THE NATIONAL QUALITY FORUM

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PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR

PEDIATRIC CARDIAC SURGERY

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THURSDAY
OCTOBER 22, 2009

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The Pediatric Cardiac Surgery Steering Committee met in Congressional A in the Hyatt Regency Washington Hotel, 400 New Jersey Avenue, N.W., Washington, D.C., at 8:00 a.m., Howard Jeffries and Lisa Kohr, Co-Chairs, presiding.

STEERING COMMITTEE MEMBERS PRESENT:

HOWARD JEFFRIES, MD, MPH, MBA, Co-Chair

LISA M. KOHR, MS, MPH, RN, CPNP, Co-Chair
SCHONAY BARNETT-JONES, MBA
PATRICIA A. GALVIN, RN, BSN, CNOR
NANCY GHANAYEM, MD
DARRYL GRAY, MD, ScD
ALLEN J. HINKLE, MD
MARK HOYER, MD

SYLVIA LOPEZ, MD
CONSTANTINE MAVROUDIS, MD
JOHN E. MAYER, MD
LISA NUGENT, MFA

NQF STAFF PRESENT:

SARAH FANTA
TINA GRANNIS
LISA HINES

ASHLIE WILBON

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8:07 a.m.

CO-CHAIR KOHR: If everybody could take their seats, we are going to go ahead and get started. So we're going to go ahead and proceed and finish up with the outcome measures first. I will hand it over to Howard.

CO-CHAIR JEFFRIES: Thanks. So we had finished 18, 21 and 12 so let's start today with 13, mediastinitis after pediatric and congenital heart surgery. The primary reviewer for that is Sylvia Lopez.

DR. LOPEZ: Good morning. Mr. Chairman and members of the Steering Committee, Workgroup B met yesterday to discuss outcome measures and one of those was 013, mediastinitis after pediatric and congenital heart surgery.

It aims to measure the rate of mediastinitis requiring re-exploration after pediatric and congenital open heart surgery.

The numerator includes patients who undergo pediatric and congenital heart surgery, meet the diagnosis of mediastinitis as defined by one of the following four criteria:

No. 1, the patient has organisms cultured for mediastinal tissue or fluid that is obtained during a surgical operation or by needle aspiration.

No. 2, the patient has evidence of mediastinitis by histopathologic examination or visual evidence of mediastinitis seen during a surgical operation.

No. 3, the patient has at least one of the following signs or symptoms with no other recognized cause, fever, chest pain, sternal instability and at least one of the following, peritoneal mediastinal drainage, organisms cultured for mediastinal blood, drainage, or tissue or a widening of the cardiomediastinal silhouette.

No. 4, patients less than or equal to a year of age who has at least one of the

following signs or symptoms with no other recognized cause, fever, hypothermia, apnea, bradycardia, or sternal instability and at least one of the following, peritoneal mediastinal drainage, organisms cultured for mediastinal blood, drainage, or tissue, and a widening of the cardiomediastinal silhouette.

Infections of the sternum should be classified as mediastinitis. Sternal instability that is not associated with a wound infection or mediastinitis is not mediastinitis.

The time window begins from the time of admission to the operating room and ends 30 days post-op or until the time of discharge, whichever is longer. The denominator is the number of patients who undergo pediatric and congenital heart surgery.

Exclusions are any operation that is not pediatric and congenital cardiac surgery. Specifications were complete and

clearly stated. There was discussion about perhaps developing risk assessment for patients with tracheostomies and gastrostomy tubes but the workgroup felt that it met the four different components needed for recommendation. The subcommittee voted in the affirmative and brings it to the Steering Committee for discussion and approval

CO-CHAIR JEFFRIES: Thank you. Any comments from either group?

DR. GRAY: I guess it's a global thing. I assume again that we are going to clarify the actual procedures and diagnosis codes, presuming ICD-9 or STS codes for that.

DR. J. JACOBS: I think I'll address this now so we don't have to address it on every metric. As we said yesterday, the scope of operations and, therefore, the scope of patients that all of these metrics apply to are the patients who undergo pediatric and congenital heart surgery.

There's a list of operations in

the STS-EACTS nomenclature which meets those requirements. Those can also be specified through CPT codes or through ICD-9 codes.

We have submitted them thus far through CPT codes because that is what we were asked to do but we can also supply that list with ICD-9 codes or with basic terminology of STS-EACTS nomenclature really in any form that NQF would like us to supply it in.

The bottom line is it's operations that meet the definition of pediatric and congenital heart surgery and we published several manuscripts that describe what operations are included in that universe. That would just apply to every metric so we don't have to discuss it over and over.

DR. GRAY: Right. I'm just wondering, though, so we are going to clarify? For example, this is presumably going to include as we have discussed like procedures on the heart and great vessels but only in the thoracic great vessels because there are

various things we have looked at that sometimes do include thoracic vascular procedures and sometimes don't.

DR. J. JACOBS: It's exactly what we published in the manuscripts referenced in the proposal was pediatric and congenital heart surgery so that includes surgery on the aortic arch, that includes coarctation surgery as part of pediatric and congenital cardiothoracic surgery. Does that answer your question?

DR. GRAY: Yes. Thanks.

CO-CHAIR JEFFRIES: One thing that we discussed was the variation among providers. It was not presented in the data that Dr. Jacobs put together but said that from his review of the database that there is a wide variation in the incidence of mediastinitis across centers. Any comments? Any thoughts? Okay.

It seems that this meets the elements of the requirements so with that

we'll put this to a vote. Sign of hands on who votes to recommend this for a time-limited endorsement. There are 12 yes votes and zero no votes.

Okay. With that we'll move onto the next measure which is measure 14. It's stroke/cerebrovascular accident after pediatric and congenital heart surgery and I'm the primary reviewer of this. The measure is the rate of new onset stroke/cerebrovascular accident after pediatric and congenital heart surgery.

The numerator is the number of patients who undergo pediatric and congenital heart surgery and develop post-operative stroke or cerebrovascular accident as defined by the following definition, the root definition of stroke is any confirmed neurological deficit of abrupt onset caused by a disturbance in blood flow to the brain when the neurological deficit does not resolve within 24 hours.

The temporal elements incorporated in the definition allow for distinction between stroke and a transient ischemic attack wherein there is a temporal loss of neurologic function resulting from a temporary alteration in the cerebral blood flow but without resulting in permanent brain injury and with symptoms that resolve within 24 hours.

A reversible ischemic neurological deficit is a subtype of stroke where the loss of neurologic function and symptoms resolve within 72 hours. The time window is one year and four years.

The denominator is the number of patients who undergo pediatric and congenital heart surgery as we have previously discussed. The measure exclusions are patients who do not undergo this type of surgical operation.

There is no stratification or risk adjustment specified.

On our review of this measure we agree that this was an important topic and,

again, similar to the mediastinitis that there need to be risk adjustment models developed over time to see if there is anything which stands out and we'll need risk adjustment in the future.

I think the majority of our discussion centered around when we first talked about seizures was a seizure a part of this. When we went through the definition an isolated seizure is not so patients who have a seizure post-operative they would not fall under this category. You need to have a neurologic deficit. An imaging infarct without systemic sequelae would not meet this definition as well.

The other aspect of our discussion, which I want to bring up here, is the discussion around timing. This measure talks about it occurring within 24 hours with a comment that a reversible ischemic neurologic deficit resolves within 72. When we looked at the adult measure for stroke

after cardiac surgery, that is specific to CABG operation, they had a 72-hour window.

Again, a lot of the discussion revolved around the fact that some of our patients who are probably at risk for this you're not going to know within 24 hours or 48 hours if they've had an event because they are heavily sedated.

They may be muscle relaxed. They may be cooled as we are waiting for the brain to recover. Again, I think, the 24-hour window versus 72-hour window is probably somewhat negligible if we are looking at the long-term outcome of the patient. Thoughts around that?

DR. GHANAYEM: As I read this, I guess, it's not within 24 hours of surgery but within 24 hours of finding the deficit.

CO-CHAIR JEFFRIES: Correct. Well, it's actually 24 hours after the disturbance in blood flow to the brain which may have been during the surgical procedure or

may have been later.

DR. J. JACOBS: I think you don't know when the disturbance to the blood flow to the brain actually occurred in many of these situations. The stroke definition is that symptoms -- a TIA is that the symptoms resolve within 24 hours of their occurrence. A stroke is if the symptoms persist after 24 hours of their occurrence.

Then there is a reversible ischemic neurological deficit is a subtype of a stroke where the symptoms resolve within 72 hours of their occurrence but the definition really can't be made on the time that the alteration in blood flow to the brain happens because there is no way to know exactly when that happened.

What you do know is when you found the symptom, when you found the symptoms or the findings. These definitions are based on resolving or not resolving within 24 or 72 hours of when the symptoms were identified.

DR. GHANAYEM: Actually, I think, that makes far more sense because it could happen in post-op day three.

CO-CHAIR JEFFRIES: Right.

DR. GHANAYEM: So, I think, that is how it was intended to read.

CO-CHAIR JEFFRIES: Is that not clear in how you think it's worded?

DR. GHANAYEM: I understood it as it was intended to read but maybe because I've seen it before.

CO-CHAIR JEFFRIES: Okay. So any thoughts about this?

DR. HOYER: Who makes the diagnosis, I guess? Who is involved with making those diagnoses? Is it anyone that could do that or just surgeons, neurologists? Just didn't know where that's going to come out.

CO-CHAIR JEFFRIES: I think the intent was anybody.

Dr. Jacobs?

DR. J. JACOBS: I don't think we specify that anymore and we don't specify who makes the diagnosis of a ventricular septal defect or tetralogy of fallot.

DR. MAVROUDIS: You did say, however, that it was an informed person or some language like that that indicated that this was a physician, etc.

DR. J. JACOBS: What the definition says is a stroke is any confirmed neurologic deficit caused by a disturbance of blood flow to the brain when a neurologic deficit does not resolve within 24 hours.

CO-CHAIR JEFFRIES: So the language was confirmed.

DR. J. JACOBS: Right.

CO-CHAIR JEFFRIES: The indication is that was made by some physician with some understanding of the process.

DR. J. JACOBS: The key word there is confirmed and this is not a definition that was written just for today. This is a

definition that has been harmonized across multiple medical societies, both neurologic societies and cardiac societies.

It's the definition of stroke used by the American College of Cardiology, the definition of stroke used in the STS adult cardiac database, and it's the definition that we've adopted in the pediatric database as well. As Gus said, the key word is confirmed.

In the chapter of this big blue book that is written about this, there is an extensive discussion about the strengths and weaknesses of this definition, why this was the consensus definition that was derived.

The chapter starts on page 234 and it's written by a team of cardiologists and cardiac surgeons with the third author being Dan Licht who is a pediatric neurologist at the Children's Hospital in Philadelphia that specializes in taking care of pediatric cardiac patients so there is substantial involvement not only of the cardiac surgeon

and the cardiologist but also the neurologist and the crafting of this terminology.

CO-CHAIR JEFFRIES: Any other discussion? Okay. So why don't we move this measure to a vote. So for a vote for recommendation can I see a show of hands, please? So 12 yes votes. Any no votes? No. Okay.

So we'll move onto the next measure, measure 15, post-operative renal failure requiring dialysis at hospital discharge. The reviewer for that is Dr. Lopez.

DR. LOPEZ: Measure 15 is post-operative renal failure requiring dialysis at hospital discharge. It will measure the rate of pediatric and congenital heart surgery patients who require dialysis whether peritoneal hemodialysis or hemofiltration after heart surgery.

This complication is to be reported if it is required at the time of

discharge or death in the hospital. Acute renal failure is defined as new onset oliguria which sustains urine output less than 0.5 ccs per kilo per hour for 24 hours and/or a rise of the creatinine of greater than 1.5 times the upper limits of normal for age or twice the most recent pre-procedural values if they are available with eventual need for dialysis or hemofiltration.

In order to be counted as a complication operative or procedural it must occur prior to hospital discharge or after hospital discharge but within 30 days of the procedure. The complication is coded even if the patient requires dialysis but the patient or the family refuse treatment.

Time window is from admission to the OR to 30 days post-op or until discharge, whichever is longer. The denominator is pediatric and congenital heart surgery. Case exclusions, any surgery that is not pediatric or congenital cardiac or a patient who

required dialysis prior to surgery.

Subcommittee recommended that we perhaps look at patients who have required mechanical circulatory support with attention to the incidence of acute renal failure in those patients.

Subcommittee reviewed the materials and felt that all the four components required for recommendation to the committee were met and we bring those to you this morning.

CO-CHAIR JEFFRIES: Any discussion?

DR. GRAY: Actually a good example of it is that in terms of exclusions that, for example, patients that don't have congenital heart surgery are not actually exclusions. They are just not included in the first place.

That is actually not an exclusion but in this case, for example, patients that did have pre-operative renal failure, that actually is an exclusion so just to clarify

the way in which we would actually use this is because the idea is that you've got people that are already in the class that you're interested in the first place, namely, people that have cardiac surgery.

But then from them you are actually excluding a subset on the basis of a reason such as this where they've actually had pre-operative renal failure so I just wanted to clarify that.

CO-CHAIR JEFFRIES: So I would be interested in having a discussion around the importance of this measure. The reason I bring it up is when we look through the definitions of importance, one of them being a demonstrated high-impact aspect of health care, affects large numbers, leading cause of morbidity and mortality, high resource use, grave illness, and patients or societal consequences of poor quality.

Clearly kids who have renal failure and need dialysis are very sick and

have lots of resource use. My concern, and this is what I wanted to bring up, I think, the numbers associated with this are quite small. I think it's hard for me to remember many children who go home with dialysis after heart surgery. They tend to die. Their death is already accounted for in the mortality measures which have already been accepted here. I would just like to hear a discussion around that.

DR. HINKLE: I would agree with that. I mean, this is one of the measures looking at it from a public reporting perspective we would see 0, 0, .1, 0, .15. I think that is a good point to bring up and let the rest of the committee discuss that whether this would be a measure that -- it's very critical when it happens.

Obviously it's a critical issue. I'm not saying that but when you look at it from a reporting standpoint, certainly from a quality improvement when these rare things

occur has high value to be noted.

CO-CHAIR JEFFRIES: Dr. Mavroudis.

DR. MAVROUDIS: From a personal experience I don't know how to do this except to tell you what it was. There were about two or three patients on whom I operated who got into the fifth time redo, that kind of thing where we had to go on bypass using sucker bypass, long pump runs and so on.

Of course, the red cells were beat up and that kind of thing. We also found out that during this time the pump runs there was something wrong with the pump runs. The white cells were being beat up and these patients got acute renal failure and some of them required dialysis.

Now, it's true what you're saying. There's no question that this is a very rare thing but sometimes it happens and it happens for a particular reason and it's a blip and this is something that if it happens, let's say, 10 years you're looking at a program.

One or two of the last two years that they had this problem and you picked it up, then you'd say, "There's room for improvement here. Your cardiopulmonary bypass machine is beating up the cells," so on and so forth. I bring that out not as a contentious issue but just as an issue that from time to time arises and we make processes to fix it. I just bring that up for a thought and discussion perhaps.

DR. HINKLE: I guess my criticism is the way it's measured perhaps, not the importance of it. It reminds me of oil spills. When you have rare events you could measure the time from the last renal failure so you would measure it differently so that it would be still -- what you are describing is very important that things can happen is what you're describing and you want to catch those particularly if there's a pattern. It might be that this needs a different measurement or way to be measured.

DR. MAVROUDIS: Precisely. I agree with you 100 percent. I don't know if it needs another measurement or that has to be changed but even as rare as it is, I like your analogy, this was in the hospital and if it's in the hospital, that's a problem and we ought to get by it.

I don't share the same concerns that both of you do. I'm concerned that two of you bring this up, and maybe others as well, and then maybe we need to rethink it but it's such a glaring complication. It's such an enduring complication that to have sets of indices without it seems like we're missing something.

CO-CHAIR JEFFRIES: Jeff.

DR. J. JACOBS: The only thing I would add to the discussion is that it's important to remember that these metrics are not just for neonatal and infant heart surgery. It's probably true that few of us can remember many neonates or infants that

left the hospital alive on dialysis but this does happen to teenagers.

It does happen in adults with congenital heart disease and the scope of these metrics is that universe as well. Patients like that can go home alive on peritoneal dialysis and on hemodialysis and that, I think, is a very important complication which is very resource intensive and really changes the entire life of the patient and cost a lot of money to the healthcare system. I think even though it's rare it's important to track, especially in teenagers and adults with congenital heart disease.

DR. M. JACOBS: I think your analogy was very interesting and very attractive. I do want to say having listened to the discussion of the preceding measures that when we talk about mediastinitis, stroke, and renal failure requiring renal replacement therapy talking about complications that occur

with a frequency somewhere in the range of 1 to 4 percent.

Not an eyelash was batted at a series durable life-altering complication that occurs when the 3 or 4 percent incidence seem to be questioning the relevance or significance of reporting one that may occur with a 1 percent incidence. I raise this not as a challenge but as a question of the intent of measures.

I'm not sure if those are ordinarily very different from one another from a quantitative standpoint. Certainly all are associated with tremendous resource utilization after tremendous impact on quality of life, etc.

DR. MAYER: I do think that from a standpoint of a quality metric that one would follow, I think, it's actually important to follow this independently of mortality even though they are coincident in many cases.

For some of the same reasons that

Gus enumerated, I think, it's actually pretty important as a quality indicator to know what the incidence of renal failure is even if the patients expire because there are lots of ways that patients cannot survive but if renal failure is a common component of all of them, then -- sorry.

If renal failure is not necessarily a component of all the reasons that people will die, then the two variables will segregate to some extent. I think that is actually important to track separate from a quality perspective.

I don't know that from a public reporting perspective it's going to have any value but, I think, as a quality indicator and a way to judge how one's own program is doing and where there is room for improvement, I think, it does have value.

DR. GHANAYEM: I actually agree. I agree with Marshall that the incidence of all these things is quite low.

You're right, Howard, that we generally not calmly send patients home on dialysis. In fact, I can't remember the last time we did but there is an injury that has occurred and it is a loss of GFR for the future and adds additional morbidity even though it's not to the point where they need to be in renal replacement therapy so there was injury, a sustainable injury. Maybe not extreme but, I think, it's worth tracking.

CO-CHAIR JEFFRIES: Yes.

