NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
July 10, 2019
7:50 pm CT

(Tamaya Eaton): Hi, this is (Tamaya Eaton).

Lee Fleisher: Hey, do we want to start roll call or do you want to wait two more minutes?

(Melissa): We can go ahead and get stated because it's 2:04 and we have five measures to get through today. So, we will go ahead and get started and while we do roll call and a quick overview, hopefully some more people will log in.

Again, good afternoon everyone. This is Melissa Marinelarena, Senior Director here at NQF. This is our second Webinar for Surgery Project in the Spring 2019 Measure Review Cycle. Thank you for those of you that joined us last week. We reviewed two new CMS Measures and today on our agenda, we have five STS Maintenance Measures to review. Two of them are Outcome Measures and two of them are Structure Measures.

If we do not get through them today, we do have another Webinar scheduled next week. I want to welcome the team here. We have Hannah and (Janaki) and Katie and Elisa, just walked in. And Karen Johnson is on the phone. And welcome to the Measure Developers and any members of the public that are listening today.

I'm going to turn it over to Lee one of our Co-chairs just to say some opening remarks. Bill, our other Co-chair is in Upstate New York with some (really shady) cell service so he may be on and he may not. So, we're going to let (Lee) carry this call today and then Bill will jump in when he can.

So, I'm just going to turn it over to Bill - I mean, I'm sorry, to Lee, then we'll do roll call to determine who is here and to see if we have quorum and then we will get started. Lee.

Lee: Yes, no I want to thank everybody. The last call we had a very robust discussion. Hopefully everyone did vote and that, at least, we had quorum for the vote. Today we have a number of some interesting Measures. Some old Measures that have been around for quite a while related to participation in a database. It's great to have (Karen) and (Elisa) on the line, since I'm sure that some of the issues of evidence and what we measure will be discussed.

I think I'll leave the comments at that and just - so we'll have one lead discussant again, like last time. A.J. did a phenomenal job. And then if others have additional comments and try to keep it brief, we'd like to try to get through most of these measures. But if there's robust concerns, I think we - that's when we'll take our time since we do have one more call. So, thank you.

(Melissa): Thank you very much Lee. Bill, I don't think Bill is on right now. I don't see him. Anyway, Bill will speak up if he does join us. So, I'm going to turn it over to (Janaki) to take roll so we can determine quorum, among some other business that we need to take care of.

(Janaki): Hi, good afternoon everyone. This is (Janaki) with NQF. Before I do roll call, I just wanted to remind you if you were not able to join us last week on

July 2nd for the first Web Meeting, you are required to disclose any conflict of interest you might have. So, while I'm doing roll call, please let us know if there is any conflict of interest you have.

We'll start with Lee Fleisher.

Lee Fleisher: None for today.

(Janaki): Bill Gunnar. Robert Cima. Richard Dutton. (Tamaya Eaton).

(Tamaya Eaton): I'm here. No disclosures.

(Janaki): Elisabeth Erekson. Fred Grover.

Fred Grover: Here and I do have a disclosure with the STS Conflict of Interest.

(Janaki): Thank you Fred. John Handy. Mark Jarrett.

Mark Jarrett: I'm here and no conflict.

(Janaki): Clifford Ko. Barbara Levy.

Barbara Levy: I'm here with no conflict.

(Janaki): Barry Markman. Amy Moyer.

Amy Moyer: I'm here.

(Janaki): Keith Olsen. Lynn Reede.

Lynn Reede: I'm here, no conflict.

(Janaki): Christopher Saigal. Salvatore Scali.

Salvatore Scali: I'm here and no conflicts.

(Janaki): Allan Siperstein.

Allan Siperstein: Here, no conflicts.

(Janaki): Joshua Stein.

Joshua Stein: Here and no conflicts.

(Janaki): Larissa Temple.

(Melissa): I think she might be joining us a little late.

(Janaki): (Barbie Vitica). A.J. Yates.

A.J. Yates: I'm here and unfortunately, I still don't have any conflicts.

(Janaki): Thank you.

(Melissa): (You're doing) something wrong A.J.

(Janaki): I have 11.

(Melissa): One, two, three, four…

(Janaki): (Can't do Fred).

(Melissa): Oh, Fred, okay. So, we have 12 Committee Members present. We're not counting Fred. Fred is recused from the discussion and from voting on the measures. We need 14 for quorum. We are at 11 right now. Is there anybody on the phone that we did not call?

Okay, so we're three people short. So, as of right now, we cannot vote during the call and we would do the same process that we did last week, is send a recording of the meeting, along with a survey and ask the committee to submit their votes online within 48-hours.

So, I think now I can turn it over to Lee to facilitate the discussion and the first measure. If there aren't any question, I'll stop here really quick. Are there any questions? Okay. Hearing none, again, feel free to raise your hand on the Webinar, if you're on the Webinar. If there's any questions, it's under the chat. Or the lines are open as well, so just a reminder to mute it if you're not speaking, but otherwise feel free to come off of mute if there's any questions or comments.

So, I'll turn it over to Lee to start - to kick off the meeting and we'll start with 0733.

Lee Fleisher: All right. So, that is Measure Operative Mortality Stratified by the Five Stat Mortality Categories. And the Developer is STS. So, Fred is recused. And who do we have on from STS?

Jeff Jacobs: This is Jeff Jacobs. I'm one of the STS Surgeon Members.

(Dave S): (Dave Shahean).

Mark Antman: And this is Mark Antman from STS Staff.

Lee Fleisher: Hi Mark. Great. Do you want to give us a two to three-minute presentation of your Measure and then we'll have the lead discussants?

Jeff Jacobs: Sure, so.

((Crosstalk))

Jeff Jacobs: This is Jeff Jacobs. The Stat Categories are a (method) of dividing all of the operations done by pediatric and congenital heart surgeons into five categories, which are designed to maximize within category homogeneity and maximize the differences between categories, with respect to the risk of the given operation being associated with operative mortality.

The categories were developed based on an analysis of 77-thousand operations in the Society of Thoracic Surgeons, Congenital Heart Surgery Database and the European Association of Congenital Heart Surgery Database. And the data is used to be publicly reported where we publicly report our operative mortality stratified by the five Stat Categories.

That's kind of a pretty rapid summary. I'm happy to answer any questions.

Lee Fleisher: No. Lynn, do you want to start us off.

Lynn Reede: Sure, Lee. I can, I had brain freeze on my computer though, but I'll do my best. Thank you. So, yes, this is a Structure Measure used, actually, as part of other outcomes and the Outcomes Measures for the STS. And it was first endorsed in 2011 and the committee recently endorsed, or NQF did, in

September 2015. It actually - you don't want me to go to evidence already? Or do you want me to?

Lee Fleisher: You're welcome. Unless you have other comments.

Lynn Reede: No. No, well numerator already discussed these (were) the patients undergoing Index, Pediatric, and Congenital Heart Surgery who do die. As a denominator, all patients undergoing Index Pediatric Congenital Heart Surgery no exclusion.

As far as evidence. It is here for maintenance. And the Developer does say that there's no underlying evidence changes since the last NQF Endorsement. As far as Committee Comments, there were no concerns and felt that evidence was adequate for this measure.

(Melissa): Lynn, this (Melissa) from NQF. Just to clarify, this is an Outcome Measure? It's not one of the Structure Measures?

Lynn Reede: Oh, I'm sorry. I'm sorry, sorry.

(Melissa): That's okay. And so, this is…

((Crosstalk))

Lynn Reede: …and with Outcome Measures because it does have a denominator. Yes.

(Melissa): Thank you.

Lynn Reede: Sorry, I read too many Measures today.

(Melissa): Thank you.

Lynn Reede: Or yesterday and the day before and - sorry. Thanks Larissa.

(Melissa): Perfect, thank you.

Lee Fleisher: And it did pass is what you're saying evidence.

Lynn Reede: Yes.

Lee Fleisher: Other comments from any other or concerns from any other reviewer?

Richard Dutton: This is Dr. Dutton. I'm on the phone now.

Lee Fleisher: Oh, great, thanks Rick. Anybody else join? Hearing none. Do you want to discuss preliminary rating for improvement?

Lynn Reede: As far as GAP? The distribution of the participants specific observed rate was stratified across the Stat Mortality Categories, was already discussed. And that they looked across 12 periods - 12-month periods to show progressively higher mortality rates as the procedure categories became more complex.

So, from the committee review and our comments, we felt that GAP existed and the measure remained useful.

Lee Fleisher: Great.

Lynn Reede: Also, from a Disparity perspective, that there is disparity data provided by the Developer for sex, race, and defined age groups in this population. And so…

Lee Fleisher: So, anybody have any other comments for GAP? So, it's rated as Moderate. How about Scientific Acceptability?

Lynn Reede: Where am I? Stability. So, Reliability?

Lee Fleisher: Reliability, yes.

Lynn Reede: Okay. The specifications for this particular measure can be consistently implemented. There are no denominator exclusions. It seems like we need some clarification regarding the level of analysis from the Developers. And that it seemed to indicate from the measure itself, the specification that we're looking at the group in the practice level - did seem that testing was done at the hospital level.

However, from the committee comments, we had no issues and we felt that the specification was good.

Jeff Jacobs: All right. And this is Jeff Jacobs from STS. We had a phone conversation with NQF Staff and clarified that the measure is at the hospital level. So, that should make this part of the discussion easier.

Lynn Reede: Well thank you. Thanks, Jeff.

Jeff Jacobs: The wrong box was checked, that's all it was.

Lynn Reede: Okay. Good to hear your voice.

Jeff Jacobs: You bet.

Lynn Reede: So, from a reliability testing perspective, this was done at the data element level looking at the data source and level analysis for this measure. They looked at the Data Element Reliability Testing and that was good. The Developer also presented information regarding their Database Audit Process using a third party. And that participants are randomly selected on an annual basis.

