have a script that we've prepared for you. We posted that on the SharePoint page and can point you to that if you have any problems finding it. But that script will actually sort of walk you through how to present the measure for the lead discussants, what question, what are the sort of key questions to ask, and how does it proceed through the evaluation of each measure.

What we're going to do is discuss each criterion. For example, importance then vote on that criterion and then move to the next scientific accessibility, discuss that, and then vote on that criterion, and so forth. That's a bit of a departure from how we've done it in previous committee meetings if you've been on a committee before. We think that helps us really focus this discussion around each of the separate criteria, and really each – address each one specifically for each measure.

Any questions on that or the approach to the meeting, or any questions about the in-person meeting in general?

Do you have anything to add, Melinda?

Melinda Murphy: No, thank you.

Andrew Lyzenga: All right. Well, Wunmi, you want to …

Wunmi Isijola: Sure.

Andrew Lyzenga: … talk about our next steps for a moment?

Wunmi Isijola: OK. So, our last and final workgroup call will take place on May 19th which is this coming Monday. This will be our last call prior to our in-persons scheduled for May 28th and 29th.

If you are, in fact, a discussant, please submit your survey by the end of this week. And just as a follow up, we did receive word from our developers, that measure 465 and measure 0533, will not be considered during this project.

We have, in fact, added measure 2559, that's the Bariatric Surgery Accreditation measure. And that has also been posted on the SharePoint site. So we encourage you to become familiar with that measure in preparation for the in-person meeting.

Are there any question? And just please note that, we will be sending you just some meeting preparation points prior to the in-person meeting for the committee members, as well as for the developers. We will be following up with you with the summaries from the workgroup so that you can prepare yourself for the discussion, particularly for some of the request by the committee for additional information.

And if there isn't any questions, we will adjourn our meeting. Thank you all for participating.

Male: Thank you.

Andrew Lyzenga: OK. Thanks, everyone.

END