MS. HINES: Just one thing to remember and, I think, Allen brought this out. These are for public reporting and all of these are very important for quality improvement and if we say no on a measure, it doesn't mean that it certainly can't be used for quality improvement.

If Ns are going to show up as unreportable across facilities because these conditions are so rare, then that is something that needs to be looked at because it is

ultimate that we are looking at public reporting that can be used broadly.

In a case such as this because, I'll tell you, a lot of people will say, "You didn't endorse that measure. Therefore, it's not important care." We are always very careful to say this is very important and this is a big concern. However, the numbers just aren't there to support a public reporting so I just throw that out.

DR. HINKLE: I would just like to clarify and make sure my point was clear that it was purely from the public reporting perspective. From my perspective, I think, the public does understand the difference between 1 and 4 percent mortality. Fortunately, you know, the healthcare system has advanced so significantly in this country they do understand that.

My only point is when it gets down to, like I said, 0, 0, .1, it becomes less interpretable by the public. This is

important and I agree with what John just said from a quality standpoint so I'm not saying don't move this forward.

I'm saying the public reporting value of it may not quite be there. We would see over time whether it's there or not but, I think, it's a critical measure. I want to make sure that was understood.

DR. GRAY: I agree. I guess, for example, if you're talking about this being, again, obviously the idea that hospitals, as we're seeing, track it internally and maybe even STS might want to, I don't know, send out a statement indicating that you think society thinks it's important and while it was not endorsed as a measure that you were encouraging people to track it.

Especially, as you're saying, it may often be a complication of cases with long pump runs or if there was a problem with the cardiopulmonary bypass and that it becomes especially remarkable in older age groups that

certainly the way to report it here it would basically not be stratified by on versus off-pump cases and wouldn't be stratified by age such that if you've got like three cases the denominator is going to be the entire denominator of all of the surgical cases that you are listing.

If you want to then do a subgroup analysis where you look among cases with pump runs or among cases that the kids are older then basically be able to maybe better identify them. If it's just reported this way just with this sort of all common denominator, you really are going to get very low numbers.

I agree that it's important from a quality improvement standpoint but from a public reporting standpoint it's not going to be that helpful and hospitals are potentially better off doing internal analyses to look at the subgroups where this is likely to be a problem.

DR. M. JACOBS: Howard, I want to

request your permission to share a piece of information. This is not an argument but it's a piece of information relevant to the question of public reporting and of small numbers. Just an observation.

The most frequently reported value in terms of medical outcome in the United States by many orders of magnitude is mortality after coronary artery bypass grafting. The public is intensely wed to making the distinction between 1.3 percent mortality and 1.8 percent mortality.

I think to make a judgment of what's important in terms of public reporting because of size of numbers is really only one way of looking at that. I think public reporting of a quality measure can be of considerable significance even when the numbers are very small.

MS. NUGENT: I would like to add something to the conversation. We don't really -- or maybe you do, I don't know. We

don't really know how the public will use these numbers that become available. I would guess that there will be search engines, there will be algorithms available that can make these numbers more usable for the public.

We are looking at them on a one-by-one basis but is that really how they are going to be used? I don't know. I think it's important to make this information or these measures available and allow the public to make sense of them. In an aggregate form maybe these small numbers will be the very thing that tips the cases as far as understanding quality of care.

DR. MAYER: Just to respond to that, I can tell you that the approach that has been taken in the adult cardiac surgery database effort has been actually to develop composite measures so that incorporate a whole series of variables including various kinds of mortality for various procedures as well as some structure and process measures and so

that gives you a composite evaluation which, I think, is what you are getting at. One might imagine that something comparable to that will be able to be developed on the congenital heart surgery side as well.

The way I have described this phenomenon and, as you might expect, the distribution looks just like a bell-shaped curve in the adult cardiac world. I view our job as the profession is to make the curve as narrow as possible so that the difference between the low end and the high end is pretty trivial, No. 1.

No. 2, we need, and we are now actively starting to do this on the adult cardiac side, is to examine what's going right in this end and try to help the people and institutions that are at this end of the bell-shaped curve. I think that I view as our professional responsibility.

To be honest with you, I'll share a little personal philosophy here. I think

this whole notion about public reporting would go away if we were able to demonstrate to the public that, in fact, we were taking care of business in that sort of way, that we were narrowing the variation among all the various institutions that are providing a given type of service and that people could feel pretty comfortable whether they went in the hospital in Omaha or in Tampa to have an equivalent sort of outcome.

That's, I think, ultimately the goal of all of this. My own personal view would be I would hope this whole pressure for public reporting and everything would sort of go away because there are a lot of pitfalls in this.

I think we've seen this, particularly in the adult cardiac world where there are pretty well-done studies that show that the public reporting creates risk aversion and that people just won't take on the tough cases. Certainly that was pretty

well demonstrated in New York State.

Yet, those are the people for whom the potential of no therapy or no surgery, in this case, versus the potential gain if the surgery were successful, that is where the delta is the biggest. There is a real tough dynamic here that, I think, we are all struggling with around this issue of public reporting.

There is data in Pennsylvania that they report the results publicly and it doesn't make any difference. In the referral patterns it doesn't make any difference where the patients choose to go. I understand where this whole trust is coming from but ultimately I would hope that the American public would figure out that we are actually trustworthy and we're doing the right thing, we the profession.

CO-CHAIR JEFFRIES: Lisa.

DR. LOPEZ: If I could just make a quick comment. At least in Oklahoma we have

noticed that patients are becoming empowered. There is a lot of internet searching.

Patients are actually coming to us and demanding that they be referred to a center with good mortality, morbidity statistics. They are demanding the best care that they can receive. So actually we are considering some of those requests.

If our numbers in Oklahoma don't support good outcomes, we are certainly considering a patient going to San Francisco, for example, just recently for neurosurgery. We just recently had a pediatric patient who has requested that they go to Johns Hopkins for treatment so we are considering those requests.

MS. HINES: Lisa brought up a good point with more or less leading to the composite work and John talked about it. We have measure No. 20 which basically is a composite of all of these what we are calling small occurrence measures. We didn't get to

discuss that in our group yesterday.

Certainly that would add an N. Just don't forget that's coming up, too. I would assume that those are for quality improvement purposes broken down by the individual measures within them.

DR. MAYER: I mean, every one of these things that is on here is tracked in the STS database so we are collecting the information. Part of the process is the information is collected and fed back. I think from our perspective that is what drives improvement as much as anything else.

There is no more powerful motivator than seeing how you or your institution compares to your peers around the country. That is the whole basis for which the databases were constructed which they have been shown to actually yield the results that we are hoping.

You look in the adult world the expected mortality is doing this and the

observed mortality is doing that. I think one cannot underestimate the power of this process of data collection and central risk adjustment feedback in that observation which is what's happening in the population.

I think we will track all of these complications. I mean, that is already built in. I think the question for this group, though, is not whether or not we are going to track all these different complications, whether the surgeons and the various congenital heart surgery centers are going to be aware of what is going on in their own institution.

I think the only question here is to we -- I mean, you could ask the same question about all of these individual variables whether it's neurologic deficit or mediastinitis or whatever. You know, you could potentially roll them all up into this one which is measure 20.

The problem with that, of course,

is that I don't think it gives you -- it obviously doesn't give you as much granularity. Then this whole what is the purpose of these measures, well, they have two purposes.

One is for quality improvement and one is for public sort of purposes. I don't think you get as much information when it's less granular to the extent that these are used for quality improvement. That's all.

MS. HINES: And your point is well taken. I'm just thinking down the road with comments and with CSAC that's one thing they are going to look at is small Ns.

DR. MAYER: Right.

MS. HINES: Just so we have kind of dealt with all of that and are able to respond.

CO-CHAIR KOHR: Schonay, I want to direct this to you. As a parent would you even know to look at this information when you are evaluating a hospital?

MS. BARNETT-JONES: No, I would not have known prior to Olivia being in the hospital but post absolutely because now I know what her transplant team and her cardiac team is looking for at this point. I know they are checking her kidneys and so forth. I think even if the incidence is pretty small that there is an interest from a consumer perspective, from a parent perspective at knowing what the expectation is.

Again, we have the opportunity to set that expectation. If we have the information available, if that helps to build partnerships with our families so that they better understand and that they can better partner with their healthcare providers, I think there is a lot of value-added in that.

CO-CHAIR JEFFRIES: Dr. Jacobs.

DR. J. JACOBS: Thank you. I just wanted to address the concept of public reporting and composite scores a little bit. I think this is pretty important. These

metrics were designed both for public reporting and for quality improvement. When we went through them that's what we thought about.

John is right that we talk within our committee about development of robust composite scores over the course of time very similar to what Dave Shahian has done in the adult cardiac surgery database world. I think that is the direction in which we are heading.

It's also correct that measure 20 is somewhat of a composite score right now and that composite score includes elements of several of these complications which are also listed individually.

Our thought was that a part of public reporting should be complete transparency to the people receiving the report and if we just report absence of the group of complications, it's really a black box composite score where the people looking at it will not then have the ability to figure

out how frequently each of the subcomponent complications occurred.

We thought it was important to have a composite absence of the group of complications but also to make available to the public the incidence of the individual complications whether they are completely common or somewhat rare because then we are really being transparent to the public.

We are not just saying, "Here is a black box of complications," and whether or not they occur or don't but we are also providing the subcomponents of the composite. This was actually put in place with the thought of transparently reporting to the public the components of the composite.

CO-CHAIR JEFFRIES: Yes, Dr. Gray.

DR. GRAY: So, I mean, in terms of this particular -- I guess, we are sort of trying to figure out what we are going to do with this particular measure I would just wonder, again, if the people who actually take

care of these patients are having difficulties remembering numbers of patients that actually had renal failure, from the same point how are we actually going to report this if you are going to be reporting percentages that are really going to be a lot less than 1 percent.

I'm not sure from a public standpoint if you are really going to be able to say the numbers are going to be so small the estimates -- with this being unstable I'm not sure what is actually being served by doing it with this particular measure.

Certainly having it as a specified component in the composite in measure 20 might be a way to do that but I don't know that if we are trying to figure out whether or not to have this as a separate measure whether or not there is anything really served by having this as a separate measure.

DR. MAYER: I guess the other question is, you know, I think we have all made a mental assumption about what the public

is. I wonder if maybe we shouldn't dig into that a little bit because the public might be a patient or a family that wants to know something.

I think there's a lot of other dimensions of what public is. There are a lot of academic careers that are made off of analyses of these kinds of data. Is that part of the public? Is part of the public the insurance companies who might want to figure out how to profile?

You know, I think, it may be worth us just spending a minute or two thinking about that because, I think, we might actually all have different mental models about what the public is. I think maybe that will help us sort of focus on this discussion and subsequent discussions on other measures.

I guess I would actually look to the NQF staff to sort of enlighten us as to what NQF thinks the public is and what public reporting means and how the data actually will

get used.

DR. HINKLE: Can I jump in here and maybe make a comment to try to clarify some of that by using the example of infertility. Infertility is a good example. The consumer who is infertile is the one that is interested in IVF centers and how they perform. In this case it would be parents who have children with congenital heart disease.

You're saying there is other public that may be dabbling and looking in this but the primary interest around this data is the person is going to face that medical procedure whatever they have to have. In the IVF world, because, I think, it's much more advanced probably than anything we are talking here, the reproductive endocrinologists grab this field and they are putting forward their measures.

One of them, for instance, is single embryo transfers which took a while for them to get it as a measure but we all know

since single embryo transfers you avoid multiple gestations and complications in the mother and the body so it's a good example.

The members in my plan want us to then build centers of excellence around, you know, if the metrics are there and the reproductive endocrinologists say, this is how we want to be measured and this is where the world should go, then we get pressure in my business to tell the members about high-quality centers.

Centers of excellence start to form and then what you're doing is you are getting more resources going to those centers that are performing the best which, I think, in the end makes them even better. There's lot of public interest probably in data.

Some of it is probably not even -- they shouldn't even be looking at it. My point is it seems pretty clear to me what the public is. The public to me is the public section of the public that is interested in

whatever the procedure is. If it can be measured, great.

If it can't be measured, so be it. You can't say much about it. For me it's fairly clear. Nothing should be put forward unless it's meaningful from the public reporting standpoint. I'm not talking about quality improvement. I didn't mean to interrupt NQF's comment on that but I was trying to help them.

DR. M. JACOBS: I was going to try to amplify a point that Dr. Mayer made earlier that may be seen as justifying reporting of individual measures and reporting a composite that includes those individual measures. I think the purposes of those types of reporting are very different.

I think as one of your steering committee members pointed out, there are going to be lots of different levels of interest and focus of interest in different elements of the public. But with regard to these measures the

reporting of a composite can give a rough measure of center performance.

Without the reporting of the individual elements the potential to use the data for quality improvement is completely absent. One doesn't report the individual elements of the composite.

You get a very general sense of performance but you don't have any rational means to focus any quality improvement efforts. I think including individual elements in a composite is not redundant and inefficient in a non-useful way.

MS. HINES: And we keep talking about quality improvement and, I think, that's a give me for these measures. They are quality improvement measures. We're looking at public reporting and certainly public reporting started out as the traditional CMS websites where it was out there.

Insurers, you know, it has been brought to the board's attention that

insurances are posting. STS is going to probably start posting on their websites. The requirement for public reporting is that the data at the end of three years will be on a public website. I think along with that, though, is the ability to report and have Ns big enough so that you don't have Ns not reported because of size so that is a concern.

As to the question of having a roll-up and not being able to get granular information, most of the time when I've seen it websites provide additional information. If you have questions contact the facility. You can get the granular information because the facilities are getting it. I don't --

DR. MAYER: I guess one other perspective here that maybe we should think about is that, you know, if the incidence of a complication is low, that is not non-information. I mean, if somebody is particularly worried about renal failure because maybe their sister died from kidney

disease or whatever, right, then it might be useful to that individual person to know whether or not this is the likely problem after an open heart surgery on their teenage daughter or something.

I think, you know, I mean, you could say, you know, "How many patients in your hospital get run over by elephants?" Well, that's probably not a reportable measure. Renal failure is pretty well established as a complication of having an open heart operation and even some closed heart operations can be complicated by renal failure.

That's what I was getting at with who is the public and what do they want to know. I think we can speculate a lot but , I think, as a general concept the absence for low incidence of something that may be in a related field is not as low in incidence and actually is an important piece of information.

MS. HINES: But I think because we

are making a national endorsement probably every measure that ever comes through NQF is important to someone. We are looking at a broader spectrum. We are looking at a higher population so certainly it is important to the people in that small percentage that it affects and their families.

But, you know, kind of taking that broader, you know, what is the impact on the larger population as a whole so that it makes it not just one more measure but there is also the concern of parsimony and burden on the facilities and intake of information on the general public so that comes into play, too, when you are looking at trying to be parsimonious and putting out maybe a smaller number of measures but with greater meaning and impact.

DR. MAYER: I mean, we could deal with this and assuming this gets published some place, you know, you could have your roll-up measure and then you click on that and

then you can get the detail. You know, that is a simple technological thing even though I know almost nothing about how you would do that but I'm told it's a simple technological thing. Dr. Jacobs knows more about it than I do.

DR. GHANAYEM: I don't think the incidence is as insignificant as what is being portrayed here. To get informed consent with the complications we talk about, infection, bleeding, stroke, renal failure, I think that covers the majority of what we talk about but I think it's significant enough that we mention it with our informed consent on a regular basis. I don't think the incidence is so low that it is insignificant or a quality indicator that we are not going to see.

DR. J. JACOBS: I would agree with Nancy. I just wanted to add a little bit about what I was discussing earlier. I think it's not enough to just include this in the composite. I think the public has the right

to have access to the data about the components of the composite.

For us to say we are just going to show them the composite but not require that the components of that composite are reported, I think, that's hiding information from the public. I also think that it doesn't increase the data entry burden because it has to be collected to create the composite anyway so why not share this information as well.

I think to make the argument, well, the public could go and look at the composite and if they want to know the components of the composite, they can call the individual hospital, the logical extension of that argument is why report anything because the public could just call the hospital anyway.

MS. HINES: Because they wouldn't know to look. I mean, the information does inform them as a first step to go. John, if that roll-up would break down, I mean, that

kind of gives you both in a nutshell.

CO-CHAIR JEFFRIES: Just one last comment.

DR. GRAY: So, as a practical matter, to we have any sense of what sorts of -- I don't know if you guys could provide any sort of number of what sort of incidence rate are you talking about because I don't know if there is some threshold below which, I'm sure there is, for public reporting that you're not actually going to report below some percentage anyway.

If that's the range that we are actually looking at here, then I think it would be good to know that. I mean, if you've got an incidence rate that is below 0.5 percent or something, it's only going to get listed as nonreporting. If we have some sense that is the aggregate range that we're looking at, then I think it would be helpful to know that.

MS. HINES: Darryl, it's been like

20 to 30 percent -- 20 to 30 cases because then you get into confidentiality issues in other reporting systems.

DR. GRAY: So it's 20 to 30 cases per --

MS. HINES: That's just based on --

DR. GRAY: Twenty to 30 cases per what denominator? Per hospital?

MS. HINES: Yes, per hospital or per --

DR. GRAY: That would eliminate all of these then including mortality.

DR. GHANAYEM: Right. I think just from a single center experience, I think complex infant surgery RACHS-4 and 5 when we looked at it, the incidence was around 3 percent. If you go to cardiac transplant patients, it goes up. If you go to the adults who have complex revisions, it's higher than that so it's not in the fractions of a percent.

DR. GRAY: And, in fact, if it's being presented as the number just among all of the pediatric and congenital heart disease cases, then it will be. That was my point before, that if you want to look in subgroups where it's important, then that is one thing but if you are only reporting those cases with the denominator being the entire surgical patient population, then it's going to be listed as a very small percentage.

DR. J. JACOBS: But there is a bigger problem in that if you have to have 20 to 30 cases, that would mean to report mortality let alone anything else. You would have to have a program that has 500 cases a year which is about three programs in the country.

MS. HINES: Well, and for confidentiality I know with Harlan's mortality measures and things the CMS reporting of that I believe is 30 cases because after that you lost all your confidentiality and that is not

an NQF rule. That is just the way it's happening.

DR. J. JACOBS: If that is the rule for these metrics, we would really have to take all the outcome metrics off the table because unless you're a program of 500 cases a year, you're not going to have 20 mortalities on the average.