And that actually there was no recommendations to change this particular measure. And that the overall Completeness of Agreement rate was at 97.68% and Data Accuracy Agreement was at 97.45. And this also is how NQF requires testing for Validity Testing, but it was acceptable at the Staff Analysis for Reliability Testing as well.

And the committee had no comments and felt that Reliability Testing was good and there were no concerns.

Lee Fleisher: Great. Anybody else have any con - comments? Okay. And has anybody else joined that we could vote? Or no?

Elisabeth Erekson: Hi, it's Lis Erekson, I'm on the line.

Lee Fleisher: So, what are we up to? Thirteen?

(Melissa): Twelve that we can count, because Fred, we can't count Fred in quorum, so we're at 12 - excuse me 12.

Lee Fleisher: Okay. Feasibility?

Lynn Reede: Okay. Do I do Validity or do we'll skip over that since we already discussed that?

Lee Fleisher: I thought you already did that.

Lynn Reede: I did.

Lee Fleisher: Did the staff say…?

Lynn Reede: It was a high level. It's going to be the same thing we think. So, from the Feasibility perspective, data was gener - well this is the same that we said for all the STS Measures, that the Data is generated Point of Care, documented, is Abstracted and that this Measure, along with all the other STS Measures, seems to not put on undue burden on the facilities who engage in this Database Reporting Activity or Quality Measure Activity.

So, we - the committee had no concerns, other than the cost burden of abstraction - three of our members had comment on that. And so, this would be rated Moderate.

Lee Fleisher: Okay. And next, Use.

Lynn Reede: From a Use perspective, this has been publicly reported since this year. So, unclear how it's used for an Accountability Program - or an Accountability Program for the Clinician. But the Dashboard was also launched in 2018 at the request of the members so that they had real-time online data. And it's publicly reported and - in an attempt to promote participation enhanced usability of about 33% of participation from the facilities in 2015, to 83% now in 2019.

And, again, the STS Congenital Surgery Task Force felt there was no modification required for this Measure in 2018. The members of the

committee felt that related to accountability and transparency, that it is publicly reported and it's good. One member said that it was unclear, but the rest of the members who commented said this should pass.

Lee Fleisher: Great. Okay. Any comments from STS on Use. It looks like it's great that you put it into your public reporting this year.

Jeff Jacobs: Right, this is a Measure that's been publicly reported since 2015. In 2015, 23% of the hospitals in the United States publicly reported this measure, but now over 80% of the hospitals in the United States publicly report this Measure.

Lee Fleisher: That's fantastic. Thank you. And Usability?

Lynn Reede: Thank you. Again, they provided us data to look at the number of participants in the Operations by Performance Groups. In the mid and low to performance for the time period from July 2014 through 2016 and July 2016 through June 2018. The data showed overall rates in the last 12-month period and the committee felt there were no concerns that the publicly reported benefits outweigh harms that's very usable. So, pass.

Lee Fleisher: Okay. So, we can vote, correct?

(Melissa): That's correct Lee.

Lee Fleisher: So, anything else. So, anybody have any other comment? Any of the other reviewers? So, it sounds like we're ready to go onto the next Measure.

(Melissa): So, the next Measure we're going to review is 2683, Risk Adjusted Operative Mortalities for Pediatric and Congenital Heart Surgery also by the Society of Thoracic Surgeons. And I will turn it back to you Lee.

Lee Fleisher: Okay. So, this is another Outcome Measure. And if the STS representatives want to start the discussion, that will be great.

Jeff Jacobs: Sure, this is Jeff Jacobs again. This is a Risk Adjusted Mortality Outcome Measure that STS Publicly reports. The outcome is operative mortality and we adjust for risks by looking at a variety of variables including the age and weight of the patient. The diagnosis of the patient and the operation performed. The Stat category of the patient as described with the previous Measure.

And then also, we're able to put into the risk model the patient's preoperative condition. For example, whether or not the patients on the mechanical ventilator or on mechanical circulatory support. And we also put into the model whether or not the patient has chromosomal abnormality syndromes or non-cardiac congenital anatomic abnormalities.

And finally, whether or not the patient has had previous cardiac surgery and whether or not the patient is born premature. So, all of those variables go into a risk model which allows us to calculate an expected mortality rate for a given program and an expected mortality rate for a given program within a given Stat category.

And then we publicly report the programs Observed Mortality Rate, the Expected Mortality Rate, and Observed to Expected Mortality ratio. And then a Standardized Mortality Rate. All those variables have been publicly

reported since 2015 and currently over 80% of the Pediatric Heart Surgery Programs in the United States publicly report these measures.

As we go through this Measure, again, it's going to be the same issue with the box that we checked. We actually do report this measure by hospital. So, when we get to that part of the discussion, this is a hospital level measure. And if I can answer any questions?

Lee Fleisher: So, Robert, are you on? No. Mark?

Mark Jarrett: Yep, I'm on.

Lee Fleisher: Do you want to lead this discussion?

Mark Jarrett: Okay. Sure. So, on the Evidence. The evidence clearly both I and everybody else felt, that the evidence has really been the same all along. It's a high-risk procedure and any information that's provided certainly improves things. In terms of performance GAP, there is a still, obviously, a Performance GAP, and as we've all read in the newspapers recently, and clearly not a topic that has been quiet.

So, the GAP still exists. It's not large, but then again, you know, because again the volumes are not huge, but the Outcomes and the seriousness of this, because it's in children, clearly outweighs the fact that the GAP is slightly small.

Lee Fleisher: Fantastic. Okay. Any other comments from the other reviewers?

Richard Dutton: I have a question, Lee. For Jeff, about the Risk Adjustment Model, I'm sure you've looked at this. What percent of the variability in Outcomes do the

listed adjusters account for? In other words, how much of the risk are you adjusting for?

Jeff Jarrett: I guess one way to answer that is based on a C Statistic and C Statistic of the Risk Models over 0.8 in both the Development and Validation Samples. So, that's one way to address that. Clearly, there's variables that don't exist in any risk model.

Richard Dutton: Right.

Jeff Jarrett: Including this one. But what I can say is that this is the risk model that currently exists for Pediatric and Congenital Heart Surgery that has the highest C Statistic of any Risk Model that's ever been created or published for Pediatric and Congenital Heart Surgery. So, it's not perfect, but it's better than anything that currently exists.

(Dave S.) Rick, I can - this is (Dave Shahean). I can probably comment a little further too. You know, explain variation for logistic or hierarchical models is a little less useful in our opinion then it would be in linear models. And, in fact, a perfect logistic model - a perfectly fit logistic model, might have, you know, .3 or .2, or .1 R Square using traditional techniques and there are, you know, there are variants that have been developed for use in logistic models that we have not generally regarded that as a major way that we evaluate our models.

Richard Dutton: Got it. Thank you.

Lee Fleisher: Okay, thank you. Next we have GAP?

Mark Jarrett: Yes, GAP - sorry, my CEO is just walking in to ask me something. GAP, the Reliability - the GAP, as we said, was - is real. I think I described before. Was - they are significant enough.

Lee Fleisher: Oh, yes, that's right. So, what are we up to now?

Mark Jarrett: Reliability.

Lee Fleisher: So, you're saying Validity?

Mark Jarrett: No, we're up to Reliability.

Lee Fleisher: Reliability. Okay, you want to go over that?

Mark Jarrett: So, Reliability, both myself and everybody else felt that there were no specific concerns on any of the specifications or under the testing. And I can move onto Validity, again. There were no major concerns either for the testing or the threats to Validity for it.

And other threats, you know, the - everybody felt the exclusions were accessible - acceptable. But it was - although the procedures have a lot of different risks because it was felt that it appeared to be more in the risk adjustment modeling. So, everybody was, again, fine with that.

Lee Fleisher: Right. Any other comments? Okay.

Mark Jarrett: Feasibility?

Lee Fleisher: Yep.

Mark Jarrett: Feasibility is like all the STS Database ones. And nobody had any concerns.

Lee Fleisher: Okay.

Mark Jarrett: That was kind of easy.

Lee Fleisher: We've already heard about Use?

Mark Jarrett: Yes. Use, I don't think that there's a - then again it was both on Accountability and Transability and Usability. The fact that it's a) publicly reported and the fact that it's hospital level, we all feel is very, very, good.

Lee Fleisher: And Usability?

Mark Jarrett: Yes. No problem. And no real areas for improvement.

Lee Fleisher: Anything else from the Committee? Okay. The next Measure.

(Barbara Vitica): I'm sorry Lee, this is (Barb). I did have a question about (733) versus this one. And what are their stratification among the facilities between these two and is there a need have both?

Jeff Jacobs: That's a great question. So, first of all, we publicly report both and they both are complimentary measures that provide complimentary information. For example, the second measure we discussed, the Risk Adjusted Model will provide the Observed to Expected Mortality Ratio of a given program for all the Pediatric Heart Surgery that they do.

So, that then allows one to assess overall performance, but doesn't say anything about case mix. The first Measure we discussed provides

information about case mix. So, it will tell us what proportion of operations are done within a given program at each of the five levels of risk or five levels of complexity. Level one through five. And by having both pieces of information, the performance and the case mix, one is then able to really make an overall assessment of a given pediatric or congenital heart surgery program.

(Barbie Whitaker): Great. That's very helpful Jeff, thank.

Jeff Jacobs: Thank you.

Lee Fleisher: Okay. Any other comments from the Committee? Okay. Now, well get into more of those with questions about the Structure Measures. So, 0456, I guess is next. Which is coming up. Participation in STS Database with General Thoracic Surgery. So, let me just pull out my sheet of who - Lead Discussants are A.J. who spoke last time, Elisabeth Erekson, do you want to, first we'll have the Developers talk about this Measure. Jeff?