DR. HINKLE: But it could be cumulative. Nobody is saying one year. Even in some I think you suggest four years so I'm assuming these could be cumulative measures over time. I'm not sure if it's a rolling four years. I don't know how you plan to do it.

DR. MAYER: I think the problem, Darryl, with what you're talking about is, you know, if you try to choose a smaller subgroup as the denominator like what is the incidence of renal failure in a heart transplant, okay, are you going to do that for every procedure? I mean, we talk about data overload for a

given patient or family or something that wants to go look and they've got to sort through three or four different levels just to get down to where they are.

There are a lot of things that we are trying to balance here and I think that is ultimately what we are trying to do is to get to something that sort of feels reasonable. I mean, I'm not sure that we can quantitate it precisely like if it's below .1 percent we don't do it but if it's above 1 percent.

I mean, at some point we are probably going to have to get to what feels reasonable to the group as a collective wisdom, if you will, and what seems like, "How many patients in your hospital get trampled by elephants?" I mean, that's obviously the other extreme so there is some balance here that we are going to have to try to guess at.

I think we all have to recognize that the next layer up in this process could throw all of this out. If that's the case, we

can't do anything about it. We just do the best we can with what we've got.

MS. BARNETT-JONES: I think Nancy made a very good point when she talked about informed consent and those categories at the bottom of that sheet that families sign off on prior to any procedure being done. As a parent, of course I would like to know what is the likelihood of any of these things occurring.

What, again, should my expectation be going into this. I think, you know, that really kind of brings it home in terms of the type of information, how much information. Those things are very important and I think they definitely add a lot of value to what parents and families want to know and want to try to prepare themselves for.

DR. HOYER: I can add something as well. I've been kind of listening and this has been interesting because I agree with everybody who has spoken because I don't know

that we are necessarily on the opposite of the fence but all the points about NQF are important.

I think it's also important to realize that anything that would not be endorsed by NQF is not necessarily an insult I think is the way I feel about it because it's obviously extremely important information for us to know about. I think we all agree with that.

Interesting to listen to Dr. Lopez talk about how they are looking at these measures to some degree and obviously you would not be able to tolerate just a composite score because it just would not give you enough information. You really want to look a little bit more and drill down a little deeper to know that information before you make that kind of a decision.

While it certainly has a very low incidence, I think when we see this on the heels of mediastinitis, stroke, etc., it is an

important thing that we have to measure and report, I think, and that the public should have access. While I was maybe a little bit vacillating to some degree and like I said, I agree with everybody, I think at the end of the discussion I feel pretty confident that this really needs to be enforced.

CO-CHAIR JEFFRIES: Okay. Thank you, Dr. Hoyer.

I think this discussion has been very helpful. I would like to take a straw vote now to see where we are on this measure to see if we can go forward with a vote. Can I get a show of hands as a straw vote who would recommend this measure?

Okay. Let's go through with a formal vote, a vote for recommendation of this measure with time-limited endorsement.

(Off-mic comment.)

CO-CHAIR JEFFRIES: Correct. So after the time-limited endorsement we'll see what the true incidence of the measure is and

make some decisions at that point. With that it looks like 12 votes said yes and zero no votes.

Thank you. Again, I thought that discussion was very helpful.

Okay. The next measure is measure 16. It is arrhythmia necessitating permanent pacemaker insertion. The brief description it's a percentage of pediatric congenital heart surgery patients with new onset arrhythmia that requires post-operative permanent pacemaker insertion.

The numerator is the number of pediatric and congenital patients with any new-onset arrhythmia requiring the insertion of permanent pacemaker after heart surgery. The time window begins on admission to the operating room and ends 30 days post-op or until the time of discharge whichever is longer tracked to one-year and four-year intervals.

The denominator is the number of

pediatric and congenital heart surgery operations. The denominator exclusions are patients who have a pacemaker implanted prior to surgery. There is no risk adjustment or stratification.

The discussion that we had agreed on the importance of this measure with the lifelong potential for morbidity that the necessity for a pacemaker causes. There was some concerns around acceptability. Some discussion, I would say, rather than concerns, some discussion around the indications for pacemaker placement and that sometimes the indications can be a bit variable from time to time.

I think the statement which was made around this measure was that for the most part when we are talking about post-operative arrhythmias the indications are not as controversial and not as different from center to center as they are for other indications for a pacemaker placement. At the end of the

discussion the subgroup recommended to put forward this measure.

So I open it up for discussion on the importance and the scientific acceptability of this measure as well as the other components. Okay. If there is no discussion, then we'll put this up for a vote. Again, I think the importance of this is clear. A show of hands for a recommendation for the time-limited endorsement. Twelve votes yes and zero votes no.

So let's move on to the next measure, measure 17, which is surgical re-exploration. The primary reviewer of this is Dr. Mayer.

DR. MAYER: So this measure is proposed by the Society of Thoracic Surgeons and is an attempt to measure the incidence with which patients require repeat exploration or operation for any of a variety of reasons.

The exclusion is a re-exploration for bleeding and -- I'm sorry. Let me just

skip to the text here. Basically the numerator is the number of patients undergoing pediatric and congenital heart surgery who require post-operative unplanned surgical re-operation excluding re-exploration for bleeding and delayed sternal closure.

The time window begins with the admission to the operating room and either 30 days post-operatively or until the time of discharge whichever is longer. The denominator is the same denominator that we have been talking about.

The exclusions again are the operations that are not otherwise included in the denominator as well as the exclusion about the re-operations for bleeding and delayed sternal closure.

In the discussion that we had in the group we suggested to the proposers of the measure that not only re-operating but catheter-based re-interventions also be included in this numerator since there are now

capabilities in the cath lab to deal with at least certain residual problems that may not have been dealt with in the operating room or were missed or incompletely or inadequately repaired.

For instance, residual pulmonary artery stenosis after repair of certain defects or residual ASD or VSD that might be closed by catheter techniques rather than a re-operation. That suggestion was accepted by the proposers.

I think this is likely to be an important measure of not only the technical performance of the operation but also the system, if you will, in the institution, the system for correctly establishing the diagnosis preoperatively.

We have an old saying, at least in our institution, that exploratory cardiotomy, that is opening the heart and then looking around to see what's wrong, is a bad operation. We do much better when we know

exactly what we have to deal with and can focus the operation in that way.

I think this is actually an important measure from two perspectives, not only the technical performance of the operation but also the ability to arrive at the correct diagnosis prior to the operation.

The subgroup voted to approve this measure as amended and we propose it to the group for consideration.

CO-CHAIR JEFFRIES: Open it up for discussion.

DR. GHANAYEM: I just have potentially one more amendment or question. There are a subset of patients who have delayed sternal closure intentionally because there is expected ventricular dysfunction impact of total body tamponade.

It's not included in here but I wonder if it's not included in here as surgeons would you be more likely knowing this is a measure to leave the chest open? And

then, to that end, does that impact some of the morbidity that you mentioned? So if you are going to get dinged for having to open a chest for tamponade physiology, not exploration, there are no residual lesions, no intervention is needed?

DR. MAYER: I think that is a reasonable question. I think there has been an evolution as I look back over my 25 plus years in our institution of the willingness or threshold, perhaps, for leaving the chest open, I think the threshold is quite a bit different than it was the first time I did it which was about 24 years ago.

We have kept track of this, you know, how many delayed sternal closures we have or how many nonprimary closures of the sternum that we have. We look at it and I don't think it has necessarily changed any one individual's threshold for this for doing that.

Based on a limited experience in a

single institution, I don't think that dynamic would work that way. I think most of the time when you leave the chest open, you know, it's because you're nervous about the patient's hemodynamic status and how big an operation they had and things like that.

I don't think it's entering anyone's mind, at least at this point, and I would hope never would it enter anyone's mind to be worried about getting dinged because your incidence of delayed sternal closer is higher.

DR. GHANAYEM: No, that's good. I actually agree with you. The more experienced surgeons do have a lower threshold in our institution, too.

CO-CHAIR KOHR: I actually have two things. One, I think the title for me is misleading, surgical re-exploration instead of re-op. Then I'm just throwing this out for discussion. In my mind I'm thinking, okay, complications, surgical complication. Your

mitral valve falls apart or whatever.

I'm thinking about residual lesion that was unexpected. What about two incidents? What about the stage repair that ends up staying in the hospital and you end up doing the Glenn because it says it's until the patient gets discharged. What about that? Do you still want to capture that? The kid for whatever reason you just can't get him off the vent or you are just concerned about whatever.

Then also what if you are leaving open intentionally, let's say, an ASD or you puncture the VSD for pop-off and then you realize that the kid is just not tolerating it. You did that as a strategy. I'm just trying to think about incidents where it may not really reflect what you are trying to get at.

DR. MAYER: Well, as I hope I tried to explain, I think this would test two things if we think about it. It would test our ability to make the right diagnosis and

the right diagnostic plan or, I mean, the right therapeutic plan prior to the operation.

If you needed to leave or it was your judgment, collective judgment, that you needed to fenestrate this VSD in this kid with pulmonary atresia and it turned out you would up with a net left to right shunt and you had to go back to the operating room and close the hole or close the hole in the cath lab or something like that.

Then, you know, that is a measure of how well you were able to predict in that situation what was the right therapeutic plan. I think that I'm less concerned about. I think you raise certainly a reasonable point about the hypoblast or something that you couldn't get out of the hospital and they were sufficiently unstable. Maybe they had neck plates or something like that and you do an early Glenn. I don't know. Would we capture that as a re-operation under the criteria that we have? I think we probably would so I think

that is a legitimate concern. I don't think it happens very often. I don't know.

Nancy, you probably have more experience even with that than --

DR. GHANAYEM: I would say really we do 20, 25 Norwoods a year and we leave about 10 percent in the hospital until the second stage operation for a variety of reasons. Sometimes they are social and sometimes they are medical.

I think it's a completely different operation and it wasn't that something was missed. It was planned and somehow maybe the wording can include that it's not an unplanned intervention. It is a planned intervention.

DR. M. JACOBS: I think the first point that was made in this discussion was that catheter intervention if required is of similar importance or magnitude as an operation. That rendered the title misleading so your amendment should be accompanied by a

change in the title.

The way the complications are coded in the STS database are unplanned re-operation during this admission or unplanned catheter intervention during this admission. If the title of the measure that we are proposing were amended to unplanned cardiac intervention during this admission, which would be inclusive of re-operations and catheter interventions, it would exclude planned re-operations. It would include the catheter interventions and it would address the vagary of the title. I think all three points would be satisfied by a title change.

MS. GALVIN: I think just one additional comment. Would this include procedures done at the bedside? I think there are times that we adjust the PA band in the ICU or take off the band in the ICU.

In the old days that patient would have been brought down to the operating room and it would have been considered a re-

operation. I guess my question is where do those patients fit into that definition of re-exploration?

DR. J. JACOBS: That is an excellent question. This metric doesn't specify the location where the procedure is done so an operation is an operation regardless of where it's done as is a transcatheter intervention and that is an excellent point. If one adjust the pulmonary artery band in the ICU, that's an operation and it's counted as an operation in the STS database.

Then there is another field in the STS database which says what the location is so you can keep track of that but an operation is an operation regardless of location and that applies to this metric and all the other ones. Excellent question.

CO-CHAIR JEFFRIES: Any other comments? Okay. So let's put this measure to a vote, a vote for recommendation, time-

limited recommendation for this measure with the amendments of a title change to "re-intervention" which incorporates unplanned re-intervention.

DR. HOYER: Unplanned post-operative re-intervention.

CO-CHAIR JEFFRIES: Is that title okay?

DR. GRAY: So we are going to call it a -- I think somebody had wording before may have been something you said before, Jeff. I think it was actually Marshall.

DR. J. JACOBS: So we can put unplanned post-operative re-intervention and that would capture both unplanned cardiac surgeries and unplanned transcatheter interventions. The word "re-intervention" is appropriate because the first operation is an intervention. The term "intervention" includes the universe of transcatheter procedures and surgeries so we would amend it to say unplanned post-operative re-

intervention.

CO-CHAIR JEFFRIES: And the numerator would be amended as well.

DR. J. JACOBS: Yes.

CO-CHAIR JEFFRIES: Okay. So with those changes let's vote again for acceptance with time-limited endorsement. There are 12 yes votes. Any no votes? Zero no votes. Okay.

So let's move on to measure 19. This measure is operative mortality for six benchmark operations. Dr. Hinkle is the primary reviewer.

DR. HINKLE: Thank you. Yes. Jeff already gave you the title. However, he gave you the title of the measure we just described. This is a number of index cardiac operations for each of six benchmark procedures which are:

(1) VSD repair; (2) tetralogy of fallot repair excluding TOF with pulmonary atrial, TOF with atrial ventricular septal

defect, and TOF with absent pulmonary valve syndrome; (3) atrial ventricular septal defect repair excluding TOF with AVSD; (4) atrial switch operation excluding atrial switch with VSD closure and/or aortic arch repair; (5) primary or completion fontan operation excluding fontan revision or conversion, i.e., redo fontan; and (6) Norwood Stage 1 univentricular operation.

That is the denominator. Obviously the numerator would be deaths with this measure. The strengths of this measure are pretty obvious. Mortality is clearly highly important measure for both public reporting and for quality improvement for both the patient and the physician obviously so this met all of the criteria very strongly of importance.

The discussion in the group was very supportive of it as well, the need for this data. These are the most common, I would say, congenital heart disease lesions.

Clearly that fits an important requirement for at least the patients who are facing and the families that are facing operations for these conditions.

There were really no weaknesses. We talked a little bit about when you get down to the volumes you might have small volumes but I think that was remedied when we talked about this is one in four years so by four years you would be out most likely to fairly good numbers over time.

A new surgeon just starting in his first year may do as many but when you look at it in four years, and this I assume would be like a rolling four years, you have plenty of volume there to not have to exclude reporting because of small volumes for that measure. The workgroup supported this and recommends that the steering committee pass it and move it forward.

CO-CHAIR JEFFRIES: Okay. Let me open it up for discussion. Again, as Dr.

Hinkle stated, the feeling was that while this is an additional mortality measure that this may have a lot of interest for public reporting because, again, a lot of these are defects which people go in for and families may want to just know how the center does on tetralogy repair and it will be right there for them. The same thing with maybe these other procedures listed here.

DR. GHANAYEM: So we are going to get with this with the next group and we discussed the center that was reporting the volume on these lesions. It seems like if you are going to report operative mortality, you have to report volume so I'm not quite sure I understand why there are two separate measures that address these six lesions.

CO-CHAIR JEFFRIES: You mean volume and mortality? Is that what you're --

DR. GHANAYEM: Right. So we are going to come to another measure in the next group that is reporting the surgical volume of

these lesions. You need to have the volume to report the mortality so I don't understand why the separate measures.

DR. J. JACOBS: Right. So when we develop the metric we use as one of our guides the STS adult cardiac surgery metric that had previously been approved. When we modeled ourselves after that, volume was a structure measure and the process of tracking the volume of your cases was a structure measure and then mortality, the denominator which in that volume was an outcome measure.

We similarly used that approach where tracking the volume of the structure measure and then doing the mortality calculations for that volume as an outcome measure. What that also does is it allows that denominator to be used for other calculations.

If you just report a percentage of mortality, you don't know what the denominator is so by reporting a structure measure of

volume and the percentage of mortality as the outcome measure, then you actually would know what the volume is. If you just had the percentage, you don't know what the volume is in and of itself.

MS. HINES: And that is not uncommon for NQF. We have many volume and mortality measures that are actually reported as paired measures so that you have mortality rate and you have the volume to put it in context.

DR. GHANAYEM: As separate measures.

MS. HINES: Yes.

DR. GHANAYEM: That seems far more complex than it needs to be.

MS. HINES: Yes. That's been the perception through time, I think, and especially with reporting out.

DR. MAYER: So the only weakness in this measure is this sort of implicit assumption that a tetralogy is a tetralogy is

a tetralogy or a transposition is a transposition is -- you know. The weakness is obviously that this is relatively, as they say, raw mortality as opposed to risk adjusted.

The state of the science is that we don't have a big enough denominator yet to really be able to risk to adjust this but I think at some point in the future as I think about patients who are sitting in the hospital right now in our unit, you know, we have a transposition you had an arterial switch who happen to be 1.3 kilos at the time of the operation.

This kid sort of walked in the River Styx up to his neck about four times and has somehow managed to survive. Anyway, the point being at some point this probably should be risk adjusted and presumably when we get back here in a couple of years and we revisit this maybe we'll have enough numbers where we could actually propose a revised version of

this measure.

I do think, as Allen correctly said, these are among the more common of the operations and there's probably some, I'm sure, interest in at least some segment of the public in what the outcomes are but I think it's just something that we need to keep in mind is that despite the fact these are relatively common they are not uncommonly associated with other things.

It may well be that in the grand scheme of things those noncardiac diagnoses, the prematurity, the associated gastroesophageal, tracheoesophageal, fistula, whatever, will turn out to be pretty important from the risk adjustment standpoint.

DR. M. JACOBS: But that's obviously an important and true statement in the discussion yesterday of measures 18 and 21 which went through the whole future of risk adjustment and congenital heart surgery. I wanted simply to point out that an element of

this, which John alluded to, is the use of the STS diagnostic codes and their consensus definitions as inclusionary and exclusionary criteria.

For example, several years ago one of the popular family magazines rated cardiac surgical centers based on volume and mortality for tetralogy of fallot without a rigid definition of tetralogy of fallot. A center could include pulmonary atresia or could choose to exclude it.

They could include tetralogy of fallot or choose to exclude it. At least in terms of trying to make it an apples to apples comparison for public reporting, this has the added benefit of having strict inclusionary and exclusionary criteria.

CO-CHAIR JEFFRIES: Any other discussion on this measure? So let's put it to a vote for a time-limited recommendation. Please raise your hands if you agree. Okay. There are 12 votes for yes. Any votes for no?

Zero votes for no.

Okay. We'll move on to the last of the outcome measures. This is measure 20, operative survival free of major complication. We did not discuss this measure in our group so this will be the first time we are discussing this measure and it's Dr. Mayer.

DR. MAYER: This is measure 20 and the title is as described, operative survival free of major complication. The intent is to determine the percentage of pediatric and congenital heart surgery free of all of the following complications that we have actually each dealt with individually. So mediastinitis requiring re-exploration, new onset stroke, cerebral vascular accident, new onset post-operative renal failure requiring dialysis of hospital discharge, new onset arrhythmia necessitating permanent pacemaker insertion, unplanned -- well, let's see.

Let me rephrase that. Unplanned post-operative re-intervention. Thank you.

All right. After pediatric and congenital heart surgery excluding re-exploration for bleeding and delayed sternal closure to be reported stratified by at least one multi-institutional validated complexity stratification tool.

Suitable multi-institution validated complexity stratification tools include the five functional RACHS-1 classifications, (4) Aristotle Basic Complexity Scores, (5) 2008 STS-EACTS mortality levels.

So the numerator is as described. The denominator is the same that we have been discussing for all the different pediatric and congenital heart surgery procedures. The exclusions are as described. I don't know if you want it now, but my own sense is this is a useful composite measure that will go some distance towards what I think ultimately will be a more complete composite measure of outcomes after this kind of surgery.

I think it probably is, although I don't know that we necessarily have data to support it but I think it has face validity that this in the aggregate would provide a reasonable assessment of the quality of the outcomes that are being obtained in a given institution.

I think if we can collect all the individual measures, it is certainly feasible to collect or calculate this measure. One person's opinion would be to approve this as a measure.

CO-CHAIR JEFFRIES: Any discussion on this measure?

MS. HINES: Can I just ask a point of clarification? So 13 through 17, the difference between 20 and individual 13 through 17, 20 is stratified, 13 through 17 at this point have no risk adjustment or stratification.

DR. J. JACOBS: That's the way they are proposed at the moment, yes.

MS. HINES: Okay.

CO-CHAIR JEFFRIES: And one other difference. Correct me if I'm wrong here but you have to survive to be counted in 20. With the other ones if you die you would still be - -

DR. J. JACOBS: Correct. What 20 is looking at is say about 4 percent of the patients don't go home alive. We are taking a look at the remaining 96 percent of them who do go home alive and say how many of these went home alive doing well, defining doing well as absence of this group of complications. It's a broad sweep assessment of morbidity.

MS. BARNETT-JONES: I think it's very important to report on 20. I think this is what we really want to know. I read it and kind of thought this is the hope measure. These are the things that are really important for families who kind of stretch it out there to say without any complications what is the

likelihood of this really turning out extremely well for me. I think this is critical.

DR. GHANAYEM: It absolutely needs to be well stratified so it's well written. This is one that should definitely be voted on the island.

CO-CHAIR JEFFRIES: Dr. Gray.

DR. GRAY: Just looking here to make sure that the exclusion actually does formally exclude people who survive. There are people who died in the hospital. I'm not sure the way this is worded here anyway, unless I'm missing it, that it does actually say that.

CO-CHAIR JEFFRIES: I think in the summary that was on this paper I didn't see it but when I was reading the numerator it said, "Essential condition for inclusion is that a patient must be known to have recovered without a complication."

DR. GRAY: I'm talking about the

denominator does not necessarily exclude patients who died.

CO-CHAIR JEFFRIES: I see. Okay. Thank you.

DR. GRAY: I'm assuming that's what you mean.

DR. J. JACOBS: I think it's an easy fix. If it doesn't say clearly enough that this metric only applies to patients who survive the operative period and go home alive, then we can modify it to say that because that is certainly the intent in the metric.

DR. GRAY: That's what I thought. I just didn't see it and I just wanted to make sure that's in there.

CO-CHAIR JEFFRIES: Thank you.

DR. J. JACOBS: We can fix it. This whole thing was about 1,000 pages of paper and I think we probably missed that so if it's important, then we'll get it in there.

MS. HINES: And just as a matter

of process, probably for this measure I would say do a vote of support because, Jeff, I think we need to put that composite overlay paper and that was our miss, not yours, just so we're covered when we move forward to the CSAC.

DR. J. JACOBS: We certainly will do whatever the NQF suggest as far as the process to get this through the NQF. Our interpretation was that an actual composite score is a score that does mathematical manipulation on multiple metrics. This is just the absence of several morbidities which, I think, this doesn't really qualify as a true composite score. This is just the absence of morbidity.

MS. HINES: Okay. I know we've said composite. If you're thinking it's not and it's just a roll-up, then that's fine. It can be a final vote and we'll just stipulate in our write-up and things but I want to give it fair --

DR. J. JACOBS: I would agree with that. I think all the STS members in here are fairly familiar with the great work Dasha Hehan with composite scores and that's work with biostatisticians and intense mathematical calculations to create a meaningful composite score.

This is just the absence of morbidity and morbidity of a roll-up of these complications so I don't think it's a true composite score. It's just a step towards eventually getting to a composite score.

MS. HINES: That's fine. I just want all the bases covered when it moves forward. We'll put that stipulation and then the vote can be --

DR. J. JACOBS: We're not putting it forward as a composite.

MS. HINES: That's cool. Thanks.

CO-CHAIR JEFFRIES: So let's put this to a vote with the amendment that Jeff will add some language to the denominator

excluding patients who don't survive. With that, let's put a vote for time-limited endorsement. There are 12 yes votes. Any no votes? Zero. With that we have completed the review of the outcome measures.

We're a few minutes early so why don't we take our break a little early and then when we come back we'll start on the process measures. We'll start up at 10:00? Or do we need to open it for public comment now? Wait until 10:00? Okay. We'll come at 10:00 for public comment and then we'll start on process measures after that. Okay. Or we can come back in five minutes and start on process measures. Okay.

(Whereupon, the above-entitled matter went off the record at 9:47 a.m. and resumed at 10:04 a.m.)

CO-CHAIR KOHR: Okay. We will go ahead and get started on the process instruction measures. We are going to go to 02 because Darryl is the primary for 01 and

I'm the primary reviewer.

The title of this measure was multidisciplinary conference to plan pediatric and congenital heart surgery cases. The description is just the occurrence of pre-operative multidisciplinary conference that involves cardiology, cardiac surgery, anesthesia, and critical care.

The numerator is a binary variable so it's whether or not they have the conference. The time window is that it's regularly scheduled and tracked at one-year and four-year intervals. There is no denominator listed and the exclusions are just descriptions of what pediatric and congenital heart surgery are.

The discussion that we had around this variable was that although it's important and we think that institutions should have this and we believe, or we hope that it's happening on a regularly scheduled basis, there was concerns about what this actually

means in terms of information being provided to the public.

The other discussion piece that we had was just clarification about what this actually is because four players are listed and if you work in a smaller institution that does not have a dedicated cardiac surgery team or an ICU that is multidisciplinary, you may not have all those players at the table. This is prone to interpretation in terms of what people believe this involves.

Some other discussion points that we had was the measurability of this variable in terms of where is this being recorded and how is this picked up. There is a comment with regards to the public having this as an expectation and shouldn't this just be part of the process that is happening in terms of what is care for this patient population.

In terms of importance we thought that it was important but we were concerned about the reporting ability. In terms of

scientific acceptability there was really nothing out there. It's low we assume.

Anecdotally we've talked about this but there is nothing out there right now. Usability we put as low and for feasibility we put as moderate. We will open this up now to discussion.

DR. GHANAYEM: Lisa's timing is perfect. So we're on the measure that talks about multidisciplinary conference to plan congenital heart surgery. A lot of the measures -- several, not a lot, of the measures we reviewed in the process and structure group don't have feasible ways to measure them and the definitions are subject to interpretation.

It seems to me that a quality measure, which wouldn't be a measure but a quality process, would be that the expectation is multidisciplinary conferences should occur. There are multidisciplinary rounds so several of these submitted measures are things that

should happen.

We know they are important -- I should say we think they are important to the quality of our care but there is no great way that is feasible to measurement so is there an opportunity for the NQF to endorse processes without having the need for some defined measure if that makes any sense.

DR. MAVROUDIS: May I?

CO-CHAIR KOHR: Yes.

DR. MAVROUDIS: Yes? Okay. I think that most groups, most programs are keeping track of this conference, who attends the conference, what the result of the conference was for surgery, who was there, etc., etc. I think that everyone is doing that.

I also think they are keeping track of it. It's just a question of how you keep track of it. I mean, it would be nice to have one database for this so everyone can use it and then you press a button and then you

get the compliance. I think this is being done already. I think Lisa brought that up.

But what about a program that is not doing it and do we want to know about that? I think the answer to that is probably yes. I think the public wants to know that this is happening or not happening because if it is happening, people are comforted by the idea that this process has included everyone and everyone is aware of the things that are obvious.

I think that while it's clear that it's being done in different places and so on and so forth, it's a pretty good indicator and I think that we'll find that maybe 5 percent of places maybe don't do it or 2 percent don't do it. It's an interesting thing to find out.

CO-CHAIR KOHR: John.

DR. MAYER: There are probably a variety of mechanisms. I mean, we actually have got our multidisciplinary conference approved for continuing medical education so

there is a need on that basis alone for everybody to sign in. We have a sign-in sheet every day or every Tuesday when we come for our pre-operative conference. That's what we do.

I would agree that this type of exercise, if you will, is pretty important and not infrequently when we have our collective wisdom in the room we sometimes change our plan. We change the operation or the tactic, strategy, whatever you want to call it, for this particular patient. I think it's an extremely valuable exercise to go through.

If nothing else, even if you're not changing the plan, the notion that you've actually got everybody on the same page and everyone has a reasonable set of understandings about what it is that can be anticipated in the intra- and post-operative course I think is really very important.

I don't know that we've studied this in some way to demonstrate that in this

particular field that is necessarily associated with better outcomes but I'm willing to say that for me, at least, this one has face validity.

CO-CHAIR KOHR: So one of my concerns is not about the importance of this. It's that even when I'm hearing this discussion and then when Marshall was talking to us about this measure is that we all have a preconceived notion of what this entails and there is no description of that meaning there is nothing that says, "We want at least cardiac surgery and cardiology at the table reviewing past medical history, reviewing any diagnostic studies." There is nothing. It just says, "Do you have this meeting." So we are all talking about this.

In our minds this is what we want this to look like but I would just feel better if there was some criteria, just not as detailed as the timeout that you did but some criteria so that it's comparable meaning

everyone at least has these essential components that we know is going to benefit the patient.

DR. GHANAYEM: I agree. We do the CME conference, too, but I'm still not sure that everyone does that and it would be incentive for them to do it. How do you measure its impact? It doesn't go into the STS database. We don't do it on a per-patient evaluation. Most patients get reviewed at the conference but not the ones that come in on a Monday and have surgery before the next scheduled conference.

DR. MAVROUDIS: It's saying you have a conference. It doesn't say that you need to review everything. I think it indicates you have a conference. The existence of a conference is the indicator, not who has to be there at any one time but the existence of a conference.

DR. GHANAYEM: But it does detail the four players, though. It does say the

existence of a conference but identifies -- But this says the conference has to have those four players there and if you're at a center that --

DR. MAVROUDIS: Maybe we can use language that says that the indicator says that it's the presence of a conference that is attended by -- not has to be attended but attended by the staff which includes but is not limited to or something like that. I mean, you can't have a conference with one person showing up.

Obviously some places have different conference structure. Some people go and some people don't. They should, I supposed, but sometimes they don't with all due respect. I didn't mean anything by it.

I really didn't. But I think if you have the wording a little bit more inclusive to include all the things that I just said, then I think it's a rather important issue. Do you have the conference

or do you not have the conference?
You don't have to absolutely state that every meeting every time that all those four players have to be there. We're wordsmiths. We can do that. I think it's important to say that you do have a conference or you don't have a conference. It's less important who is there and I think we can wordsmith that.

DR. M. JACOBS: May I? I think in the subgroup yesterday there were some important and appropriate concerns expressed by Lisa about the description of the conference, about Nancy, about the ability of a smaller program to involve the disciplines represented.

I think as Gus suggested, my feeling is that is a matter of wordsmithing. Remember this is put forward as a structured measure and the issue is having structure as part of your approach to congenital heart disease or not having the structure.

I gave the example yesterday I

can't speak to the present but 15 years ago when I did adult heart surgery for acquired disease, it was quite common to have a can with a angiogram sent to my office from an outside hospital, meet the patient the night before surgery and the following day do his coronary bypass operation.

Happily in the majority of cases it turned out all right. This measure addresses the fact that we don't think that's an inappropriate approach to the care of children with congenital heart disease. We think an appropriate approach is a programmatic approach which involves a review by the various disciplines involved in car before the operation is selected, finally determined, and performed.

I think that's what John was referring to in saying that the collective wisdom often results in an alteration of the plan and one hopes to the patient's advantage.

We can wordsmith this in a way

that satisfies the spirit of an NQF structure requirement but we advocate this on the basis of it being very different if an institution or program has such a structure, has such a conference from one that does not on a regular basis.

CO-CHAIR KOHR: Is there anymore discussion?

Mark.

DR. LOPEZ: I'll just make one quick comment.

CO-CHAIR KOHR: Oh.

DR. LOPEZ: At our state agency this is a very important part of our quality audits. We really look for this when we review medical records from providers. We don't always get the complete medical record but if it's missing, we'll call and find out and see if perhaps we didn't get the complete medical record and is there something missing. This is just as important as the other aspects of the medical record.

CO-CHAIR KOHR: But just for clarification, this is on the individual patient. It's noted that this has been discussed. Is that right?

DR. LOPEZ: We do audits for providers, just random audits, yes. When we look at the medical record we always request the complete medical record but this is something we always look for.

DR. GHANAYEM: But this is something that doesn't end up in the medical record. We review cases two weeks out. It's in the surgeon's chart. He brings his chart and he writes down his notes but this is something that doesn't end up in the medical record regularly. Again, how do we track that this is happening to suit the NQF measures and the third party requirements?

DR. LOPEZ: No. There are many times when we actually have a note. It may not be a three-page dictated note but there is a note that there was a conference. A lot of

times we will have some kind of reference to a conference.

CO-CHAIR KOHR: I think Mark was first.

Did you have something you wanted to say?

DR. HOYER: I mean, I appreciate hearing that kind of perspective because I guess I would have thought from a public reporting standpoint the importance of this is not as important as outcomes, mortality, morbidity and all the complications that we talked about.

Whether somebody has a conference or not I think we all know and I completely agree and insist on having a conference because I think it improves our patient care. There is no question.

At the end of the day, I think, you know, the person that is accessing that public information, which is usually the patient with problem X, whether a conference

exist or not they could probably infer there might be some improvement with that but what is most important to them is what is going to happen, is it going to be a good outcome or not.

Since we have kind of established that public information is also gleaned by other sources than just the consumer and the patient, I think, therefore, there must be something that is of value there that was beyond what I might have thought to begin with. I'm just kind of playing a little devil's advocate there but I think it's important to know that.

CO-CHAIR KOHR: John.

DR. MAYER: I think, again, maybe I don't understand this very well but this difference, you know, what actually a structure measure is. Whether or not we can track every individual patient who went through a given institution or whatever I'm not sure it's necessarily what this is

intended to address. I think the question is: is this part of your regular work week. Right?

Does your program or department or whatever have this kind of a conference as part of its regularly scheduled activities. I think that in the same way there is another structure measure, I think, further down do we have what I will refer to as an M&M conference.

You know, do we go over the cases and discuss and try to evaluate how we could have done better in a given patient who had a sub-optimal outcome. I think the fact that those exist is an appropriate structure measure, I think.

I mean, this is sort of baked into surgeon's cultures because that is part of all of our training but there are huge areas of medicine where that doesn't occur and so just having that structure would actually in and of itself have some significant opportunities for

improvement I would say.

DR. HINKLE: I would just add that, you know, JCAHO at the state level when they accredit hospitals, a lot of these types of measures are there. Granted there is a process measure but process measures then lead to the ability to have outcome measures afterwards.

The first step, you know, did you get your Hemoglobin A1c. Yes, no. Then what's the value and is it in control or not. I look at this as kind of part of an institutional -- I don't want to use the word accreditation but how you look at the institution to say is it performing well as a team.

I mean, this is one of the pieces that I would say you would check the box. It's like pilots and all other industries where they have these that would seem nonsensical but I would think they are important.

DR. HOYER: We did kind of flesh out some of those ideas and thought about maybe rolling two or three of these things into really a programmatic -- you know, if you have a pediatric cardiac program does it include bing, bing, bing. We did kind of think about those rather than separate them out each one individually.

DR. GHANAYEM: The question I have for Lisa, is there an opportunity to do that with several of these process measures?

DR. MAYER: This is a structure measure.

DR. GHANAYEM: I'm sorry, the structure.

MS. HINES: That can certainly be a recommendation to the developers and we do capture research recommendations or things at the end. So, yes, that is a possibility to make recommendation.

I think just from an historical standpoint some things to consider, or some

things that we'll have to answer, is the measurements forward. We are capturing kind of a global picture here. Should it not be done on an individual child basis?

Let me go through first, and these are some things that I'm kind of trying to put my CSAC hat on to answer questions that we've heard. If this is important globally, why wouldn't you track it individually on a patient? How is it tied to outcomes because that's a question that we routinely get with any process or structure measure. How is this going to affect the outcome?

NQF surely has a lot of efforts going on and are trying to focus on care coordination and patient engagement. Is this purely medical, surgical, or is the patient's family involved as far as the conference putting some more definition around so for those facilities that aren't doing this, you can teach them to the test to say this is what a team should look like. Those are kind of

things that come to mind when I look at this. Not saying they should drive the decision but that we're going to have to answer for all of these measures as we go forward.

CO-CHAIR KOHR: John.

DR. MAYER: Maybe I can just address the individual patient question. I think Nancy alluded to it. You know, short of having a conference every day, which I think most programs couldn't support just for time constraints if nothing else, there are patients who are going to come in off-cycle in such a way and have to go to the operating room right away.

You know, you get obstructed total veins, you know, you wait until the next conference you're going to have a baby not leave the hospital alive. I think there are logistical issues here.

I think one of the things that's important about this type of a conference and, again, having lived in an environment where we

have done this every since I've been there and before I was there, there is a sort of collective institutional wisdom that arises from seeing things over and over.

It is a forum, at least in our institution, for generating new ideas, thinking about problems other than just at a single patient level. I think the notion that one would tie this just to the individual patient level underestimates the value of what this type of conference does.

I think this sort of both generating a common sort of set of understandings among all the participants in the program as well as generating new ideas are very important benefits that I think go well beyond the individual patient level. That's why I think this is actually a pretty important structured measure to have.