Mark Antman: Thank you, Lee. This is Mark Antman of the STS. As you see on the screen, this is a Structure Measure entitled Participation in the Systematic National Database for General Thoracic Surgery. Again, the description is Participation in Multicentered Data Collection Feedback Program that provides benchmarking of the physician's data relative to National Programs and Uses, Structure Process and Outcome Measures.

This Measure was most recently re-endorsed in 2014 and it's, although as a Structure Measure, this isn't strictly - strictly speaking this is not itself publicly reported. But having this Structure Measure for our General Thoracic Database does provide the basis for the publicly reported measures for the General Thoracic Database.

The Lobectomy composites currently endorsed by NQF, is our currently publicly reported General Thoracic Measure. Coming this summer, there will also be a publicly reported esophagectomy composite. So, that's probably enough as an intro.

Lee Fleisher: Great.

Elisabeth Erekson: Great.

Lee Fleisher: So…

Elisabeth Erekson: Do I actually - this is Lis Erekson. I can start talking through the Measure. I actually did have a question. Because it says - it says physician participation. Is it truly per surgeon or is it at the hospital level, because it seems like things are publicly reported at the hospital level for this dataset?

Mark Antman: Correct. This dataset publicly reports information at the hospital level.

Elisabeth Erekson: And is the Measure at the hospital level or the physician level?

Mark Antman: Hospital level.

Elisabeth Erekson: Okay. Thank you. So, just walking through Evidence and Performance GAP. The Measure Developer showed that in 2014 there were 244 participants and there has been increasing uptake of this dataset with 298 in the beginning of 2019.

And then our Committee - our Prework Committee when they reviewed it, actually showed that there was some additional evidence for participation in

the dataset having those surgeons - or those hospitals that are participating in the dataset having better outcomes. So, all of that would support the Evidence for this Structure Measure.

Lee Fleisher: Well we did have a preliminary review. NQF Staff? I'm not sure who wants to discuss this from the NQF perspective.

(Melissa): Hi, (Karen) perhaps you can provide some more input into that?

(Karen): Sure. I think the preliminary analysis was focusing on a lack of systematic review and grading of the Evidence. And I think what we should make sure that the Evidence really provides and not worry so much about whether there's a systematic review or not. But has the Evidence that is provided basically shown that hospitals that participate with this registry have better outcomes then hospitals that do not.

So, if you feel like that the articles that have been discussed and show - number one show that. Number two, do you have a flavor of, you know, how many studies there are and, you know, the strength of that evidence? So, you know, not just there were studies, but they were strong enough studies that you would accept that data.

Then you would, according to our Evidence Algorithms, it would eligible for Moderate. So, I think, probably the biggest question in our mind had to do with, was there really evidence showing particip - you know, could you actually say that nonparticipating hospitals did not do as well?

And that might be something that Mark or Jeff might be able to just elaborate on a little bit for us so that we are all very clear about what the Evidence is for this Measure.

Jeff Jacobs: Well, this is Jeff and I could - there's a couple of things that we can talk about. Initially, there's a manuscript that is published by the first author named (Tom) that looks at the number of Lobectomies done in the United States. And of that, how many of those Lobectomies are done at a Society of Thoracic Surgeons participating hospital?

And in the article, data's shown that the number of hospitals that do Lobectomies and participate in the STS Database increased from 1.2% in 2002 to 25% in 2013. So, unlike our Cardiac Surgical Databases where our penetration is over 90%, the penetration here is growing every year, but still only 25%. And part of the reason for that is that a large portion of Lobectomies in the United States are not performed by thoracic surgeons but are performed by general surgeons.

So, that fact of increasing participation in the STS Database of hospitals performing lobectomies needs to be combined with data that we've published that documents that outcomes of hospitals participating in the STS Database are better than outcomes overall in the United States using data from a Nationwide Inpatient Sample or NIS.

It's not easy to get a handle on what the outcomes are in hospitals that don't participate in the database, because that database doesn't have data about that hospital. But for the Thoracic Surgical Analysis, we're able to augment our information with data from the Nationwide Inpatient Sample, which is Administrative Data. And that data demonstrates that outcomes after lobectomy are improved or better at hospitals participating in the STS Database.

So, I think those two pieces of information combined provides support for this Measure.

(Dave S): And this is (Dave). If you're at your computers and you pull up the STS public reporting microsite and go to General Thoracic and just pick any program - I happen to be looking at Albany right now. But you'll see that for each program we show the results for the participant in the database. And then we show the comparable results for all participants in the STS Database.

And then, as Jeff said, the National - Nationwide Inpatient Sample. And, you know, virtually, uniformly, if you just go through sites, you will see that the results for our database participants are far superior than those in the Nationwide Inpatient Sample. So, you can take a look at that anytime. It's pretty compelling.

General Thoracic is somewhat unique in comparison to Cardioth - those for adults and pediatric cardiac because we do have more of a penetration GAP. There are a lot of smaller General Thoracic Programs that are not participating yet and there are also many Non-Board Certified - Non-Cardiothoracic Board-Certified Surgeons who are doing General Thoracic Surgery in the United States. Many of whom do not participate in our database, although they can. They're allowed to.

So, this is a unique situation in general thoracic where we feel particularly strongly about maintaining this Structural Measure.

Lee Fleisher: Great, that's fantastic (Dave).

Woman 1: Can I ask a question to the NQF Staffers? This is an Endorsement Measure. So, the Committee reviewed the Evidence supporting this Structural Measure

twice before, it looks like, in 2008 and 2014. And had obviously thought that the Evidence was higher than insufficient. Or - I'm trying to understand why, now, the Evidence is rated as Insufficient when previously this Measure has been endorsed?

(Karen): This is (Karen). That's a good question. I think for these kinds of Measures as Criteria for Evidence really has not changed, so, although I think in 2015, we - that was about the time that we invoked the Evidence algorithm that we have now and it kind of became a little bit, I would say, probably a little bit more rigorous in trying to just really make sure that we're all clear on what the evidence is so that we can be transparent about all of these things.

So, it could very well be that we really didn't ask as hard of questions back in 2015 when it was, I think - was it first endorsed in 2015? Or that was the last (unintelligible) it had? So, I think that's probably what it was. We were in a bit of transition, just in (timing) and since that time, we, I think (across the board of staff) we are really trying to pay a lot more attention and make sure that, you know, number one, that we really do understand what was presented in terms of Evidence and in terms of the other criteria, as well.

If we're unclear, then we generally will rate in the preliminary analysis as insufficient. And that doesn't mean low. There is a difference between low and insufficient. Insufficient just means, hey we need some more explanation. We, you know, internally, were not able to actually apply the criteria in a way that we felt comfortable doing. We just need more information. So, that's the Insufficient there.

Does that help you? Hopefully that does.

Woman 1: Yes, thank you.

((Crosstalk))

A.J. Yates: Lee, this is AJ Yates. Can I ask a question of STS?

Lee Fleisher: Sure.

A.J. Yates: The question is, Causality? And it's great that the hospitals where there are thoracic surgeons that choose, or their hospital along with the surgeons choose to participate in the STS Thoracic Surgeons Registry - do well. It's great that they're doing well. But is there not the possibility that those surgeons that are better trained or have been through thoracic training and feel the urge to be part of the registry and also, maybe are already doing well, want to have that measured. And that it's not so much that being in the Registry causes their performance to do better. Because you're looking at a static picture.

The question is, can you show that those hospitals that weren't involved with the STS Thoracic Surgery Measure - did they get better? Can you show that there is a before and after?

(Dave S): We don't have those data available. And as Jeff mentioned, one of the problems is we have overall aggregate data from the Nationwide Inpatient Sample, but we can't - we can't do a hospital-by-hospital analysis from the NIS and say, okay this hospital is participating in the database, this one isn't.

There may be some way to do the analysis that you suggested, which I clearly agree would be the ideal way to do this. But I don't have a - I don't have an idea about how to go about that methodologically.

A.J. Yates: But you understand that you're not showing - again there's a higher bar for Non-Outcomes Measures such as a Structural Measure. And that bar is just showing a logical - at least some evidence of logical improvement for participation in say, a Registry that I'm not seeing here.

I'm seeing that there's a dichotomy between places that pride themselves on being in the Registry and those that don't. But I'm not sure if it's the Registry causing it. You know, the one thing that I do think would have been worthwhile is just to use the surrogate of those registries that can say that. Whether it's (NISQIP) or other different registries, even the STS itself and use the surrogate, that it has been seen that in surgery, participation in a registry and looking at the data from the registry does cause all ships to rise at that hospital.

But you're not offering those surrogates in this case, for this particular question. And, you know, I just wonder whether or not it would be better to, you know, provide those surrogates as evidence and, you know, hold off on this Measure for right now, given what the staff has said, because the staff has basically said that this shouldn't pass GAP, or shouldn't pass Evidence.

And that would leave it dead in the water before we get to even the rest of the Measure. I'm just throwing that out to you that there's probably a surrogate set of studies out there that would, you know, make the point. Even if there's not direct Evidence for thoracic surgery.

(Dave S): Well we have provided to staff multiple publications showing, what we believe is, at least circumstantial evidence that the dramatic improvement in - on the cardiac side, particularly in adult cardiac - have been largely driven by participation in the database and staff has had those papers actually for several weeks now.

A.J. Yates: Well, they're not in the Measure Worksheet here? So, I just - or they weren't mentioned by the staff in terms of the Measure Worksheet. Were they put into this particular Worksheet or are they just there for the rest of the other Measures?

(Dave S): Mark, can you address that?