I can tell you this is what happens when you get to be a no hair/gray hair is, you know, you get to go around and consult

in places where there have been self-perception within the institution that, "They're not doing so well and can you help us figure out what to do and how to improve?"

I would say that not rarely is the absence of this kind of combined conference been one of the things that you find when you go to a place and find out it's under-performing and you try to identify how to help them get better. This was one of the suggestions about how you would get better as an institution or program.

MS. HINES: And I apologize. I don't have my specs in front of me. Is this stated as once a week or is there a time frame?

MS. GALVIN: That's what I was going to add is that on this measure, I mean, this doesn't disclude the discussion about individual patients on the unit before bringing the patient to the operating room. I think what it's addressing is that there is

a multidisciplinary collection of minds to discuss the plan for the patient.

MS. HINES: And with my other hat on, the difference between -- we've got No. 3 coming up with multidisciplinary rounds versus the multidisciplinary conference.

DR. GHANAYEM: That is the post-operative.

MS. HINES: Yes.

CO-CHAIR KOHR: Allen.

DR. HINKLE: Yes. I mean, I think John summed it up perfectly. This is an important element in building teams. It's a team building and you start taking down some of the silos that are around individuals. Communication is key as all these people in this room know. That's how I see this as a team.

I'm sure what John described when he goes into an organization some of that's not taking place and that's a highly complex environment. You've got to have that. That's

critical to the successful performance, I think, in the organization.

CO-CHAIR KOHR: And we talked about that as group A. We talked about the individual as a group and we came to consensus that we were talking about the group collective because you could not really do it on a patient-by-patient basis.

Is there any other discussion? I think that --

Go ahead, Lisa.

MS. NUGENT: One of the things that came out of our discussion over this cluster of measures which are similar is what are we trying to measure and is it the baseline of adequate care or are we trying to measure a level of excellence and that was one of the issues with this because, you know, you can say, "Well, okay. So they had a conference."

But not all conferences are the same. Not all rounds are the same. Not all

of these are the same. That's where it gets to be a gray area and there's a tension.

What I'm seeing in all these conversations is that we have the science and the art of medicine. It's very easy to measure the science and then when we get into the art, the dialogue, the multidisciplinary craft, how do we measure that?

I think that is a real challenge for the NQF going forward because we don't want to handcuff providers to doing something that we deem is right. We can all agree it's right but then there is abuse in that, too. I don't have an answer to it but I do see the challenge that is on the table.

DR. J. JACOBS: I think that is an excellent point. What I would say is that there are some programs that exist that do not do these basic things that we're listing as important. They do not have conferences to discuss the cases.

They do not have multidisciplinary

rounds but instead they have rounds made separately at different times of the day by cardiology, surgery, and critical care and the communication between those teams is made by leaving notes to each other in the chart and leaving messages to each other with the nurses.

By putting these measures forward we're saying that level of practice is not adequate and that multidisciplinary rounds are important and that a multidisciplinary conference is important to have as a basic structure measure. Either you have it or you don't. I think that in and of itself is a measure of quality and it's an important structural component of a program. That's why the STS puts these measures forth.

CO-CHAIR KOHR: So if I'm hearing correctly, you are submitting this as a standard of care, an expected standard of care. Correct?

DR. J. JACOBS: I'm submitting it

-- we are submitting it as a structure measure and expected standard of care of a quality pediatric and congenital heart surgery program would be that these structure elements are in place.

CO-CHAIR KOHR: Okay.

DR. MAVROUDIS: And mentioning further, we are not saying what has to be discussed. We're not saying that the quality of discussion has to be a certain level presence or absence of this conference.

CO-CHAIR KOHR: So my last comment, and I'll just make sure there are no other comments, that's my primary concern. Even though this is a yes/no deal, how do you compare --

DR. MAVROUDIS: You don't.

CO-CHAIR KOHR: -- my conference --

DR. MAVROUDIS: You don't.

CO-CHAIR KOHR: Just a second -- in terms of the content meaning you covered

the patient's past medical history. You covered their diagnostic tests and you had at least the surgeon and cardiologists in the room.

DR. MAVROUDIS: You don't. You don't do that. It's just too cumbersome. If that's the intent of this, then it would have to be a different kind of survey of an analysis of that conference which, you know, the information you want would require a significant evaluation of that conference which would require some database functioning, some standards that have to be met, how long the conference is, do you show every picture, etc., etc.

I don't think this is the survey that we want to look at. This is not the registry. The registry is, "Do you have a conference or do you not?" I would assume that human beings with degrees who go to this conference will do something other than play Tiddlywinks. They'll talk about something.

DR. J. JACOBS: The intent is to say whether or not it's done.

DR. MAVROUDIS: Yes. And that's all. Do you have it or do you not have it. I think that if we get caught up with -- and they are not minutia, they are important information but if we get caught up with the particulars of the conference, then we will really need a database to put all these particulars in and these items in.

I would suggest that we say what I have been saying all along, "Do you have a conference or do you not have a conference?" Then you assume at that conference something good will take place, you know, what John was saying.

CO-CHAIR KOHR: John.

DR. MAYER: Yes. I think there's precedent outside of our field for this to happen. I know, for instance, in the transplant world now, you know, there is a requirement from, I think, CMS, somebody,

whoever it is, that a multidisciplinary conference be held, patients be discussed.

You know, we check off when we're there at the transplant conference. We check that the physical therapist and the nutritionist and whatever are all there.

Again, I think, you know, the way I view this is this is one of those necessary but not sufficient deals so that I think it's important that we say, "You ought to be getting together in a multidisciplinary say and talking about the patients before you operate on them, a majority of the patients, or the ones for whom it's feasible," etc.

I would agree with what Jeff that, you know, to the extent that we actually prescribe what has to be included in that content of that meeting obviously is not the intent of this proposed measure. I think it would be a nontrivial undertaking to actually prescribe that because there may be some places where -- I don't know if I can think of

a reasonable example.

I can tell you that in our institution the cases -- I mean, we actually have layers of review so that we have every echo before the patient gets to the conference is reviewed by two echocardiographers independently.

If there is no controversy at that level and it's a straightforward problem like a secundum ASD, that patient may sort of have a sheet of paper with all the information on it and we say, "There is no controversy. We know what the diagnosis is. We're not going to discuss this further." That's it.

I mean, it's a 10-second review. But I'm not sure that what we happen to do in one institution is necessarily what we should be prescribing for every institution in the country because maybe they don't have the opportunity to have two echocardiographers independently review the study before it gets to -- you know, I mean, that's the sort of

thing.

I'm worried that if we get into too much detail here we are going to spend a lot of time and I'm not sure it's worth the effort to be honest with you.

DR. GHANAYEM: Actually, I think that's very helpful, I do. I think some of the discussions we had yesterday are going to be a little bit curbed today because we did struggle based on the evaluation tool that we had, how do you take some of these measures and measure them and link them to outcomes.

We felt kind of constrained by the tool that we had. I think you've all put it in perspective for some of the discussion work I have later which will go, I think, a lot easier but that's very helpful

DR. HOYER: And, again, I would kind of consider the notion of a programmatic measure that would maybe include all of those elements.

However, then if one program had a

weekly conference and didn't do multidisciplinary rounds, didn't have a combined quality assurance/M&M conference, only met one of those three things, you know, they wouldn't meet the criteria for programmatic measure, whereas if you do separate them out you would be able to meet some of those but not all of them.

I don't know how we would then evaluate that from a consumer standpoint whether somebody meets the criteria for one or two but not three so you have higher quality here, lower quality here, higher quality here and how one kind of evaluates that information.

Again, whether to separate them out into three or whether you just kind of make it as one combined but I can see some of the deficiencies if it were combined.

CO-CHAIR KOHR: Yes, Lisa.

MS. HINES: Back to the point of definition. Certainly there is going to be

different staffing and the transplant example you gave where is there a PT, is there a nutritionalist and stuff, obviously there is some group of core individuals that are expected to be there.

I think probably there are some simple core, "You really should always do this," items that you're going discuss. I really think they are going to look for some definition because this would be too easy to just check box and become documentation that I saw Darryl down the hallway and we said, "You good?" "We're good." Check box and you got credit but it wasn't, again, defined.

DR. HOYER: But, again, that would be on a patient-by-patient basis whereas, again, this is really a dichotomous plus minus. Do you have the conference or do you not.

MS. HINES: Or if you did it for all patients.

DR. HOYER: Then there's

Thanksgiving, holidays, etc., you know, that you're not going to have a conference every week but basically do you have a conference in place that is there with rare exception that you don't have it. I think from that standpoint it would certainly meet that.

I would agree, though, with rewording it so that you don't have to say that all these players have to be present and one would say, you know, the major stakeholders or the cardiologists, cardiac surgeons so at least they are there but could include anyone who wants to join the party.

MS. HINES: Gus had said "but not limited to" and I think that could be as long as there was this kind of least common denominator that we're expecting. If you go above that, great. I think your concern, you know, it's always half full/half empty.

Those that do it all the time are going to want to get credit for having a conference and show that they can. Those that

don't have this maybe they don't know -- this is going to sound really stupid but maybe they do it and they just don't know that they're doing it.

If they look at the criteria, "Oh, we do that." Or it's kind of chaotic and they don't talk about all the points that should be talked about so those you're kind of teaching to the test. If this is going to be 90 percent of the people do it, going forward it may be questioned is this necessary.

If there's a good piece of folks that aren't doing it, do they know what they're supposed to be doing and what the expectation is. I don't want to make it cumbersome but I think they are going to look for some parameters and a little bit more definition.

DR. M. JACOBS: I don't think it makes it cumbersome. I think that's a very concrete suggestion and it's not different from Dr. Mavroudis' spirit if you do it or you

don't do it but we could very easily amend the first line of this to say what it is.

Rather than simply calling it a multidisciplinary conference, call it a multidisciplinary conference which includes a review of the patient's history, diagnostic studies, and planned procedures.

You either have such a conference with representation of several disciplines or you don't. The conference is framed around those tasks. I think that is the spirit of what we proposed and it's a little more descriptive.

MS. HINES: And I don't know that it would have to go in the title but even kind of as a definition.

CO-CHAIR KOHR: Any other comments before we go to vote?

Darryl.

DR. GRAY: Yes. It sounds like we're saying -- I mean, I think in the subgroup yesterday that we had the sense that

most places would actually be able to say yes to something that wasn't necessarily that constructive.

It sounds like, for example, John's experience is that maybe obviously you're going to places that are actually having difficulty so that's where you're finding places that don't have that.

If it sounds like it could be worded in such a way as to be at least reasonable discriminatory to where you actually are identifying some proportion of programs that actually don't have this so that you actually will be able to have it as a discriminator, then it's probably helpful.

I'm assuming that seems to be what we are, at least, trying to refine it to some degree to at least make it a little clearer as to what this is still with the assumption that places that would presumably be forthright enough to say that they don't do it are places that should be doing it or the places that one

might want to consider not taking their child to have surgery.

CO-CHAIR KOHR: Okay. We're going to go ahead and go for a vote so it sounds like -- just raise your hand if you are in favor of recommended for time-limited endorsement with conditions and that would be the change in the title that is a little bit more descriptive of the measure. It looks like we have 12 our of 12.

We're going to go ahead and pause right now in terms of proceeding with the process and structure variables because we need to open this for public comment.

MS. WILBON: Yes. We actually kind of skimmed over that. We were supposed to do that at 10:00 when we regrouped so I'm just going to pause and check with the operator.

Operator, are you there?

OPERATOR: Yes, ma'am.

MS. WILBON: Is there anyone on

the audience line?

OPERATOR: No, ma'am. Not at this time.

MS. WILBON: Okay. Thank you.

OPERATOR: You're welcome.

CO-CHAIR KOHR: We'll go ahead and go back to submission 01. Darryl, you were the primary.

DR. GRAY: So this says, "Participation in a national database for pediatric and congenital heart surgery." The brief description was that it's participation in at least one multi-center standardized data collection and feedback program that provides benchmarking of, it says, the physician's data, although I think that could be actually the institution's data, relative to national and regional programs and uses process and outcome measures.

The numerator statement is just whether or not there is participation in at least one multi-center data collection and

feedback program with a time window of one year or four years. There is, actually, therefore to clarify that there's no real denominator here.

In a way it's analogous to the other structural measure we just mentioned, the question of whether or not the program presumably participates in such an effort. So we did want some clarification regarding what participation actually means and what the options are.

It seems as a practical matter obviously STS would be -- certainly the primary example of this there may be a few other alternatives and certainly the measure is not designed to indicate solely that STS is the only one that would fulfill the criteria but there are actually relatively few others. We felt that with that clarification that would actually be helpful.

It just occurred to me actually that participation is not being defined as

actually submission of any actual patient data. You're saying that you're participating which is fine at least at this level. After we clarified that we felt there was general agreement that this would be an important measure to be tracking.

For one thing, a measure of the program's commitment to quality improvement. We felt the scientific acceptability was moderate only in the sense that certainly the presence, participation in quality improvement efforts like this has been documented in other specialties.

It seemed to have a fairly clearly salutary effect on improving quality but there not yet specific data regarding its effectiveness in doing this for pediatric cardiac surgery but there is certainly no reason to expect that there wouldn't be. That's the reason we considered the scientific acceptability being moderate.

The usability was certainly felt

to be high. One might question that there might be some centers that don't do this for reasons that are not necessarily indicative of lower quality but that is relatively unlikely to happen and probably is a fairly usable quality measure.

We felt certainly that the feasibility was high because it really just requires documentation that the program participates in a national or regional database initiative like this. Therefore, the group recommended this for acceptance.

CO-CHAIR KOHR: Any discussion?

CO-CHAIR JEFFRIES: Can you clarify what you mean by participation which would not include submission of data?

DR. GRAY: Actually, what I'm saying it doesn't actually say anything about that. The measure is only described as participation. It occurred to me that it was sort of interesting that there was no specific criterion for performance but I'm assuming

that the measure developer just meant that if the center participates.

I mean, I would think there actually should be some requirement of some either absolute number or proportion of patients but that was not addressed in the description and I'm not sure operationally if we want to get into deciding what the criterion would be for adequate participate or not.

DR. J. JACOBS: The measure developer defines within our own database participation as a complete submission of data. However, Darryl is correct this is a metric that is not specific to one database so we would be very happy to replace the word participation with participation and complete submission of data.

MS. HINES: Just as a point of reference, NQF does have two existing measures that endorse participation in the National Cardiac Surgery Database, participation in the

National Thoracic Surgery Database. I think the issue of complete submission may come up in definitions but it has not been required in the titles for those.

DR. J. JACOBS: When we put this together we harmonized this with those other two metrics. We think it's different because the congenital heart surgery database is different from an adult cardiac or adult thoracic as we previously discussed but we wrote this with the same scientific basis and justification as the other two metrics you described.

We can go either way. We are happy to leave it as it is. We are also happy to change "participation" to "participation and complete submission of data." We are happy either way.

CO-CHAIR KOHR: Any other comments?

John.

DR. MAYER: Well, only that I

think participation, you can't participate unless you submit data and you certainly don't get any data back unless you are a participate so I'm not sure I understand how one could participate without submitting the data. By definition that is what participation means.

DR. GRAY: I mean, there was nothing in there defining what participation means in this context and I don't know whether or not a center that submits some proportion of data but on audit is found not to have submitted completely whether or not that's considered adequate participation.

DR. MAYER: Maybe if we gave you the definitions of what is required of participants in the STS database that would help you understand this. I think this is angels on the head of a pin discussion right at the moment.

DR. HINKLE: I would leave this at "participation." You start adding complete submission, we could argue here what is

complete. What is complete submission of data. Then that takes us down this pathway where we've got to define complete submission of data. It just seems to me "participation."

DR. GRAY: Okay. Again, that was a suggestion that Jeff included, I think, because it probably does mirror the STS definition but obviously the measure developer can -- I'm not sure what participation in STS is specifically defined.

As a commitment to submit all data, then that is probably fine but, again, since this is not necessarily being restricted to STS, then we certainly can use STS' language. I was saying before I thought just some clarification of what participation actually meant should be included here.

CO-CHAIR KOHR: Any other discussion? So we'll go for a vote. It sounds like we want to recommend this for time-limited endorsement with the condition of adding the clarification as to what

participation is based on the STS database.

Yes, Dr. Mavroudis.

DR. MAVROUDIS: No, I'm voting.

CO-CHAIR KOHR: Oh, okay. Please raise your hand if you're in support. We have 12 out of 12. Thank you. So we'll go ahead with 03 which is Nancy's.

DR. GHANAYEM: This discussion will be a lot easier since we did 02. This is a measure that includes multidisciplinary rounds involving cardiology, cardiac surgery, and critical care.

The description is implementation of the multidisciplinary rounds including professionals from cardiology, cardiac surgery and critical care for pediatric and congenital cardiac surgery patients. The numerator is whether or not the facility implements these rounds involving those disciplines for the surgical patients.

Couple things that came out that we hadn't discussed this morning with the

other measure is when we talked about this as a subgroup yesterday it actually was my error because I read this as being physician-centric and not inclusive of the other resources, nursing, therapy, pharmacy, family members. Other than family members it really doesn't say physicians. It says, "Professionals associated with those disciplines."

I think the description does cover the scope of the professionals, not necessarily the family members. Schonay did bring up yesterday the inclusion of allowing family members to participate or be present during rounds.

The other question that came up is who does this include. Does it include all surgical patients in the hospital or just patients in the intensive care? I suspect the intent was just to include those that were in the intensive care unit and not those who were on telemetry or step-down floor that house the less acute cardiac patients but it's not

listed in here.

I just wonder whether we shouldn't change it from involving professionals from cardiology cardiac surgery to just cardiovascular services so that the cardiac surgeon who is in the operating room, even though you may have talked to him, might not be present but there are some representation from the cardiovascular service that could be included; cardiologist, surgeon, PA, fellow resident.

DR. J. JACOBS: Let me try to answer several of Nancy's important questions. First of all, we didn't specify the unit that the rounds had to be made in by intention just like we didn't try to specify in too much detail the components of the conference.

I think the important concept here is that joint multidisciplinary rounds are made by the team and I think each hospital or institution can individualize what words and units would be most appropriate for that to

happen. I think it's okay as it stands with that regard. I don't think we have to specify where it applies.

That is something the hospital can decide on its own as long as they are doing this. The important thing is that they are doing this and there is a process in place to communicate about the patients on rounds by rounding as a team and not by leaving messages to each other in the chart, which happens.