Mark Antman: No, they were not put directly into this Worksheet. No, we provided them when we spoke with Staff and Karen Johnson a couple of weeks ago. We resent some of these articles late yesterday. If they're not considered to be part of our Measure Documentation, we'll be happy to provide them as references for the Comment Period if that's the next opportunity to introduce them into the Documentation for the Measure.

A.J. Yates: Well, I for one, would be comfortable accepting the Staff saying that they have Evidence presented to them if they would accept this as showing that the Cardiac Measures show that Registry Participation does cause Quality Improvement. Or that it can be inferred that Outcomes are improved. And I would accept the Staff having had reviewed that, making that comment as - so the ball can be in play here.

Because the way it's been presented to us on paper, if we had a quorum there's a possibility of the particular Measure being stuck in the mud right here.

Lee Fleisher: So, A.J…

A.J. Yates: I don't know, I'll put it back out to Lee.

Lee Fleisher: A.J.?

A.J. Yates: Yes.

Lee Fleisher: So, this is Lee. What I would propose - there's a couple things. I actually just reviewed a lot of this literature. And (David), I think should send around the paper that just came out at the Joint Commission. I reviewed it for actually an article for Health Affairs with Don Berwick. And I will tell you if we're asking for Evidence that Measurement makes a difference, the Evidence is not there, but for any Measurement. Or, for very little. Except for STS.

So, I would propose, if it's okay with Staff, we (this year) a proposal that Lis said she's comfortable - can we send around the papers before the vote?

Elisa Munthali: Hi, yes, Lee. This is Elisa. I agree with that. I think we can send that to you to help to inform your discussion. And we do apologize. I know, process wise it feels a little uncomfortable because you do have questions about the Evidence, but we also have an alternative (outlay) for insufficient Evidence.

But for you to know that, you'd have to review the additional materials that we received very recently. But we want you to be very well informed and so we'll send that out to you. But unfortunately, because we don't have quorum, we do have to go through the rest of the Criterion. But we will be happy to send that to you. So, that you can have an informed decision and vote offline.

Jeff Jacobs: So, this is Jeff…

((Crosstalk))

A.J. Yates: Trying to find a way out there.

Mark Antman: No, we have a way out.

Jeff Jacobs: Yes, the literature that was sent to NQF Staff that addresses this question. In the minds of NQF Staff, is that sufficient.

Elisa Munthali: I think, you know, the Committee, it'll be up to the committee to decide on that. These are your decisions. We think that it was important to share with you and so we will share that with you.

I think, what I'm seeing from the staff - and this is Elisa Munthali - and from our team here, that it may have been received at a time that we weren't able to send it very well in advance. So, we apologize for that, but we will send it to you to help inform your vote. And it will be up to the committee.

This is the challenge of not having everyone on the call and voting on the call and discussing everything on the call.

Lee Fleisher: So, what I'm hearing and the reason Karen is - Karen is saying that the preliminary read of the Evidence is Insufficient not Low. So, that's not a Do Not Pass. It's a Committee decision when looking at the totality of the Evidence as content experts on top of the Preliminary Review from the Staff. Is that a correct interpretation?

Elisa Munthali: Yes.

Lee Fleisher: Plus, the new Evidence.

Elisa Munthali: Yes, that is correct. We're not saying it's Not a Pass.

Lee Fleisher: Okay, so we will assume that on the vote, we will - the Committee will be able to determine in total, whether there's sufficient Evidence. So, we should discuss GAP then, since it wasn't - so from a GAP perspective, Lis?

Elisabeth Erekson: So, in terms of GAP, I think there's a demonstration that not all providers performing Lobectomies are participating in this database and that the database is increasing its number of participants. So, I would say that there's still a demonstrated GAP.

Lee Fleisher: Okay.

(Karen): And Lee, this is (Karen). Just a couple things that I wanted to make sure that everybody is clear about. Is - I know that we're going to send around those articles that (David), Mark, and Jeff provided so that you can look at them for Evidence.

Are those kinds of things, and brief summaries of those, along with any other types of information as we walk our way through the Criteria? You know, if Staff said Insufficient, what we allow is, at the Evaluation Meetings we do allow our Developers to answer and present things verbally, which is what Mark, and (Dave) and Jeff have done so far on Evidence.

And we will ask them to actually, a little bit later on, actually insert that into the submission material so that going forward, we don't have to remember that, oh these were extra articles that were passed around to the Committee, kind of, you know, while in the middle of the evaluation. We'll actually add that submission materials. So, going forward, we'll have all of that in there.

The other thing, jumping forward to GAP. I think we had probably marked Insufficient on this as well. And at the end of the (game) what we were really

wanting to see and, I think, probably, this has already been given by Jeff or Mark, I'm not quite sure, but if not, they know that what we were looking for, for GAP really is penetration of participation in the Registry. So, I know you mentioned it for one type of surgery. I don't know if that varies across types of surgery.

Everybody knows I'm not a clinician (there) so, you know, I don't know that part. But that's what we were really looking for, for GAP is the penetration.

Lee Fleisher: So, Mark, as far as the STS Staff, can we for the, it's in the transcripts for those who (were) not here, it could be put back into the Submission. But can you also, maybe give us a one-page cheat sheet on those two issues of the just citing the key papers and maybe the (pertinent) ID?

Mark Antman: Yes, we'll be happy to do that Lee.

Lee Fleisher: I think that would help the Committee be able to quickly look at it. And if you want to put a brief Summary, that would be great, rather than just the transcripts. Is that acceptable Janaki?

(Janaki): Sure, that works.

Lee Fleisher: Great.

(Barbara Whitaker): So, Lee, this is (Barb). Just to your point though. You know, I don't want to be looking at skewed literature or literature that drives us in one direction when there's other literature out there that would say that participation is not - does not drive quality.

So, I'm having some angst about being directed in a certain way when there's other literature out there that might come to opposite conclusions.

(Dave S): (Barb) I can comment on that and you're correct. The two papers that come immediately to mind are from (NISQIP) one by (ESGI One) and the other by, I think (Osborne), with a commentary by Don Berwick in the same issue of JAMA. They looked at participants in the (NISQIP) Database and did not, in general, find that simply participating in (NISQIP) was enough to drive Quality Improvement compared to other programs.

So, there is competing evidence out there. I think we're struck by the magnitude of our improvements on the cardiac side, which, you know, we think would be, you know, just based on our knowledge of how those results motivate programs and the magnitude of the improvements that Lee alluded to, we haven't seen that anywhere else in healthcare.

And we have to think that it's related to the database, but we can't prove it. So, I agree there is another side to this story. So.

Allan Siperstein: Allan Siperstein here. A couple comments. When I was first going through this Measure, I was either overthinking it or underthinking it. Because, obviously those people that are participating, their individuals from hospitals also have their results.

But I think the, and particularly in this era where, you know, we kind of look more favorably upon composite outcome measures rather than what we think of as a more primitive Structural Measure, I think the argument given by STS, you know, I agree with.

And this is a somewhat, I want to say unique situation. But you have a group of providers with varying training background and widely varying volumes of cases that they do annually. And I think that's going to kind of differentiate the provider base that is doing this, where I see value in this Measure based on that.

And so, I think we have to, you know, and I'd be also very interested in looking at those - the literature that you mentioned. But I don't think we can kind of lump all of these together. I think we have to look at those unique properties of the disparate providers doing these particular operations, when we think about it.

Lee Fleisher: Can I ask the STS Cardiac Database participation? Is that still an endorsed measure?

Jeff Jacobs: So, the Congenital is an endorsed Measure that's going to be reviewed again today and same with Thoracic. The Adult Cardiac one, I believe, was - what's the word?

Mark Antman: Jeff, this is Mark. I can help. It was re-endorsed, but placed on reserve status.

Jeff Jacobs: That's the word. The word reserved.

Lee Fleisher: Right. So, that realistically the issue of GAP, this you were able to demonstrate a GAP, but we know that in the Adult a minimal GAP. So, that's helpful to understand what we…

((Crosstalk))

Jeff Jacobs: Great and that's why the Adult Cardiac was put on the Reserve Status. That's the word I was looking for. I think that, it sends a very different message to endorse and put something on Reserve Status versus to Not Endorse it.

Lee Fleisher: Right, but there's clearly a GAP in this particular one.

Jeff Jacobs: Yes, there's…

Lee Fleisher: From my perspective.

Jeff Jacobs: Correct, there's less than half the programs in the country participate.

Lee Fleisher: Okay…

((Crosstalk))

Man: Lee, Lee, can I ask the Developer a question?

Lee Fleisher: Sure.

Man: How much does it cost the hospital to participate per year in this Measure? Like, does it cost a fortune to be able to participate in such that hospitals that are opting not to participate may be different systematically then those who are? Or is it a minimal cost?

Jeff Jacobs: Mark, you want to give the numbers?

Mark Antman: Happy to. I think we have that in the Measure Documentation somewhere. So, let me just page forward.

Elisa Munthali: Yes, it's in the Use Section.

Richard Dutton: This is Rick. Let me weigh in there. Part of the cost that's never in these documents is the need to actually gather the data to put into the Registry.

Jeff Jacobs: Sure.

Richard Dutton: Do you guys have an estimate on what the (true input) is for an Abstract for this or for hospital who is hiring somebody to abstract the data from charts to the EMR? How many cases a year can that abstractor do?

(Dave S): Rick, it's (Dave). I don't think we have that for thoracic, but we do for adult cardiac and it's about 3 to 5-hundred cases per abstractor per year depending on the case mix complexity at a particular institution. The - in order - and then you'll see when you look at the cost, the actual cost of participation in the database is very small. And you're right, the biggest cost is abstraction of data.

And the general thoracic folks have tried very hard to do everything they can to minimize those costs. So, for example, they have restricted the number of procedures that they're now collecting data on. They tried to hone down the number of data elements, which we're also doing in all the other data bases as well. We reduced the data elements in the Adult Cardiac Database, this upgrade by about 35%.

So, we're very sensitive to that. (STEs) are clearly biggest cost. And we're also exploring the potential for automated or facilitated abstraction of some data elements directly from EHRs, but despite vendors - multiple vendors saying they can do that, we have yet to see one that can do it with accu - the kind of accuracy that we demand.

I'm hopeful that, this will come, but that's obviously a kind of - that's our goal is to automate as much of this as possible. I hope that helps.

Lee Fleisher: Yes, it's in there. Thank you, David. Good answer.

Mark Antman: And, this is Mark Antman. With respect to the question about direct cost for participation. This is in the Measure Documentation. We indicated that the participation pee - excuse me, the participation fee for the General Thoracic Surgery Database is on a per surgeon basis. For each surgeon joining that is an STS Member, the fee is $550.00. For each surgeon joining that is not an STS Member, the fee is $700.00.

So, as Dr. (Shahean) and Dr. Jacobs said previously, I think, that participation fee is minimal.

(Barbie Vitca): Right, but this is (Barbara). I mean, I think what we're getting at here is that in high volume center with adequate volume of cases, I mean what we may be seeing here is that the better facilities with higher volume are participating and the ones that are lower volume or who have a general surgeon occasionally doing a Thoracotomy or Lobectomy are not investing in participation, because for them these are costs that are beyond what their volume would support.

So, there's a lot of - because I have a lot of concern about causality here. There's association, but I don't know about causation.

Mark Antman: Yes, that is why I brought it up too.

Lee Fleisher: Great. Other comments or questions?

(Karen): Yes, this is (Karen) again. I'm sorry to interrupt you. It probably would be a good idea just to remind folks that because the Systematic Review's weren't - and grading wasn't supplied for this Measure, you'll be looking at Boxes 7, 8, and 9 on the Evidence Algorithm as you think about Evidence. So, I just wanted to point that out and kind of locate you where we are or where we would be on the Evidence Algorithm.

Lee Fleisher: Thank you, (Karen). So, Scientific Acceptability?

Elisabeth Erekson: I think that means we're moving onto Reliability Testing.

Lee Fleisher: Yes.

Elisabeth Erekson: And I think this is where I'm trying to, as a Committee, remember how we considered these Measures. So, the question is how do you prove that somebody is a participant in the dataset and where do you come up with numerators and denominators for this? And, at least on the Worksheet, am I reading correctly that there's not a grading for the Reliability from NQF? Is that correct?

Jeff Jacobs: Reliability is left on the Worksheet.

(Melissa): Hi, this is (Melissa) from NQF. That's correct because there's (unintelligible) for this one that you had if you need a criterion for Traditional Measures that we're used to for a Structure Measure. But I think (Karen) has talked a little bit more about what we would expect to see.

Lee Fleisher: That was difficult to hear. So, (Karen), are we going to hear from you?

(Karen): Yes. Yes. What (Melissa) was saying - (Melissa) your microphone got a little fuzzy there, so it was kind of hard to hear you. These are Structure Measures and we don't see a lot of Structure Measures these days. And when we do, you know, the first thing you do is just scratch your head and say, oh my gosh, how do - you know, what is the (unintelligible) you know, what do you do to show Reliability or Validity of a Structure Measure when, a lot of times, and especially the two Participation Measures for each hospital, the answer is yes or no. They do or they do not participate, right?

So, that's you know, what kind of test do you usually, you know, would you expect to see? So, it's not the usual things, right? So, basically for Reliability, you know, I think most people would agree with me and just say that, you know, if I'm to understand the specifications, you know, what's being asked for, for this measure - you know, participation or not?

If you understand the specifications, then that's what you're really voting on in terms of the Reliability. What we're really interested in for the two Participation Measures, has the - you know, we're expecting probably more along the lines of data element validity. And, I'm sorry, I didn't catch your name, but you had it exactly right.

Basically, what we want to know, is, you know, how do you know for sure that the participants actually participated? Right. So, that's what we want to know. You say, you know, hospital gets a yes for participation. So, there're kind of two parts to that. One is, kind of understanding what STS means by participation. And then, two, how have they - or have they demonstrated that we have - or they have in their Registry all of the data that they're expecting.

So, for Measure 0734, which is the one I believe we're on, I hope we're on. Or - it's the same really for 0456, so I think that's the one we're on. They talk

about - and Mark and (David), Jeff, just please correct me if I don't quote this right - but you say in the testing (unintelligible) that participants have met 100% of cases (semi-annually).

So, we were taking that at NQF as that's what you mean by participation in the Registry. So, that would be our first question for you. And then the second question is, how do you know that the people who are participating are giving you all their cases? They're not just giving you, you know, some of them or something like that?

And I know you have…

((Crosstalk))

Jeff Jacobs: I think they have.

(Karen): Yes, I was just going to say, I know you talk about the audit process that you have. And I think (Weesa) had some questions based on what was submitted. And I think verbally you could probably add to that and explain to people (where) that audit process.

Jeff Jacobs: Yes, thank you. That was a very nice, kind of summary of the state of affairs. Participation means that the hospital submits their data and STS requires submission of all - of 100% of the operations eligible for each of the databases that a site participates in. We verify this with our audit process and we sent documentation to NQF describing the audit process.

But part of the audit process includes a comparison of all the cases submitted to STS to all of the cases that are in the hospital's operative log. So, during the audit, the log of all operations done at a hospital is reviewed and compared

to what's submitted. And from that information, we've been able to document that, at our sites that are audited, pretty close to 100% of the cases that are eligible for submission are actually submitted.

Lee Fleisher: Thank you. Other questions?

(Karen): Again, this is (Karen) here. So, this is one of these places where they had told you verbally what they found with their audit. Mark, you're going to be doing your (unintelligible) like a (101 Pager). And I know you sent, right before the call, you sent a little bit out of your (TeleGen) Report. I don't know if, I didn't have a chance to look at that really closely, but if there's anything from that, that would just reiterate what Jeff just said verbally, I think that would probably be helpful for the Committee.

Mark Antman: Yes, we can certainly share that. That is - that won the portion of the results of the audit report of the - that portion of the final report, that is. This was specific to the Congenital Heart Database. We also have that for the General Thoracic and, as Dr. Jacobs just said, the one that we sent to you this morning - and I know it was just a short while before the call - that does demonstrate that in this instance, over 98% of the cases that they said were completed were - the submission was 98% complete.

We can provide the same information for the General Thoracic Database and we can certainly provide excerpts from those audit reports and as someone suggested earlier, a cheat sheet summarizing that information as well, if that's helpful.

(Karen): Yes, I would love to see that and have that documented in your submission material. So, that, to me, that would be exactly what we would be looking for

to understand, you know, that completeness or coverage, or whatever you want to call it, yes. That's what I would be expecting.

Mark Antman: Yes, we can certainly provide you…

Jeff Jacobs: We'll provide that. And, in fact, the material sent today was from a Congenital Audit of 2015 that shows a 98% completion. In fact, since that time, the completeness is a better term to use - the completeness of operations submitted over operations eligible for submission is now a lot closer to 100% then 98%. It's 99 point something percent.

So, the worst-case scenario is what you have in your hands. And, in fact, the data since that time is even better and we'll be able to share that with you.

Elisabeth Erekson: I would also - this is Lis Erekson, I would also ask for one more thing. Maybe I'm being greedy at this point, but the final question is, how many hospitals were participating in the program and then withdraw from the program and what is the time lag to then registering them as not being a part of the program anymore.

And it sounds like you guys have that data as well.

Jeff Jacobs: We can get that data. It's pretty rare.

Elisabeth Erekson: Yes.

Jeff Jacobs: It's pretty rare, but we can get that data.

Lee Fleisher: This is a robust discussion and I'm just wondering offline, if we can figure out how to make sure that some of the things that we're now asking for is clear for

the submission what should be included if this is going forward. And I'm not talking about STS, I'm talking in a more general perspective. Because it's clear you're providing additional data (unintelligible) (for us).

Preliminary Ratings for Validity, Lis?

Elisabeth Erekson: So, the Preliminary Rating for Validity was judged as Insufficient. When we start looking at Validity, it starts to look, just remind myself, and orient myself, the Validity looks at the data elements, but there really is only one data element in this Measure, participation or not. At least the way I'm seeing it.

Lee Fleisher: (Karen) - (Karen) can you help us?

(Karen): Yes, she's exactly right. So, when you're thinking about Validity, you're kind of thinking about two separate things. One is, what we would call testing for Validity. You could do that by showing data element testing or score level testing.

What we have been discussing up until now, is what it directly considers data element testing that one data element of participation or not. So, it sounds like you're going to be able to share is completeness results to share that 98 to 100% for the various Registries.

So, that would be your testing that we would be looking for. I think the other thing to think about here is potential threats to Validity and the - these may be somewhat moot, I think, for - and we can just walk through them real quickly. For Structure Measures that are, you know, so simple, it really is one data element.

We think about exclusions. So, are there exclusions that, you know, need to be in the Measure? For Outcome Measures, is there Risk Adjustment? Well this is a Structure Measure, so we don't need to talk about Risk Adjustment.

Is there, let's see, clinically - I'm not saying the right - clinically meaningful and (physically) significant differences in providers. And this is another one where the answer is, either yes or no. So, that one kind of goes - we don't have to worry about that.

There's not multiple data sources or specifications. So, we don't worry about that potential threat. And then, finally, we have this idea of missing data. And, again, that one, for this Measure, is probably a moot point. You're looking at the logs and the answer for this one is either yes or no. So, you know, there are no missing data.

So, for the most part, except for exclusions and, forgive me, I've forgotten, I don't - there are no exclusions I would think for this measure, right. It's a simple Structure Measure. So, in this case, we really don't have threats to Validity unless the Committee Members can think of other things that we don't have to just systematically think about, you know, all of these things, not just (listed).