DR. GHANAYEM: But, Jeff, I'm going to respond to that. I think the onus would be if something happens to a patient on the floor and was not rounded on by the critical care team in conjunction with the cardiologist or the surgeon, I actually think that is not in line with daily rounds of a subset of patients who are not in the unit.

DR. J. JACOBS: I agree completely. All I'm saying is I don't think we have to specify within the quality metric itself which units are covered. What you say

is absolutely correct but I think as long as we say that multidisciplinary rounds are made, I think that is enough for this metric.

There was another question you had asked. Your second question was?

DR. GHANAYEM: My comment was although not specified in the numerator statement but it can be assumed in the professional's description would be the inclusion of the other ancillary staff.

DR. J. JACOBS: I think the term multidisciplinary probably means that. I think it's important to leave in the definition components of the cardiac surgery and cardiology teams. One intent here is the program would not quality for this if rounds are made on a daily basis that exclude the surgical team completely.

We don't say that the surgeon has to be there every single day because there are days he's going to be doing emergencies -- he or she is going to be doing emergencies. We

say that in general multidisciplinary rounds include the surgical team, the cardiology team, and the intensive care unit team.

DR. GHANAYEM: On a daily basis.

DR. J. JACOBS: Pardon?

DR. GHANAYEM: On a daily basis the surgeon has got to be at rounds the way this reads.

DR. J. JACOBS: That's not what --

DR. GHANAYEM: That's exactly what it reads. "Conducted on a daily basis the presence of these professionals."

DR. J. JACOBS: Right. Somebody from the surgical team. It doesn't say the surgeon that did the operation.

DR. GHANAYEM: Sure.

DR. J. JACOBS: But I think that's true. Somebody from the surgical team needs to make rounds every day on the patient. I think if you don't do that, that's part of being a surgeon. You make rounds on the patients you operate on or someone from your

team does.

DR. MAYER: Maybe I -- I think I know where Nancy is coming from. Maybe if I restate it a different way. I think the notion is I think you're trying to get at is that people are talking to one another about individual patients and it's not just the surgeon going by doing his thing or somebody coming by doing their thing that there is actually some meeting of the minds that goes on.

Maybe the distractor, if you will, is in what some of us would think about as multidisciplinary rounds where we all get together in a herd and we go around bed space to bed space and make rounds on individual patients.

My sense is that is not what you intend but that you intend more for there to be a multidisciplinary discussion. Typically in our unit it would be between the surgeon, the intensivist/cardiologist, the bedside

nurse, and the respiratory therapist on every patient.

DR. J. JACOBS: Yes. That's exactly what we mean.

DR. MAYER: It's not like you assemble everybody. Is that distinction helpful?

DR. GHANAYEM: Yes, but I don't think that --

DR. MAYER: You don't think that's what this says.

DR. GHANAYEM: That is not what this says.

DR. J. JACOBS: Suggest a revision.

DR. GHANAYEM: I suggest a revision. Oh, you want me to --

DR. J. JACOBS: Yes.

DR. GHANAYEM: I would call them multidisciplinary discussion or dialogue involving the components that John has mentioned. I wouldn't call --

DR. J. JACOBS: You want to take out the word round?

DR. GHANAYEM: Yes, because rounds by any definition that anyone who does rounds envisions rounds sitting with a group of people whether it's by the bedside, in a room formally discussing the patients. That's what rounds means.

MS. BARNETT-JONES: If we take out rounds --

DR. J. JACOBS: Shouldn't he do that, though?

DR. GHANAYEM: Multidisciplinary discussion would be, I think, a better phrase than rounds.

MS. BARNETT-JONES: But if you take out the word rounds, then how does it differ from the previous measure?

DR. MAYER: Oh, no. The previous measure is for preoperative.

DR. GHANAYEM: Right. This is post-operative.

MS. BARNETT-JONES: This is post-operative care management.

CO-CHAIR KOHR: I can tell you, Jeff, when we talked about this everybody at the table thought the same thing, that this was rounds because Schonay said the family needs to be involved so they can hear what the plan of care is for the day.

All of us thought the same exact thing based on this and we all had concerns that within our institution not everybody comes together. There is dialogue that happens but I can tell you the surgeon isn't on my rounds. What I call rounds they are not on our rounds.

A PA may be intermittently but they are not on everybody's. We have two teams and a PA goes to whatever team has the most critical patients. There's a dialogue between the surgeon and the intensivist and the intensivist shares that with the rest of the team but it doesn't happen on --

DR. J. JACOBS: If fixing this is done by changing the word "rounds" to "discussion" I think we could do that. Changing one word and then what happens?

MS. BARNETT-JONES: I think the spirit changes if you take out the word "rounds."

DR. J. JACOBS: So do I but I'm just trying to find a way to fix it.

DR. HOYER: Rounds implies a daily check-in. You could take it out and say discussion it's not that much different from the discussion that occurs during that conference that we talked about so you would have to say something like multidisciplinary daily discussion.

DR. J. JACOBS: Daily patient care discussion.

DR. HOYER: Something like that. Again, you know, including a minimum of people like we talked about and it doesn't have to be absolutely everybody every day. Does it?

Multidisciplinary to me is more than one.

DR. J. JACOBS: If we replace the word "round" with "multidisciplinary daily patient care discussion?"

DR. HOYER: Right.

CO-CHAIR KOHR: Well, what about doing the same discussion that we had previously where you could still say, "multidisciplinary rounds but including but not limited to" and put the members there.

DR. J. JACOBS: I would be happy if it said "including but not limited to."

CO-CHAIR KOHR: Right.

DR. M. JACOBS: What about, "Daily review of patients' status and plan of care."

CO-CHAIR KOHR: There's the wordsmith for you.

DR. J. JACOBS: So here's the proposal then. I don't know who is taking the minutes for this one but here's a proposal, "Multidisciplinary rounds, parenthesis what Marshall just said, "daily review of patient

care, close parenthesis." That then defines rounds as something that might be palatable to everybody.

MS. GALVIN: I have one suggestion that might clarify it is I think what Nancy is referring to is a bedside discussion. I think that is how most people interpret rounds is that this group goes around the unit bedside to bedside and that would also then include the parents. Moving forward that's our intent. It could be that it's rounds at the bedside, discussion at the bedside. Wordsmithing could include that piece.

DR. GHANAYEM: A dialogue between the intensivist and the surgeon or the cardiologist and the surgeon can't be sufficient because it's not multidisciplinary. It does not include the bedside nurses who cannot walk away from the patient to go hear the hallway discussion.

DR. J. JACOBS: I agree completely.

DR. GHANAYEM: So it's got to be rounds. It's got to be inclusive and it cannot --

DR. J. JACOBS: Multidisciplinary rounds --

DR. GHANAYEM: -- member of a surgical team to be at the bedside when they actually need to be somewhere else.

DR. J. JACOBS: Multidisciplinary rounds including all members of the healthcare delivery team.

MS. BARNETT-JONES: Would the measure consider specifically including the family?

DR. J. JACOBS: I think that's reasonable.

DR. MAVROUDIS: The only trouble is the family is not always there.

MS. BARNETT-JONES: Understood.

DR. J. JACOBS: I like that. Family participation is welcomed and encouraged. How's that? If we add the

sentence, "Family participation is welcomed and encouraged" to that, I think that is a strong statement and I think it's important.

DR. HINKLE: My question was just clarity. I assume daily does mean weekends and holidays as well as multidisciplinary during those --

DR. J. JACOBS: Oh, yes.

DR. GHANAYEM: Yes. There's always going to be a nurse at the bedside.

DR. HINKLE: I know. I just wanted to make sure, you know.

CO-CHAIR JEFFRIES: I guess I'm just a little confused by the discussion. I understand where we're going but I had a sense from Nancy that you are not in favor of rounds including the surgeon, that it wasn't going to happen.

DR. GHANAYEM: I am always in favor of rounds including --

CO-CHAIR JEFFRIES: But that you are uncomfortable with the measure --

DR. GHANAYEM: I think by putting it in there, that is why I thought cardiovascular services might suit the needs of the cardiologist and the surgeon who can't always be there because they are busy. They are operating.

Even though there is a discussion with a surgeon and intensivist, that shouldn't count as multidisciplinary rounds. It didn't happen at the bedside and include the nurses. I think rounds that exclude the nurses are not sufficient rounds.

MS. BARNETT-JONES: I agree with that.

DR. GRAY: Now, again, this is just a structural measure. We're not talking about what happens in individual patients, although we may end up getting to that.

I don't know if you want to say that sort of as a structural matter we want to indicate the services that we think should be participating with the understanding that for

any individual patient that all the services may not be there but when we are talking about the structural measures, we want to actually specify the services that we actually want included in this or not?

DR. HOYER: The more I look at this, I'm going to retract my previous statement. Let's leave it at rounds. Rounds is rounds. Just say, "Involving multiple members of the cardiovascular care team."

DR. J. JACOBS: I like that.

DR. HOYER: Then you don't limit yourself to cardiology, cardiac surgery, and critical care, and anesthesia, and the family. I mean, everybody is a stakeholder in this including the family so I think if you say they are all members of the care team so why not leave it that way. It would be generic enough and it would basically include all the elements that we talked about.

DR. J. JACOBS: So if we put, "Including multiple members of the healthcare

team," I think we should also have the sentence that, "Family participation is welcomed and encouraged," because some places don't consider the family part of the healthcare team.

MS. BARNETT-JONES: Absolutely. That's what I was going to say.

CO-CHAIR JEFFRIES: Again, it doesn't necessarily have to be inclusive but you could put a few of those folks or elements that could be in the description of the care team you're talking about.

DR. J. JACOBS: So if we say, "Multidisciplinary rounds involving multiple members of the healthcare team," and then the next sentence says, "Family participation is welcome and encouraged," does that address everybody's concerns?

DR. HOYER: Or you could just say, "This includes but is not limited to," etc., etc., etc. could be in the description.

DR. J. JACOBS: Right.

DR. GHANAYEM: Actually, I would be specific in the description so that the hospital gives weight to putting resources on pharmacy and nutrition and social work and all those things that are imperative to the care of the patient. I would be more specific on who those members of the healthcare team are.

DR. J. JACOBS: I think we have to be careful here because not all hospitals are going to have the ability to have a pharmacist make rounds with a team every day.

DR. GHANAYEM: Yes, but if you don't make it that they have to be there every day.

DR. J. JACOBS: But that's a little different from what we're getting at here. We are trying to say that multidisciplinary rounds aren't made every day. I don't think specifying whether or not a pharmacist is participating is the intent of this.

DR. MAYER: I think the reality of

it is that logistically the more people you add to the group, the harder it gets to get everybody in one place at one time. I think, you know --

DR. J. JACOBS: That's the way it is.

DR. MAYER: Surgeons have to go to the operating room and anesthesiologists have to go to the operating room and the pharmacists may not work, you know, 6:00 to 4:00 or something like that. Not everybody is as nutso as the docs who work 12, 14, 16-hour days.

There are a lot of people who would not be willing to participate at that level. I think we need someway to sort of reconcile this with what the realities and the logistics really are of getting that many people together in one place. I think there is also -- I mean, I think we all understand the spirit of this. Right?

DR. GHANAYEM: Yes.

DR. J. JACOBS: We want to have people talking to one another about the given patient on a minimum of a daily basis. Certainly in our intensive care unit sometimes the discussions are three or four times a day that go on between surgeon and cardiologist/intensivist, etc.

But, you know, I don't quite see. Maybe there's a way to wordsmith this in such a way to reflect that spirit of what it is that we want to be sure happens without getting so perspective that it gets us into trouble some other way.

DR. MAYER: So I'll come back to what I said. Just say, "Multidisciplinary rounds involving multiple members of the healthcare team. Family participation is welcome and encouraged."

CO-CHAIR KOHR: Go ahead.

DR. J. JACOBS: Did somebody write that down?

CO-CHAIR KOHR: I did. I wrote it

down already.

DR. J. JACOBS: Excellent.

MS. BARNETT-JONES: I'm sorry. Not to be a stickler but if we put, "Family participation is welcomed and encouraged," instead of saying, "To include the family as a member of the healthcare team," I think it makes a much stronger statement.

DR. J. JACOBS: I agree with that.

DR. HOYER: With all due respect again, I mean, I would have to take a little issue with that because the family will not always be there. We happen to know that.

Sometimes given the level of people's education there are certain things that are difficult to talk about in rounds with the entire group and the family because it's a different type of discussion that's had with the family there as compared to when the healthcare professionals are there.

DR. J. JACOBS: We could say, "Inclusion of the family as a member of the

healthcare team is welcomed and encouraged."

DR. HOYER: Are you thinking of putting that in a brief description or --

CO-CHAIR KOHR: Yes. I think in the description you could say, "Recommended participation is family, nursing, social work, pharm." You can put all these people in there. This is our recommendation but it's not an absolute.

I agree. I think that based on the family and what has been happening with the patients sometimes the choice is to discuss at the bedside and then go back to the family so you can have an in-depth discussion.

The reality is if you have 26 beds you've got to keep moving and if you need to really spend a concentrated time with that family, you don't want to shortchange them so you come back and say, "We're going to come back and talk to you after rounds and really make sure all your questions are answered."

CO-CHAIR KOHR: Absolutely. I

agree with that just based on my experience to be included as part of that team because at the end of discharge it's the parent who will be taking that child home to maintain and try to keep the same standard of care outside of the hospital environment.

I think the family is a critical part of that partnership. I definitely agree that, yes, families can't always be involved but those times when they are able to be there they need to be included. Most of the cardiac families that I know they are pretty savvy when it comes to their child's care. They do lots of research.

They come to the table with lots of questions and ideas which they do share with their medical staff so I definitely think we do make a strong statement in terms of creating partnership and keeping those lines of communication open because what we don't want to happen is to have the family not be aware and the child have to return to the

hospital with perhaps a more critical case than when they left so that is why I say it's very important to make that statement and make it very strong. We have that opportunity to do so.

CO-CHAIR KOHR: Absolutely. Any other discussion?

DR. GRAY: I'm just sort of thinking about, again, from sort of my perspective of how we would actually be trying to develop a category 2 code if it comes to that when we actually get this so saying something is encouraged it becomes hard for us to know whether or not the instructions, therefore, mean that -- what that actually means.

I mean, again, this is a short-term measure. We are not talking about whether or not in any given case the family was present at rounds on Tuesday. I just think we need to be clear as to what the requirements are for satisfying the measure

and just making that clear.

Saying that things are encouraged just becomes kind of hard for us to know how to interpret that when we are trying to code the measure. I guess we need to either be clear that it's either what's required for coding it -- just to be clarifying as to what that is.

CO-CHAIR KOHR: John.

DR. MAYER: So Lisa reminds me that "encouraged and not limited to." Probably we could use the "not limited to" sort of wording. I think the important thing and I understand the logistical question here about how you actually are going to collect the information in any sort of routine fashion. I think the fact that rounds occurred again is just like preoperative conference and planning conference occurred.

Again, it's one of those things. I mean, the real question is: is it baked into the culture and the organizational structure

that you're working. Right? I mean, we all recognize that not everybody is going to be able to show up every day.

Not every institution is going to have the resources to assign a social worker to spend four hours every morning making rounds in the intensive care unit and go from every patient to every patient. I mean, you know, those are the realities of things.

I think the issue is this part of your organizational structure that you have these rounds and do they occur on a daily basis and do these things include all the different disciplines that we're talking about. I mean, I think that's the spirit again of what I think we are trying to accomplish and what we would want to measure.

I suppose one could walk around with a clipboard and check off, you know, for every patient whether or not you did that but I'm not sure that's the intent of what we're trying to do here when we are looking at this

as a structural measure.

CO-CHAIR KOHR: So I guess the question is are people comfortable with it as a description rather than title including the players versus listing them. Just saying multiple members of the healthcare team and then under the description putting in all the members including family obviously.

DR. HOYER: As long as all elements aren't required.

CO-CHAIR KOHR: No. I think just recommended. If you just say recommended, it's not required. Or are not limited to.

DR. GHANAYEM: I think that would satisfy all the concerns.

DR. LOPEZ: I just have a minor point real quickly. Could we also include with family primary care giver? Some of these infants are in DHS custody.

CO-CHAIR KOHR: Absolutely. Good language. Thank you.

Okay. So we'll go ahead and move

forward for a vote. Recommend for time-limited endorsement with the condition of the change in the name and then a full description of our recommendations in terms of the participants in multidisciplinary rounds. All those in favor, please raise your hand. Twelve out of 12. Thank you.

We'll move onto the next one which is 04 and that's Lisa Nugent.

MS. NUGENT: The title of this measure is, "Regularly scheduled peer review quality assurance conference." There is a recommendation to insert "surgical" into the title, "Regularly scheduled peer review surgical quality assurance conference," I'm assuming or something. I'm not sure where it would go but it goes somewhere in there.

The description is the implementation of regularly scheduled peer review quality assurance conferences to discuss care provided to patients who undergo pediatric and congenital cardiac surgery

operations.

The numerator is whether or not the facility implements regularly scheduled peer review conferences to discuss care provided to patients who undergo pediatric and congenital cardiac surgery operations.

I think we've touched on many already, many of the concerns that our group had. We recognize that the regularly scheduled peer review conferences are essential for high-quality patient care.

We agree that there is a need -- as listed in the measure we could agree that there was a need for improvement in participation in these conferences. There was a survey that most respondents cited education and prevention of future errors for principal goals of an M&M conference.

So as we've been discussing, you know, it's hard to determine the quality of the conference. Not all conferences are the same so simply having a conference meaningful

it seems as though this morning we've had a lot of conversation around that, that perhaps yes, indeed, that just the occurrence within an organizational structure may be enough of a measure.

Yet, within the proposed measure it did call out some of the challenges that are inherent in the critique process such as identify an individual or an institute for a given problem. So, you know, there is this challenge of the quality of the content in this peer review process. Perhaps that's out of our scope and, again, we are just identifying that we want this to be part of the organizational structure.

I'll open it up for other comment.

CO-CHAIR KOHR: One of the things that came up was similar to one of the other measures that we talked about in terms of just not necessarily having criteria but at least adding a little bit more clarification in the title with regards to what our expectation of

an M&M is.

All of us in our group immediately thought that you discussed mortality. You identified either a process structure issue and you came to some discussion about how you could improve care if at all possible to prevent or at least prepare for this event happening again.

None of that is presented within that measure but we all had that -- I think if I asked all of you independently you would come to that same conclusion that's what that meant.

Again, it's open to interpretation from institution to institution about what this looks like. Is it just presenting a subset of your patients so I'll put that open for discussion.

MS. NUGENT: I think when I read this my initial thought was, well, a peer review is quite different from an M&M. A peer review really is looking at what the person

did sort of in the context of their role so that concerns me that would need to be a part of this.

I think with some more clarity around what this peer review quality assurance maybe it is M&M or that complications, morbidity, mortality, are discussed would seem more likely.

CO-CHAIR KOHR: That's where Lisa's comment came in with the post-surgery because immediately we were talking about -- initially when I read it, too, I thought the same thing, is this just a QI program or is this M&M so we had some dialogue around that as well.

DR. M. JACOBS: Well, I think those are very appropriate criticisms and appropriate questions. I think this was proposed again as a structure measure as a suggestion of what ingredients are of an effective well-organized cardiac care program for an institution where patients are

undergoing surgery for pediatric and congenital heart disease.

As was pointed out by the subcommittee yesterday, JCAHO and other oversight organizations mandate that hospitals have M&M conferences and mandate that in the setting of sentinel events there is a separate formal peer review process.

In a way that I think John Mayer has done more effectively than I, let me try to restate what the intent of this measure was. As opposed to a circumstance where a hospital has a monthly M&M conference that's scheduled at the convenience or around the events in the life of the Chairman of the Department of Surgery and the general surgical chief resident and the orthopedic surgeons, we're suggesting that a cardiac care program have an M&M conference that is scheduled in such a way that cardiac surgeons, cardiologists, cardiac critical care physicians, anesthesiologists, cardiac care

nurses can be present to discuss the outcome of surgical procedures and, in particular, to have a discussion and evaluation of patient deaths or other adverse outcomes.

Conventional discussions of adverse outcomes include classifying a type of complication to include making as ascertainment of other avoidable or unavoidable related to patient disease.

The spirit of the measure is that this is a cardiac service activity which is carved out within the calendar of the cardiac care team separate from what the hospital does to fulfill his JCAHO obligation having an M&M.

So it is an M&M conference but it's a regularly scheduled cardiac care team M&M conference which we think because of access and availability is a very different commitment on the level of an institution's cardiac care team from merely fulfilling a JCAHO obligation for M&M.

The term peer review, you're

right, is misleading because it does conjure up root cause analysis of sentinel events which was not the intent but it should appear somewhere in the description since the intent is for the content of such an M&M process to be protected under peer review from discovery.

M&M's primary peer review is secondary but the overriding issue is that it's a cardiac care team QA conference as opposed to a hospital or department of surgery QA care conference. That, I think, was the intent and I think all the questions you raised yesterday have helped me to try to articulate that more clearly.

CO-CHAIR KOHR: Thank you.

Allen.

DR. HINKLE: Yes. I don't know if you strike the peer review term from it but for me I read this one peer review is there would definitely be another pediatric cardiac surgeon would be doing the review of the operative procedure.

Then you get into internal external so you start dragging in, well, the fair way to do it is you get an external, somebody who didn't participate in the care. I think what I've just heard from Marshall is that he's suggesting that maybe peer -- he wants it under the peer review umbrella.

I understand that but that's different than peer -- you know, a lot of people interpret peer review as I've just described so just clarification around that I think is going to be important here.

DR. GHANAYEM: I actually think that's very important just knowing what the hospital administration is going through in trying to separate out peer review from case review and M&M.

Peer review does imply it is a review of professional behavior whether it be related to the patient or related to professional behavior with each other. I think the language is probably inconsistent

with the JCAHO based on what the intent is of this measure.

CO-CHAIR JEFFRIES: Two things. One is the term "regularly scheduled." Is there any limits around that? Is once a year enough? Again, in some ways this is provocative but just so we can get an understanding of what that means.

The other thing, I agree with what Nancy was saying as well as Allen but I think a QI or QA process across the cardiac program is really important. The comment peer review started me thinking down a different path and that is we have -- I've been a part of M&M conferences which are heart center oriented.

I think because there is little peer review at the conferences when you have a smaller program for the cardiac surgical procedure some of it becomes challenging to actually get good review. If you have one cardiac surgeon in your program, it's hard, I think, to have peer review. As an

intensivist or cardiologist we can't critique what was done in the operating room. Clearly we can see what was on an echo but we don't handle tissue ourselves and we have different ways that we deal with things. I think having adequate peer review that is challenging.

Again, I'm not sure reduces the importance of this measure. I think having a QI process for a program is important. Also, if I could just get some comment around what regularly scheduled would be.

DR. J. JACOBS: First the intent of the measure is basically to get all members of the healthcare team together in a room to talk about, "This didn't go so well. How can we do it better?" That's in everyday English what we're trying to put down on paper and it sounds like we probably could have done it better.

We went back and forth about regularly scheduled under our million phone conferences about this. People advocated

weekly, people advocated monthly. Finally we said we shouldn't specify to each hospital what the best choice for regularly scheduled is. Clearly once a decade to be regularly scheduled would be inadequate. Clearly daily is too frequent so it's got to be somewhere clearly between that.

I think we would be open to some reasonable suggestion for what time period to use. The intent is simply to get the members of the team together to discuss what they can do to do a better job when something bad happens.

CO-CHAIR KOHR: So we've already talked about we're trying to achieve a standard here and I think this is an opportunity for us to identify what at least the minimum would be whether that's twice a year, four times a year. I think we have an opportunity to set that bar. You can say it's at least this but not limited to or something.

DR. J. JACOBS: Quarterly.

CO-CHAIR KOHR: Quarterly?

DR. J. JACOBS: Quarterly. I'd like to do it more frequent but that may not be realistic. If you make it any longer, you don't remember exactly what happened so quarterly.

CO-CHAIR KOHR: Does anyone have comments about quarterly?

DR. HOYER: Yes, quarterly I think is a minimum. Sounds like it would be a good thing. That would allow you to go much more like monthly if you could do that but semi-annually, every six months, I don't think that's frequent enough.

The only other thing is I have a question for Jeff. Why the peer review in the title?

DR. J. JACOBS: Well, because we originally wrote this as an M&M conference and then the abundance of surgeons in the room said that an M&M conference is an outdated term and the modern terminology for it is a

peer review conference. That's all.

DR. HOYER: You could even take that out and just say quality assurance and then also equate that to M&M, I guess.

DR. J. JACOBS: I think what if we just said regularly scheduled at least quarterly quality assurance and quality improvement multidisciplinary conference.

DR. HOYER: I just wanted to make sure you weren't trying to satisfy some other kind of hospital or administrative requirement that it be called such.

DR. J. JACOBS: No. It was just a bunch of guys on the phone at night. One said, "It's not called an M&M conference anymore. It's called a peer review conference." And we all said, "Okay." The last quote that I said does that solve these problems?

MS. NUGENT: I have a quick question because in the measure you've had a survey with some stats of participation and

non-participation so is that relevant to how we're morphing this?

DR. J. JACOBS: I think that if we say regularly scheduled minimum quarterly quality assurance, quality improvement multidisciplinary conference, I think that is enough. I think just like we're not specifying in great detail the requirements for who attends rounds or attends patient planning conferences. We don't have to specify in detail who is going to be there. A group of healthcare professionals having a quality assurance, quality improvement conference will be able to figure out on their own who has to be in the room to have a meaningful conference.

CO-CHAIR KOHR: John.

DR. MAYER: Yes. I just wanted to comment a little bit about the use of the word peer because I think in a smaller program there may only be one surgeon. Again, without trying to get into a lot of semantics, you

know, I think you may or may not be able to determine whether somebody is putting the stitches in right or not or how they are handling the tissues but everybody is looking at the same result.

In that context I would say that the intensive care doctor, the referring cardiologist, the whatever, at least to my way of thinking, peers in the sense that at least they have an idea about what the outcome is.

They may not understand whether or not there was some problem with the bypass machine or there was some problem with how you put the stitches in or did you put the patch and close the hole in the wrong place, that kind of stuff.

We are all looking at the same end result so I'm not as concerned about peer meaning necessarily somebody whose got exactly the same set of diplomas on the wall as somebody else as much as I am that all of -- I think the intent is everybody who is

involved in the care of this particular patient. As many of them as possible who can be there should be there for the discussion.

I mean, you know, I can tell you in our own institution, you know, we try to make sure at least one of the surgeons goes to the cath lab M&Ms and we try to show up for the echo lab M&M where they go over all the situations in which a diagnosis was either incomplete or wrong or whatever.

I think the critical piece of this is the multidisciplinary aspect of it and the fact that we are getting a bunch of people together who all know something about the care of these kinds of patients and who are, again, trying to share collective wisdom. I think that is really the intent of this.

DR. HINKLE: I would add that peer review process to me, and I think to the greater world, is your clinical judgment so a pharmacist can't understand what your clinical judgment was. That's really what peer review

is about is the clinical judgment.

I agree with you that you're trying to form teams and all that but you can't expect, as I said, the pharmacist so that's how it's used, at least, broadly. In my industry, and I think around the world, it's kind of understood to be that.

You uniquely have your clinical judgment. Gus could look at your clinical judgment and say, "What did you do here?" but I don't think anybody could unless they are trained in your clinical field.

MS. GALVIN: I would have to add that even in our institution the term "peer review" does mean a sentinel event is reviewed by a group and presented in that way.

DR. MAYER: I think the words have a lot of stuff hanging off them that is where we get different mental images of what it is we are actually involved in.

DR. HINKLE: I mean, if it's a QA conference in most hospitals that is not

discoverable. It's protected, I think, in every hospital in this country at least. As long as it's a QA you don't need the peer review.

DR. MAYER: Not Florida.

DR. HINKLE: What was that? Not Florida?

DR. MAYER: Not Florida.

DR. HOYER: Okay. So, anyway, I think the peer review if that was the reason it was put in there these should be protected.

CO-CHAIR KOHR: The only other question I had was whether we need to insert surgical in there because if you put it as it stands, I could think that we have a QI for the ICU and there is nothing that reflects that it's an M&M. I mean, we are all talking about M&M conference but you are trying to stick with new lingo. I wonder if we need to put the word "surgical" in there?

DR. GHANAYEM: I actually wouldn't because, I think, if we are going to approach

this as a team every aspect has touched the patient; anesthesia, critical care, cardiology, surgery, it should not be limited to a surgical conference. We do ours monthly and we will do cath lab cases sometimes and we'll do surgical cases.

We'll do the case that will provoke the most discussion to change the system, adjust the system, review the outcomes. I wouldn't just say surgical because there is more than just the surgeons that are touching the patient.

DR. J. JACOBS: I agree 100 percent. We purposely did not say it was a surgical conference because it's a team sport and we want all members of the team there to discuss how to do better the next time.

MS. NUGENT: I have one other question just for clarification. In the measure that you've drafted there is opportunity for improvement and you've called out these stats of 76 percent of responding

institutions presented deaths. Only 50 percent presented all the complications in their M&M conferences. Only 56 percent of these institutions deemed attendance mandatory.

I guess what we're saying is that in this measure we're at least saying participation is encouraged. Just as sort of a lay person I'm looking at this as are we going to be able to increase the percentage of reports or that is just a side issue and really it's going to increase quality of care just through participation?

DR. J. JACOBS: I think the reference shows that this is being done inconsistently across the country so there is variation in pattern of implementation of this concept. I think that very active saying that this is one of the indicators that is endorsed by NQF will increase the likelihood that people actually do this.

I think it's beyond the scope of

what we are trying to accomplish for us to detail exactly who wants to be sitting at the table and exactly how frequently it is and exactly what the format for those discussions should be. I think quality of care will improve just by having those discussions period.

CO-CHAIR KOHR: So I think we are ready for a vote. Recommend for time-limited endorsement with conditions and that would be a change in the title of this measure to something like, "Regularly scheduled, at least quarterly multidisciplinary quality improvement and assurance cardiac care conference."

Oh, geez. Okay. "Regularly scheduled, at least quarterly -- okay, you can put it in the description, "Quality improvement and assurance cardiac care conference." All those in favor, please raise your hand.

Okay. "Regularly scheduled -- and

we decided to put the time in the description which would be at least quarterly -- multidisciplinary quality improvement and assurance cardiac care conference." We didn't want to put surgical in there. Right. All those in favor? Twelve out of 12. Thank you.

The next measure, which is 05, is also presented by Lisa.

MS. NUGENT: The title of this measure is, "The availability of a TEE -- I'm not going to try to pronounce that. "The availability of a TEE for pediatric and congenital heart operations."

And the numerator is whether or not TEE is available. Our group seemed fairly easy to endorse or recommend because it's a device that is currently in use and it's proven to improve quality of care and cost effectiveness. It's a device that provides unique visibility for the care team and guidance for the surgeon during the procedure. Who wouldn't want that?

CO-CHAIR KOHR: All right. Is there any discussion around this measure? Okay. It looks like we're ready to vote. Recommend for time-limited endorsement. All in favor, please raise your hand. Okay, 12 out of 12.

The next measure is going to be presented by Mark.

DR. M. JACOBS: Is there any possibility that measure qualifies for a non-time-limited endorsement considering published data that proves regular availability of use.

CO-CHAIR KOHR: I think that goes to the NQF group. I mean, that wasn't one of the options that we had.

MS. HINES: I think the other thing would fall in it hasn't been publicly reported yet so you may want to just leave it and get some more data. That's a good question.

DR. M. JACOBS: Thank you.

DR. HOYER: Okay. Thank you.

I'll do measure No. 6.

DR. GRAY: Sorry. Just a point of procedure. Since I wasn't actually in the room for the vote, can you actually say 11 out of 12?

CO-CHAIR KOHR: Oh, I'm sorry. I thought you were in the room.

DR. GRAY: I said Howard.

CO-CHAIR KOHR: Oh, Howard wasn't. Oh, then you have to do 11 out of 12. Sorry.

DR. GRAY: Sorry.

CO-CHAIR KOHR: I didn't realize he went out of the room. Yes, he did but I didn't see him walk out.

PARTICIPANT: He probably went to check out of the room because we've got to be out of our rooms by noon.

CO-CHAIR KOHR: Oh, okay. And there he is.

We already voted and I didn't realize you weren't here.

Do people need to check out

because we can take a break real quick? Okay. Why don't we do that before, Mark, you present. I know you're all ready and anxious.

(Whereupon, the above-entitled matter went off the record at 11:47 a.m. and resumed at 12:30 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

12:30 p.m.

CO-CHAIR KOHR: So, Mark, why don't you go ahead and get started presenting the next measure. There's two people from our group that are gone who are intimate with those. Sylvia is the only one who would need to get caught up.

DR. HOYER: Are you all set?

CO-CHAIR KOHR: I'm all set.

DR. HOYER: Okay. Sounds great. Thank you. So this is measure No. 6, "Availability of an institutional pediatric Extracorporeal Life Support, or ECLS, program for pediatric and congenital cardiac surgery patients."

The numerator statement is whether or not a facility or institution has an ECLS program for pediatric and congenital cardiac surgery. Again, the information, as with the other measures, will be tracked at one and four-year time intervals.

The only exclusions are the usual exclusions that have been mentioned with all of the other outcome measures, for the most part, with any operations that are not pediatric or congenital.

It's a dichotomous score. You either have the program in place or you don't. There is a thought that maybe a passing score defines better quality. This is a structure measure.

Basically just to summarize a little bit, post-operative care of cardiac surgery patients can be complicated by severe ventricular dysfunction or cardiac arrest requiring Extracorporeal Life Support, or what is called ECLS.

Also, cardiac failure from things like cardiomyopathies may result from a variety of causes and those include viral induced, drug induced, or even hereditary reasons. In those types of situations other forms of ventricular assist devices can be

life saving and have been proven to be such.

Unfortunately, due to patient size limitations in a smaller pediatric population the use of such mechanical assist devices is limited and not readily available so that ECMO, or extracorporeal membrane oxygenation, has become the primary method for providing cardiac assist in those situations. The specifications for this particular measure was really clearly stated and it seemed to be complete.

The STS database has been in existence for several years. I'm talking now about some of the strengths of this particular measure. They have shown evidence to track information clearly. There is no doubt about that. The feasibility of this has certainly been very proven and would be highly ranked by us in the subcommittee.

There have also been numerous publications on the effectiveness of the ECLS and increasing survival in heart surgery for

pediatric and congenital heart disease patients so the importance and value of this measure is clear we believe.

There is also a registry called ELSO which is the Extracorporeal Life Support Organization, which also regularly reports data to contributing institutions. We had several discussion points that I'll outline just briefly. While we realize that the ELSO reports, ECMO results for all institutions the STS would simply track ECMO and mechanical support data specific to cardiac indications so we raised the issue of what kind of overlap there would be with the STS reporting of such information in the presence of that program ultimately and how much gets overlapped with the ELSO reports that currently exist.

We discussed how this measure would, therefore, also be reviewed by institutions where ECLS may not currently exist and where some pediatric and congenital

heart surgeries are currently being done.

Some of us felt that the institutions performing lower complexity cases, say maybe VSD, ASD, straightforward tetralogy, they might not feel the need to fund such a high cost program such as ECMO, for instance.

In that case it was thought that maybe even access to a regional or nearby ECLS program might be sufficient. On the other hand, though, we recognize that the need for ECLS exist even for patients whose procedures are straightforward so that, in other words, you may have a lower complexity procedure and not anticipate the need most likely for ECLS support when, in fact, you may need it and whether we would be able to get one quickly enough would be an important issue.

Finally our discussion centered on patient safety and so for public purposes we thought it would be extremely useful to know which programs had ECLS programs in place for

such complex cases but as well as for the easier cases when unanticipated circumstances do occur.

As stated throughout many of the measures, there have never been any formal studies to test quality metrics for validity and reliability, at least within the field of pediatric cardiac surgery. However, there is established information regarding reportability from, for instance, the ELSO registry which currently exist.

So while we kind of followed this one right up with the TEE, transesophageal echo, which Lisa stated one wouldn't want to be without, I would state that this would be another one that one wouldn't want to be without when one needs it.

We basically recommend and we gave high marks across the board for this one and felt this should be recommended for endorsement.

CO-CHAIR KOHR: Any discussion?

Okay. We'll proceed with the vote. Recommend for time-limited endorsement. All those in favor please raise your hand. Okay. We have 11 out of 11.