Lee Fleisher: So, the - if you were to rate it again, would you still rate it as Insufficient?

(Karen): I would not rate it as Insufficient once I would see the numbers that - I think it was Jeff who mentioned the 98%. So, basically what I - when we look at these kinds of things, we are basically looking at the methodology that's used in testing and then the results.

So, the methodology, if I understand correctly, is to audit some proportion of hospitals. I don't think you said all of them, but some proportion are getting audited. And you look at the surgery logs and you compare what's in those logs to what gets submitted to the STS Registry.

So, I would say that that is an adequate methodology that sounds reasonable to me. And results of 98 to 100% also sounds reasonable to me. It sounds really great as a matter of fact. Because it is, what we would call data element testing, it would not be eligible for a high rating for Validity. It would only be eligible for a Moderate.

But as long as the Committee is satisfied with the methodology, you know, again, including how many facilities are audited, you know, is that a reasonable number of facilities and a reasonable number of - well it's obviously a reasonable number of surgeries, because they're looking at the logs.

All right, so if that seems reasonable and you're happy with that 98 to 100% match or completeness, then they - the vote that we would expect you to cast would be Moderate for Validity. Does that make sense, Lee?

Lee Fleisher: Perfect. Any questions or additional comments? Okay. So, we are on to the next. And I'm just pulling up, getting my paperwork.

Elisabeth Erekson: So, Feasibility next?

Lee Fleisher: Yes.

Elisabeth Erekson: And I think we've actually had a fairly robust discussion surrounding the Feasibility, which is the cost for participation in the database is not high. It

looks like they're saying, if the surgeons an STS Member it's $550.00. If they're not an STS Member, it's $700.00. But the discussion we've had is that you have to employ a data abstractor at your site to make sure that they're abstracting all of the data elements that the dataset needs.

And we've also had a discussion around trying to get this data out of an EMR and all of the complications around that.

Lee Fleisher: Great. Any ques - comments from the rest of the Committee? Okay. Then we're onto Use.

Elisabeth Erekson: So, this Measure is currently in Use. Now, I don't believe - and if the Developers can correct me if I'm wrong - I went and looked at the Public Reporting and participation in the dataset isn't necessarily Publicly Reported, except your hospital is listed on the Registry on the STS Public Reporting Web site? Is that correct?

Jeff Jacobs: So, what happens is not all hospitals that participate publicly report. So, the first decision is, does the hospital participate or not participate? And for the thoracic database that we're discussing now, the majority of hospitals in the country do not actually participate yet, that's why there's a GAP.

So, we have data that shows that we can estimate now that the penetration of the General Thoracic Database in the United States based on Lobectomies from Medicare, like I was talking before, is about 25%.

So, Step One of this discussion is that 25% of the hospitals in the United States that perform Lobectomies participate in the General Thoracic Database. Then Step Two, is what percentage of those hospitals publicly report? And for the General Thoracic database, 27.2% of the hospitals that participate in

the General Thoracic Database publicly report? The hospitals that will show up on the Web site are those that are publicly reporting. Because they volunteered to share their outcome data on the STS Web site.

Does that answer your question?

Elisabeth Erekson: Yes, thank you.

Jeff Jacobs: Excellent.

Lee Fleisher: Great. And then Usability?

Elisabeth Erekson: So, this is talking about if there's been any improvement over time. I think STS has demonstrated that there has been more uptake of the Use of this dataset over time other than (penetrants) are still low. And, you know, maybe we'll look into the literature of what they're - what will be provided us in terms of how the Outcomes by people who participate in the dataset are different than National averages.

Jeff Jacobs: Right. And this ties into before where (Dave) pointed out that on the current public reporting Web site there's documented data showing the difference in outcomes after lobectomy. The most common operation in the database for hospitals participating in the STS database versus the aggregate outcome of lobectomy of all hospitals in the country from the Nationwide Inpatient Sample.

We obviously can't do an analysis of participants versus non-participants, because we don't have the data of nonparticipants, but we can prepare participants to the aggregate in the country.

And there's data that we put on our Web site that shows a substantial difference.

Lee Fleisher: Okay. Any other questions?

(Barbara Whitaker): So, this is (Barbara). I just have a comment after all of this discussion about a Structure Measure and that is more of a philosophical question for this one and the next one, as well. And that is, have we at NQF gotten to a place where having this kind of a structure measure is really still of any value? I mean, what the public cares about, what we're trying to drive is improvement in outcome.

And we need to have measures that talk about how our patient's do, not necessarily about whether we participate in a database or not. And so, I really, when we think about how many Measures there are out there, and what their purpose is, I'm not sure that I'm really seeing this as of major value to the public. Or to us as clinicians as we try to improve.

Mark Antman: You know, this is Mark and I would second exactly what you're saying. It's not the fact that people shouldn't participate in databases and perhaps participation in certain databases, is requirements for Centers of Excellence by societies or things like that.

But to make it a Measure, you know, it makes the laundry list of Measures, as you said, just way too long. And it just doesn't apply to STS. I mean, it applies to everything else, that is just a structural Measure like that. I mean we certainly have to evolve past it in saying that these are measures that we're endorsing and saying have to do with health outcomes, because they really don't.

They might affect health outcomes, but they're not measures of health outcomes. And that's what we should be endorsing.

(Barbara Whitaker): And we have better things. I mean it's you know, in the early days, maybe we didn't.

Mark Antman: I mean, in the early days, we wanted to know did you have an (intent) for this and do you have an EHR? I think we're well past that now. And it's not to diminish the fact that people should participate in these, but you know, then, you know, maybe you needed to get your gold star from Joint Commission or something else.

But that doesn't mean it's a Measure per se, that indicates Quality.

A.J. Yates: Yes. This is Yates. And, in my comments earlier, to quote Shakespeare, I was here to praise STS, not to bury them. I would disagree. And I'm going to just take you a little bit out of this world and into my world. And what I can tell you is, is that being encouraged either by National Mandate or by being thrown - being given a chair and a stick and to participating in a Registry, does affect patient outcomes.

And it's going - it's more apparent in my world where Registries that have included prosthetics has made a huge difference. And, for instance, the initial concerns over failures of metal-on-metal hip replacements only came to the public, only became public and became a major healthcare issue based on slight variations in revision rates in both the British Registry and the Australian Registry.

The New Zealand Registry, which is run by surgeons and all the surgeons are encouraged to participate in, in New Zealand, has changed the way that I

actually perform prep and drape and how I put on my gloves based on Registry data that only can exist in a Registry not in an Administrative database, because surgeons thought about things to ask about.

Now, those are hard prosthetic outcomes, which is different then some of the things that you capture in a Thoracic or Cardiac Registry. But I think that it's very clear that the Cardiac Registry has caused a normalization of behavior. A normalization of outcomes. People have, in looking at themselves have found the best pathways to improve.

I don't know that (NISQIP) has had the same effect as STS. But these Registries are very fragile and they do cost money and, in an age, where people blow off belonging to even the state society for 200 bucks a month. They're going to blow off belonging to a Registry that might cost a thousand or two thousand or three thousand dollars, because they just don't see the value in it.

And giving them a reason to see value in it, is a tide that causes all ships to rise. And I don't think we're past the point of having robust enough Registries to make this same point that STS has made over the last two decades with their Cardiac Registry. And I'm all for providing some sort of a stick. If this is nothing more than something that's used as a mix measure by participants so they can say they actually participated as a Structural Measure and they can use this as one of their six MIPS in MACRA.

Bless their hearts if that gets them to participate. That's more data. That's more data to parse. That's more information. And it directs people to the right answers, not the wrong ones. So, I'm going to get off my soapbox, but I think that there's - these are fragile things and I think that it has to be - there's a GAP here obviously. And I think that they - I think we need to generate

those other papers, have them sent around. And, I'm not going to repeat this lecture again when we get to the cardiac Measure, but I'm that's my two cents.

Jeff Jacobs: This is Jeff Jacobs. I'd just like to add one other piece to that. And that is that (un-endorsing) this Measure could potentially have unintended consequences as well. It's not unusual that a surgeon is meeting with a Middle Manager in a hospital negotiating to get money to support participation in a Registry. And during those negotiations, it's not unusual for the surgeon to say, well this is an important registry to participate in.

In fact, it's endorsed by the National Quality Forum. And I think that is a fairly valuable statement when meeting with the Middle Manager in a hospital to obtain the resources to participate in a Registry. And I think it would be a shame to see that level of support removed.

Mark Antman: You know, this is Mark. Maybe, you know, maybe it's the way we look at it. My concern is, and I'm just saying it from my viewpoint, you know, as Chief Quality Officer. I and my staff, everybody is inundated with ten thousand measures. And that's not to say, but I believe firmly is Registries, don't get me wrong. I think they do serve a purpose if nothing else, besides the fact that we learn things, it forces people to actually look at their data because they're bothering to put it in.

So, I don't disagree with it. And now, I'll turn it back to the NQF people. Perhaps we need endorsement, but with like a different - no, I don't want to say different level - but to separate it from the ones that truly are outcomes. So, because I always worry about people using Structural Measures rather than Outcome Measures like Managed Care Companies and others, just because it's easier for them.

And that really, kind of begs the question of, you know, really where we should be going today. So, maybe it's a matter of how we classify them rather then they're endorsed or not endorsed. But having a different category, so to speak. Now, I know, we may not be able to do that now, but it's just a thought.

Lee Fleisher: Okay. Any thoughts? Well.

Amy Moyer: Hi, this is Amy Moyer. I just wanted to weigh in as a Purchaser. This is a Measure I would see myself using. I very much believe in Registries. And we have other - Purchasers have other means at their disposal of getting people to participate in registries.

For instance, we set their expectations that in our (state), we expect if you do joint replacements, you're part of the AAOS Registry and our - Wisconsin went from almost no participation to full participation at the state. And we didn't need an NQF Endorsed Measure to do that. I wouldn't ever ask someone, give me the results of, you know, NQF 0456, as a way to get a Registry in place as a Purchaser.

I want more information than that. And part of it, you know, would be just until we got the measure results - great, you have the Registry. What are you doing with it? show me where you're using it in your Quality Improvement Meetings. Show me where you're meeting with the Surgeons.

Other aspects of it like that, for a Registry, (we can), yes, we have it in place and we're meeting.

A.J. Yates: Yes, this is Yates again. And I'm sorry. I'm going to speak one more time. But again, if - to get something to be an applicable MIPS Measure, so which

has economic impact and can - you know, and those six spots have to be filled - having, giving the fact that they've spent, maybe the surgeon himself has spent the money to be in the Registry and participates fully and is audited and they're captured, that's a lot of work to get one MIPS Measure.

But you can't use if as a MIPS Measure, if it's not NQF endorsed. You know, they're not going to allow you to count it towards MACRA. And so, this becomes, and even if it's paid for by the hospital, or measured at the hospital level, that's a selective benefit that is not to be denied at a Financial Level and (unintelligible) incentivization for this.

So, I don't think it's as simple as, you know, local purchasers and stuff, you know, asking for people to participate. I think that there's a fundamental National purpose for having it NQF Endorsed.

Lee Fleisher: So, I think we've heard - does anybody feel they have not expressed their opinion in general about whether or not this structural measure should continue with Endorsement? Does STS, (David), Jeff, or Mark, want to make a last comment from their perspective? Does NQF Staff want to make any last comments? (Elisa) or (Karen)?

Elisa Munthali: No, but I agree with you that this is a very rich discussion and we thank you because I think it does speak to the value of NQF Endorsement. And our brand with endorsing measures.

Lee Fleisher: So, I think that it really will come down to the vote and it'll be very important that we ensure that others listen to the tape. Do you want to go onto the other Database and see if there're any uses not discussed with that Database? Because we still have 23 minutes and I don't think we need to repeat some of

the same discussions, except for different information, if that's okay with the rest of the Committee?

A.J. Yates: Okay with me.

Elisa Munthali: Good with me.

Lee Fleisher: Great.

Man: Good with me.

Lee Fleisher: I mean, it's an incredibly robust discussion. So, the next one, therefore, we'll have one final Measure to do next week. So, we hopefully can get done in an hour, is 0734. Participation in the National Database for Pediatric and Congenital Heart Surgery. And what I would suggest is - and (Barbara) do you want to lead the discussion?

(Barbara Whitaker): Sure. So, I think the only place where this is substantively different from the last one is in the GAP. So, in 2013 there were 108 of 125 hospitals participating. And in 2019, there's 117 of 125 in the U.S. So, the question is, is that enough of a GAP to justify a Structure Measure?

Lee Fleisher: So, I apologize to STS. I didn't give them a chance to discuss it. And this is currently endorsed and has been endorsed. Why don't I let Jeff, or Mark, or (David) give their own review and address (Barbara's) question. Did we lose STS?

Mark Antman: No, we're still here. Jeff, this is Mark. Do you want to introduce this one since this is Participation in the Congenital Database? So, we may have lost Dr. Jacobs. So, again, this is Mark Antman. Just very quickly, this is 0734, is

Participation in the National Database for Pediatric and Congenital Heart Surgery.

It is a Structure Measure like the one that was just discussed. But again, this pertains to our Congenital Database. This was endorsed - re-endorsed most recently in 2014. And, if I may, I will echo what Dr. Fleisher said, just obviously from the STS Staff Protective, encouraging the Committee to, hopefully discuss this quickly on the chance that perhaps you can get to the one remaining Structure Measure today, so that perhaps the call next week might not be necessary. But beyond that, I'll defer to all of you.

Jeff Jacobs: Okay, Mark, this is Jeff. I (guess) (unintelligible).

Lee Fleisher: Jeff, do you have any comments? The only comment from the Committee and from (Barbara), was the GAP.

Jeff Jacobs: This is on the Congenital Database Participation Measure now?

Lee Fleisher: Yes.

Jeff Jacobs: Yes, sorry. I think I would say what I said the last time. And I noticed this (unintelligible) of heart surgeons (unintelligible) program. When we asked to participate in data bases, we meet with the Middle Manager in the hospital that can approve the budget (unintelligible). And NQF Endorsement of that Measure is an extremely helpful tool when we request the budgetary funds to participate in the database.

And it is a fact that the Congenital Database Participation is now over 90% in the Country, but it's not 100%. And I think it sends a very bad message to say

that all of a sudden, the endorsement of the Congenital Heart Surgery Database has been removed and it's now been de-endorsed by NQF.

I think that's not the message that NQF would want to (send).

Lee Fleisher: I'd like to just get a read from, Elisa, particularly. Because we have these endorsed Measures. People are beginning to ask whether there's evidence they could choose not to endorse it. Or what's the current thought on Reserve Status? Because we did do that for the other database.

Because the issue of GAP is really important here.

(Janaki): Hi, this is (Janaki). Elisa just stepped out of the room. But (Karen) or (Melissa), do you guys want to comment on that.

(Melissa): This is (Melissa). So, there is actually criteria that measures (need-to-need) in order to qualify for Reserve Status. You have to meet the Evidence Criteria. Obviously there has to be GAP. And then for testing, they have to have done Measures for testing for both Reliability and Validity.

So, for these, if you were to (accept the testing on the) (unintelligible) is data element, I believe. Because of the audits that they do in the database. So, technically, they would not be - they would not qualify based on the current criteria that we have right now for Reserve Status.

(Karen): And this is (Karen). (Melissa) is correct about that. So, the idea there is the only one that could sit on Reserve Status (on either the Measures) that have been (unintelligible) and various ways and tested in various ways.

So, that testing criteria is the holdup on this one. We've also been talking internally about Reserve Status and, you know, is it something that even NQF wants to keep. And I think, for now, where we're tending to be is, we are going to keep things on Reserve Status that we had not, in the past, been very good about, kind of taking Measures off Reserve Status and kind of blowing off the dust and relooking at them again.

We've been kind of a little bit lax about that. And we will, for Measures that are on Reserve Status, we are going to systematically go through and bring them back through and look at them again. So, they're not just going to sit on the Reserve Status shelf, you know, continually. That's kind of what we're thinking more strategically about Reserve Status.

Jeff Jacobs: This is Jeff Jacobs again. I would just come back to what I had said before about the message that one would send by not endorsing participation in one of these databases. And I think it would be an especially dangerous message if the decisions are that we took our STS Adult Cardiac Surgery Database, moved it to Reserve Status, but then a few years later we decided to de-endorse or remove endorsement from the Congenital Heart Surgery Database.

I think that's a really dangerous message that just wouldn't play out well in a lot of forms.

(Karen): Jeff, this is (Karen) from NQF. Can you just remind me, I missed it when you said it? What is the penetration rate of this Registry?

Jeff Jacobs: Ninety percent.

(Karen): Ninety percent, okay.

Jeff Jacobs: Right. And that's - when the Adult Cardiac Database reached the penetration of 90%, that was when the decision was made to move it to Reserve Status. And it's interesting because over the - this is the third time that we've discussed this Measure at NQF over the last decade or so and the initial discussions were, is the penetration high enough for us to endorse this as a database that's really a National Database?

And it was felt to be not good to endorse something with low penetration. And now it's the opposite discussion where low penetration is good because it's a GAP and high penetration is bad because it's "topped out".

Either way, I think, you know, it might be reasonable to say that since the penetration is over 90%, we can move this to Reserve Status, similar to what we did with the Adult Cardiac Database. But again, I think it sends a very bad message that we're just going to de-endorse the database.

Because that message would be spread maybe without all the science behind the rationale for doing it.

Lee Fleisher: Thank you for discussing your concerns. It's appreciated. And then the Committee and NQF will continue this discussion. It's helpful. Other comments from the Committee? Do you want, from STS perspective, do you want to try to start 0732?

Jeff Jacobs: Yes.

Lee Fleisher: Okay. Do you want to give some background for two to three minutes?

Jeff Jacobs: Yes, this is very similar to what we discussed earlier in the call. This is just the Structure Measure of Tracking the Number of Operations Done Within a

Program that are Classified into Stat Category 1, 2, 3, 4, or 5. Or the small number of operations that are non-classifiable.

And this is a Structure Measure that can support the Outcome Measure of reporting operative mortality stratified by the Stat Categories and that subsequently, then reports are Risk Adjusted Mortality Measure which is reported stratified by the Stat Categories.

So, to summarize, this is basically a Structure Measure that supports the two Outcome Measures that we discussed earlier in the call.

Lee Fleisher: So, this is very similar to our discussion at the last meeting. The Spring Meeting, the, I guess, the Spring Meeting where a component - is this Publicly Reported?

Jeff Jacobs: Yes, this is Publicly Reported so that if one goes to the Public Reporting Web site, one can see the volume of operations done in each of the five Stat Categories. And I think, I know the reason that, that makes this Measure particularly important, is that the Measure that we discussed earlier was reporting Operative Mortality Stratified by the Stat Categories.

And that's the Outcome Measure that was endorsed and from that we can learn that the Program might have a mortality rate of 1% in Category 1, and 20% in Category 5. And then would be performing at exactly the average.

But what one wouldn't know, if one was at a hospital that had a 20% mortality rate in Category 5, which is the National average, is that a hospital that has only done five of those operations in the past year with one death? Or is it a hospital that has done 50 of those operations with 10 deaths?

And when we put this Measure together, we felt that it was important to publicly report the number of operations done in each Category and not just the percentage mortality. So, that if a family is trying to chose the hospitals to receive health care, if they were only able to access 20% mortality in Stat Category 5, they would not know the difference between a hospital that's done five of those operations in the last year or has done 50 in the last year.

So, therefore, providing volume stratified by Stat Category, we felt provides very important information to families and referring doctors.

Lee Fleisher: Thank you. Before I get to Lead Discussants, (Tamaya), given the discussion over this and the previous two Measures, as our patient perspective, are there any comments? I don't know if you're still on. We may have lost her.

Is this Mark, again? Or is, who else is on who's been with the Lead Discussant? Mark, are you able to…?

Mark Antman: I mean, I don't think there's anything different then we've said before. I mean, you know, I think, you know, the breakdown into Categories I think is worthwhile. I think it really - the volume is important and you needed to be able to develop the Outcome.

So, I think it does give information. It does give information from the public because when people know the volumes of the local issues. So, I think all the other evidence, everything else is just the same comments that we've heard before.

Lee Fleisher: Other comments from the Committee?

Man 4: And the question is, is there an opportunity to fuse these two Measures together to harmonize them?

Lee Fleisher: Jeff?

Jeff Jacobs: Yes, well, so, the last time this was discussed at NQF, it was felt that they should be kept as separate Measures because of the fact that not all operations are classifiable within the Stat Categories and one Measure gives a percentage mortality in Stat Category 1, 2, 3, 4, or 5. While the other Measure gives the number of cases done in 1, 2, 3, 4, 5 and not classifiable.

And there was a lot of discussion at the last NQF Meeting where this Measure was previously endorsed about should they be combined into one Measure or not. And the recommendation from NQF was not to do so, because they provide separate pieces of information and primarily that was because there's a subset of operations that don't fall into any of the Stat Categories.

Mark Antman: This is Mark Antman at STS. If I may just add to what Dr. Jacobs just said, it's maybe worth pointing out with respect to this Measure being independent or not, in 2011, in re-endorsing this Measure and 0733, the Operative Mortality Outcome Measure, NQF did pair those two Measures as Measure 1815. It hasn't been addressed since then as a paired Measure 1815.

But according to the database of NQF Endorsed Measures, 0732 is officially paired with 0733.

Lee Fleisher: Any comment (Karen) or (Melissa)?

(Karen): This is (Karen). I think I have two questions about this Measure and how they might be different than the two previous Measures. One is, is it - what

Evidence was provided to what I would expect, I guess, is to know that volume is associated with Quality. So, I guess one of my questions would be, was that shown? Or was something different shown? I'm not as familiar. And I apologize I'm not as familiar with what was shown for the Evidence with the Volume Measure.

And when it comes to the data element Validity Testing, you know, the Participation Measures are just, you know, did you participate or not? This Measure is the volume along with a Stat Categories. I think I'm using the right word. So, maybe, I'm assuming the volume also comes from the surgical logs. Maybe just some discussion or a little bit more information about how you know those Categories that are being used for the Measure are actually submitted accurately. Because that would be the other piece.

Jeff Jacobs: Sure, that's easy. So, the operation is assigned to a given Stat Category based upon the primary procedure of the Operation. In our audit process, we audit the Primary Procedure of the Operation and we know that the accuracy of that field from our audit process is over 95%.

The given hospital submits for every operation, what the primary procedure of the Operation was. We know that that's 95% or greater, accurate. And then the data warehouse, and up until this point, it's been a Two Clinical Research Institute assigned to the given operation of (steps for a Stat) Category based on the coded primary procedures. So, we have an algorithm where every single primary procedure has a score and a category that was derived from (unintelligible) analysis that created the Stat Mortalities for.

And that's automatically assigned to the data warehouse. So, if the primary procedure is correct, then the staff mortality category is correct. And our audit tells us that the primary procedure is almost always correct.

Lee Fleisher: Other questions?

(Dave S): If I may, this is (Dave). I'll just make a couple more comments about the particular value - I think the increasing value and importance of volume, particularly for fields like, Congenital Heart Surgery - I think those of you who are involved in health policy know that there is increasing discussion regarding Regionalization, volume thresholds for complex procedures.

So, I think you're going to see this become more and more important as we, as insurers for example, try to decide where to send patients. I think a lot of it is going to be volume drive. We also know, that for infrequently performed procedures, although we prefer outcomes in general, for infrequently performed procedures, it's very hard to reliably estimate performance in a typical one, or two, or three-year period.

And volume in that case becomes an important surrogate for quality, probably better than they're trying to measure Risk Adjusted Mortality. And finally, the relative distribution of high and low risk cases between institutions, is a factor that may do some quirky things to the statistics of Risk Adjusted Outcomes.

You've read about Simpsons Paradox for example. But the relative proportion of high and low risk cases, can impact how you compare two programs doing procedures and can make programs with similar results in high and low risk categories look as if, overall, they have quite different results. And it's purely driven by differences in volume.

So, for many reasons, I think, volume is an important metric and I kind of hate to see this one go.

Jeff Jacobs: Right and that's great (Dave) and I would add that we sent several articles to NQF that have been published in the Peer Review literature specific for Pediatric Hearth Surgery, that document the very important relationship between programmatic volume and outcome. And that document that this relationship is even more significant and more important with the higher complexity cases.

(Karen): And this is (Karen). Do you - were those articles that you sent - were those summarized in the Submission Materials that you provided for this Measure?

Jeff Jacobs: Just to the extent of what I just said that these references document an important relationship between programmatic volume and outcome, which is especially important with high complexity cases. That's a one sentence summary of about eight references.

(Karen): Okay. I think this is probably another one where Mark may need more like a one-and-a-half pager or something like that. If we could just get a little bit more of a summary of those articles. Because I think that's the crux of the evidence question and probably why we didn't - we marked it as insufficient. And we do want to know a little bit more about the (cities) themselves. So.

Mark Antman: We can certainly provide that (Karen).

(Karen): Thank you. I think that would be helpful. Hopefully the committee would agree?

Lee Fleisher: Yes, that would be great. So, any last comments from anyone on the Committee? And any chance our Patient Representative rejoined us? So, I want to thank everyone. Does this - (Melissa) does this mean - or (Janaki) do we need the next call?

(Janaki): Let me ask (K.J.). (Karen) are you satisfied with the conversation today and what was presented around Evidence and Testing for these Measures? Or does there need to be additional discussion after the materials are provided to us from STS?

(Karen): I think, I think (unintelligible) fine in terms of the evidence and the testing that was done. If they can, kind of write that up and basically, you know, support to some extent the statements that they made, I think that is probably what the Committee would need to make their decisions.

There was also, on one of the Measures, and I apologize, there was a question about Accountability. And that might be moot. Was there anything else you wanted to talk about that or we may have covered that by knowing - I guess I don't - this one is, the volume measure is publicly reported? Right? That one, we know the volume, we were told that?

Jeff Jacobs: Correct.

(Karen): I think we're okay. I'm sorry, I'm going over my notes now of things that I know we talked about that were a little confusing to us (as Staff).

Lee Fleisher: So, what I would suggest actually, is why don't we read the meeting on the books. We will reach out and see if anyone wants to have a brief call on Monday. Maybe 30 minutes max, to discuss any of the other issues. Is that fair? Because we have to go out for Public Comment too. Correct?

(Melissa): Correct. I agree. I agree. Because it's (unintelligible) provide additional ratings based on the information that STS is going to give us, so we're going to leave that up to the Committee. And we have to do everything in a

transparent manner. So, I think it would be best. So, I think, right now, because we are at the top of the hour, we do have to go to Public and Member Comment.

If there is anybody on the phone who would like to make a comment? And I know that staff is monitoring the chat box if there's any comments in the chat. Okay. So, in case anybody is (unintelligible) to provide a public comment. I just want to check with Mark from STS on how quickly you can turn this around, this additional information that we can share with the Committee?

We are required to have a vote within 48-hours. We will have to check with Leadership around contractually what we have to do, what we can do around that.

Mark Antman: So, this is Mark. I was going to ask if you could provide us with a little bit more leeway, in that you're asking for some significant write ups related to the various articles that we've provided. If you can provide us with a little bit more time, that would be much appreciated.

So, can you get back to me and let me know if you - if it's essential that that vote occur within 24 - oh excuse me, 48-hours or if you can extend that period slightly?

Lee Fleisher: I would propose, if it's possible, that the vote, that we have the brief meeting on Monday and the vote occur within 48-hours of that meeting, waiting for this additional information. If that would, if I could ask Staff to just, to check if that's acceptable?

(Melissa): (Karen), what do you think? If the Committee defers the vote until Monday?

(Karen): I think that's reasonable. That gives Mark a little bit more time - this is - what is today? This is Wednesday. Yes, Mark, we'll get with you, what we'd really like, if at all possible, is you know, to have the maximum amount of time for the Committee Members to look at this additional information and be able to think about it a little bit. So, we'll get with you a little bit offline and try to figure out what that is.

And we'll try to maximize the time that the Committee would have to look at your - your updates.

Lee Fleisher: I think that would be very wise and, you know, given what we may or may not be able to review by then, if we happen to have a quorum on Monday, we can use the voting poll tool and we can move on being informed rather than being open-ended like we are now. So, what I would suggest is we just have a 2 to 3 o'clock call, so that, would that be acceptable to Staff?

(Melissa): Yes, if that works for the Committee that…

Woman 2: That would be fine. Yes, we already have it on the books. So, we will forward (unintelligible) new information from STS and then we will gather again on Monday.

Lee Fleisher: Great. But I think people can (unintelligible) the second hour which will be helpful and that way have a maximum of one hour. Thank you all.

((Crosstalk))

END