All right. We'll move on to the next measure. Mark.

DR. HOYER: I have a comment to NQF and it seems like this is kind of a funny way that we approach it. Do you usually do structure measures first as opposed to outcome measures or not necessarily? Random?

CO-CHAIR KOHR: Just a matter of how they come in.

DR. HOYER: Well, because if we don't endorse this next one, which is surgical volume then, of course, the other ones have to be nixed out. I'm going to present measure No. 7 which, again, is a structure measure and it's the, "Surgical volume for pediatric and congenital heart surgery," so this would be all volume.

The numerator statement is the

number of pediatric and congenital heart surgery operations done. If one were to contribute to the database, one would be tracking simply the number of operations period.

Exclusions were the same. Those that are not pediatric or congenital cardiac with the idea, at least from the submission, that a higher score, meaning a higher volume would, therefore, potentially equate to better quality.

Although it was stated very clearly in the submission for this measure that there is -- while one could surmise that a higher volume would typically equate with maybe higher quality, there is a lot of variabilities that exist; operator variability and skill level, institutional facility support, etc., that might make outcomes good even with lower volume institutions. There were some references cited to support that information.

Basically we are dealing with a structure measure that talks about although I've mentioned the numerator statement, this is intended ultimately to be the denominator for all of the other outcomes that have been already discussed in the first half of this morning and some yesterday.

We kind of felt that this was something that was of high importance against which nothing else could be adequately measured. The numbers would be meaningless if you didn't have some type of a denominator in which to report them. This is kind of in some ways a straightforward thing.

By itself volume doesn't mean anything except for how it is compared with other things. We, nonetheless, felt that it was important to measure and report this information, that it was still scientifically acceptable but very usable and feasible and, therefore, we recommend an endorsement of this measure as well.

DR. HINKLE: I have a question.

CO-CHAIR KOHR: Allen.

DR. HINKLE: I always have questions. My question is this is just total volume I assume, total number of cases. I assume is there granularity in the reporting around type of tetralogy or is it just how many cases?

Wait, let me finish where I'm going with this. In a lot of complex surgeries the evidence is emerging that volume is important maybe by surgeon and my institution, or at least in adult literature.

The question is would you be able to have volume -- the one I did was No. 19 which had the six in congenital heart disease. We have volume for each one of those procedures or not. I guess the answer is would not.

DR. HOYER: Right. I didn't state that. That is a good comment. This is not risk stratified. This is basically all comers

so this is the total volume that would be -- there is another measure that will be discussed here in a moment that is about the volume of those six benchmark cases which, of course, we discussed the outcome for it first but one would have to have a denominator for that.

We are going to provide that denominator hopefully here in just a moment about those six benchmark cases. Again, this is not risk stratified at all.

CO-CHAIR KOHR: There's the one for the six and there's also one separately for stratified so we have two other ones that we're going to be talking about. They are still in the docket.

Is there any other comments? Okay. So we'll move forward for --

CO-CHAIR JEFFRIES: can I just hear from the developers on what the benefit of this measure is over the complexity stratified one?

DR. J. JACOBS: It provides the denominator for several of the other outcome metrics. Also it provides the scope of the patients that then will be stratified into the complexity stratification metric that we're going to talk about as the next indicator.

Finally, it allows one to figure out how many operations are excluded from the complexity stratification metric. For example, RACHS allows classification of 84 percent of operations.

The Aristotle methodology allows classification of 96 percent of operations and the STS mortality score allows classification of 99 percent of the operations. None of those numbers will be known if we don't have the overall denominator so that's three reasons why we felt this was an important structural metric.

CO-CHAIR JEFFRIES: One more question. What is the reconciliation between this and the previously endorsed NQF measure

340 which is about pediatric heart surgeon volume?

DR. J. JACOBS: The difference is that this metric states that the volume needs to be classified through counting cases that are coded through a clinical database. The previous AHRQ metric classifies counting volumes through administrative database. In the packet we provided several references showing that counts coming from those administrative databases can be inaccurate.

Specifically three references that have been published in the peer review literature, one that shows that a case count from the ICD-9 codes showed a large amount of inaccuracy compared to a review of the clinical database, a second that started reviewing a clinical database and showed that it had a large inaccuracy with the ICD-9 codes that were actually coded, and a third done by CDC which concluded that outcomes analysis based on purely administrative coding is prone

to substantial misclassification. The difference between this and the previously endorsed metric is that it requires the volume to come from a clinical database.

CO-CHAIR JEFFRIES: So how does NQF deal with two measures that for all intents and purposes look similar, though they do come from different sources?

MS. HINES: I would think there are differences in the codes, too, as I recall from what the AHRQ measure has and some of the stratifiers. I know Kathy was talking yesterday about the use of the RACHS in the AHRQ measures.

Darryl, you may know more.

CO-CHAIR JEFFRIES: There's a volume measure and a mortality measure. The RACHS stratification is within the mortality measure and not in the volume which is PID-7 or one is 6 and one is 7.

DR. GRAY: One of the things is that Jeff Marshall and some others have been

having conference calls for about a year and a half trying to actually develop a crosswalk between the STS and ICD-9 diagnosis and procedure code specifically to address in part --

Well, hopefully we'll actually get to do a concordance study looking at individual patients but first just to document the overlap or occasional gaps between the ICD-9 and STS codes to identify the fact that, for example, there is no specific ICD-9 procedure code for Norwood so you end up having to figure out a combination of diagnosis and procedure codes that actually capture those.

In part we are actually trying to make sure that we can actually have a way that if you are using a database that is based, for example, on ICD-9 diagnosis and procedure codes that you can actually compare that to something like, for example, STS, and make sure that you are actually capturing the exact

same distribution of diagnosis and procedure so that is part of what we're doing.

CO-CHAIR KOHR: John.

DR. MAYER: I think there is one other intrinsic problem with the administrative claims database and that is the data that are being acquired for that purpose are being acquired primarily so that the hospitals can get paid for what services they are providing.

So there is always a little bit of risk when you start using data that was acquired for one purpose and try to use it for another purpose. I think the references that were cited here are all in the pediatric realm where there seems to be a nontrivial discrepancy between the administrative claims data and so-called clinical data. It's not confined to congenital heart surgery.

In Massachusetts we had a little bit of a natural experiment where as part of changing what institutions were allowed to do

adult heart surgery in Massachusetts under a certificate of need process there was a requirement that all institutions in the state participate in both the STS cardiac surgery database as well as the interventional cath database.

The hospitals at the same time were continuing to have to report all of their claims data to the Department of Public Health as part of how they sort of keep track of what is going on and it had some payment implications and some other things.

So, you have two concurrent patient populations that, for all intents and purposes, should have been exactly the same patients. Yet, if you compare just the denominators -- so how many patients were classified as having isolated coronary artery bypass in these two data sets, there's a 27 percent difference in the denominator.

The caveat here is that the STS data was all audited so it was quite clear --

this was in circulation the last year or so or maybe two years -- it's quite clear that the administrative claims data has got some at least potential pitfalls.

Remember who is actually putting the data in. Right? It's not the clinicians that are putting the data in for diagnosis and procedure in the hospital database. It's the people in medical records and I've been down there and I've talked to those folks.

It would be unreasonable to expect that they would have the same level of sophistication and understanding what might appear to be subtle but, in fact, are very real and really important clinical differences. I'm worried if we are just relying on administrative claims databases.

I think that is part of the reason why there is as much emphasis as there has been from at least the professional side in trying to encourage and expand the development of clinical databases where the data are

actually being captured and reviewed at all by the clinical staff as opposed to the hospital building staff.

CO-CHAIR KOHR: Lisa.

MS. HINES: I think my bigger question would be, and I understand having to have volumes set for denominators but is that public reporting? All of our other volume measures have been tied to mortality. A number in and of itself, as was said here, doesn't indicate quality.

However, you know, volume and mortality as the next two can be paired up. They match up nicely with their mortality counterparts. Certainly that adds value and context for public reporting by others.

I'm not sure that a volume measure like this in and of itself has a purpose for setting the denominator is something that would be good for public reporting out of context, I guess. It has no tie to quality.

DR. J. JACOBS: I think, first of

all, there is already an NQF endorsed indicator for reporting pure volume out of administrative databases. And we felt that that if that is going to exist there should be a parallel one coming out of clinical databases which we think will be a more accurate volume count.

MS. HINES: The AHRQ is tied to mortality and it's a paired measure. One can't be reported without the other as NQF endorsement.

DR. J. JACOBS: Second of all, we feel quite strongly that reporting of mortality without any complexity stratification should not be done. In other words, one should not ever report pediatric heart surgery outcome with the numerator the number of patients who have died the denominator just the number of cases done.

That's why we don't want to tie this to a mortality measure. But we do think it's important to know the overall number of

cases done at a program for a variety of other reasons.

It's hard to even begin to assess what the scope of a program's worth is or the quality without knowing how many cases they do. If that is not tracked, it's impossible to know how many cases are missed with the other complexity stratification tools.

I think just because we don't want to stratify -- I'm sorry, just because we don't want to report mortality based on this indicator as a subsequent outcome indicator doesn't eliminate the need for reporting this indicator in and of itself as a structural assessment.

CO-CHAIR KOHR: Mark.

DR. HOYER: I just have a question for Lisa to clarify that a little bit. I'm trying to figure out how one would publicly report the information of the outcomes without the denominator.

I'm foreseeing that somebody has -

- if you can't report the number of cases that were done and you were simply reporting, let's say, a percentage, I could see that maybe, but if you reported one death at one institution and they did two cases that year, that's 50 percent.

That's not too good. If you just said one and an institution that did 500 cases has 20 deaths or 10 or whatever, it seems that would be very misleading information so I just don't know. I'm just curious is it possible that you can't -- they have to be inextricably linked I would think.

MS. HINES: And I'm agreeing with what you're saying. We have always linked a volume measure with a mortality measure in our current endorsed measures. However, there is no mortality counterpart to this specific measure.

It's going to be a nine and it's going to be 8 links to 18, I think, and 9 links to 19 so that question is answered but

just a general volume. I'm not saying it can't go forward. I'm just saying this historically --

DR. HOYER: But the complication rates that we talked about before, too, in the outcomes measures all of those three, mediastinitis, stroke, renal failure, would have to be also tied to something with total volume. Would it not?

DR. J. JACOBS: Exactly.

DR. HOYER: Right. That's the way this ties in.

DR. J. JACOBS: That is the denominator for the four free-standing morbidity measures for which, to date, there is not complexity stratification tools developed.

In order to report mediastinitis rate, stroke rate, pacemaker rate, renal failure rate, and rate of re-operations, five of them actually, this is the denominator for those. In other words, those would just show

up as a percentage without a denominator. That is kind of part of the whole object for being a structural measure.

MS. HINES: I am just thinking paired making sure that they get reported together or something but that's different. Thank you.

CO-CHAIR KOHR: Darryl.

DR. GRAY: So, Lisa, you're saying that they -- Lisa Hines, that is, you're saying that 6 and 7 as they are now, I mean, they still do get reported. They get reported late but they get reported nonetheless. Right?

MS. HINES: Your PDI?

DR. GRAY: Yes.

MS. HINES: PDI-6 and 7.

DR. GRAY: I'm sorry. Right.

MS. HINES: The AHRQ measure. Yes. They do get reported. They do get reported as a paired measure.

DR. GRAY: I would think in order

to be able to put those numbers into context even though they have been accepted it actually really is important to actually have, to the degree possible, the parallel volume measure from STS for people to be able to, for example, look at those instances until, God willing, we ever actually get to do this concordance study to look at how accurate the administrative data actually are.

Until we do that it will really be important for people to actually have the STS numbers which probably are better to be able to -- the volume numbers to actually be able to interpret that.

CO-CHAIR KOHR: Any other discussion? Okay. We'll move forward with the vote. So please raise your hand if you are in support of recommendation for time-limited endorsement. That's 12 out of 12.

Okay. We'll move forward with the next measure. Darryl.

DR. GRAY: In the interest of time

I'll just say briefly this allows for the risk stratification to be included for what was done in measure 7. There's not much else to say about it. Just a point of clarification, I guess.

The document -- in a couple of cases it makes reference to risk adjustment and it's actually risk stratification because you're not doing any adjustment to the volumes as a function of risk categories. Beyond that there's not much to say about it, just that it's obviously not specifically endorsing any specific risk stratification scheme but just is allowing for one to be used.

CO-CHAIR KOHR: Any discussion?

DR. HOYER: Just to beat the obvious. It does say it's stratified by complexity and I think the complexity stratification versus risk stratification is a better descriptor.

CO-CHAIR KOHR: So are you recommending a change? No?

DR. HOYER: That's the way the newer version was. I think when we had our conference call there were some suggestions made to change it already so it already said that.

CO-CHAIR KOHR: Okay. All right.

DR. HOYER: The current version does say complexity.

CO-CHAIR KOHR: Yes.

DR. HOYER: I mean, obviously the complexity stratification is driven in part by perception to the difference in risk but it is still a complexity stratification so, yes, just make sure that the language always does refer to that.

CO-CHAIR KOHR: Any further discussion? Okay. We'll move forward with a vote. Those in support of recommendation with time-limited endorsement please raise your hand. Okay, 12 out of 12. We'll move forward with the next measure.

Nancy.

DR. GHANAYEM: The next measure is the operative mortality for the six benchmark operations that we spoke about, I believe, in measure 19. They have a surgical volume of the operative mortality. I'm sorry. I pulled up the wrong one. This is the surgical volume for those six pediatric and congenital heart operations that were, I think, reviewed when Allen did his review.

I think there wasn't much more that I would add on top of the discussion we had earlier. I think we need to have the volumes to be able to look at the operative mortality to provide the denominator. I think it needs to be done.

CO-CHAIR KOHR: Okay. It's open for discussion. Any comments?

MS. HINES: Just a point for the group. As we've said, the other measures, volume and mortality, have been reported as a pair. Would you want these to be reported as a pair?

DR. GHANAYEM: It makes sense to me but I have a very simplified view on the whole process so I don't have the knowledge or the foundation that all of you have in terms of why not do it that way.

DR. HOYER: So the question is: is there any other reason that you would need that volume for those six benchmark procedures. If you don't, then they could be theoretically paired is what I'm hearing you say.

You're having the volume for the six benchmark procedures and then you're going to see how many of those benchmark procedures that you do so that's an numerator. Those seem to be linked without really being useful by themselves in any other regard whereas the volume overall was different. That could be used differently for many, many different numerators. This seems like this one is tied. Again, I'm simple thinking, too.

MS. HINES: And it would be like 8

and 18 the one that you just discussed and 9 and 19.

DR. GHANAYEM: Jeff, maybe you can shed a little bit more light on that.

DR. J. JACOBS: Again, when we submitted them separately we were just following the model used by the STS adult cardiac metrics where volume is a structural metric and mortality is an outcome metric so we were just following what has already been done.

I think it's important to know both because the percentage of mortality isn't so good without knowing the number of patients involved. And also that then allows one to calculate confidence intervals. Just knowing a percentage without the denominator you can't do confidence intervals then either.

MS. HINES: I would just want to make sure that may be a recommendation down the line that the two be reported together and would like to be able to say that the group

felt that was viable that they should be reported together to show context.

CO-CHAIR KOHR: Any further discussion?

Allen.

DR. HINKLE: Really just a question not about this particular measure but maybe to the experts here whether they are ever entertaining like a coefficient of variation or some other metric to get at variation within any of these measures. Maybe I should ask at the end of the meeting. It's not relevant to this particular --

CO-CHAIR KOHR: Yes, let's finish the measures first. Is that all right?

DR. HINKLE: Okay.

CO-CHAIR KOHR: Okay. Any further discussion on this measure? Okay. We'll move forward on voting. Recommendation for time-limited endorsement with a condition of pairing 8 with 18.

DR. GHANAYEM: I think we should

condition it but I think it should be endorsed regardless of whether it's paired or not so I don't want to affect the endorsement by putting a condition on the endorsement.

MS. HINES: You can vote and we can just put in the narrative what the suggestion would be.

CO-CHAIR KOHR: Okay. Let's rephrase that. Recommend for time-limited endorsement. Those who are in support please raise your hand. Okay, 12 out of 12.

We'll move forward with the next measure. The next measure is timing of the antibiotic in administration for pediatric and congenital cardiac surgery. It is focused on the patient receiving prophylactic antibiotics within an hour of surgical incision or two hours if they are receiving Vancomycin.

It has appropriate exclusion criteria. The discussion that our group had -- and, Schonay, you can add to this -- was that this measure should be combined with No.

11 because if you don't give the appropriate dose of the antibiotic it doesn't matter what time you give it it's not going to be effective. That was basically our main comment about this measure.

I will open it up for discussion.

DR. HOYER: You said it both ways. You enter the data in the same spot. You put the time and you put the dose and so, therefore, we thought --

CO-CHAIR KOHR: It would be easy to capture this data together.

DR. HOYER: -- this was a little bit of a nuance in separating those two things. You can't really have one without the other

CO-CHAIR KOHR: I thought you were going to say something else.

Okay. Any other discussion.

MS. WILBON: I just had a quick question and clarification from your discussion yesterday. Did you want the

measures to be paired or you wanted them to be combined into one measure?

CO-CHAIR KOHR: Combined into one measure.

MS. WILBON: Okay. I just wanted to clarify that.

CO-CHAIR KOHR: Yes.

DR. J. JACOBS: That is also fine by me but, again, if I remember right, there are some antibiotic measures that are in the adult cardiac proposal that were separated out for some reason and we were just trying to be consistent with what the National Quality Forum has done in the past and clearly they did have a reason for separating out the antibiotic proposal into two metrics.

That is the reason it has then been carried out at other levels where those metrics were then adopted into PQRI as two separate metrics. So if we are going to be consistent with what NQF has done in the past and then what the federal government has done

by applying NQF metrics in the past, we would have to keep these as two separate measures.

If we combine them, we are doing something different and breaking precedent, which, to be honest, I have no strong feelings either way but we were just trying to follow what has already been done by several groups.

CO-CHAIR KOHR: Can you provide the rationale for that because, if you don't give the appropriate dose, it doesn't matter if you give it on time. I know I keep saying that. I've said it like five times.

DR. GHANAYEM: When you get one wrong, you've got it wrong.

CO-CHAIR KOHR: Yes. That's right.

DR. GHANAYEM: One wrong is both wrong.

MS. HINES: I don't disagree and I think the thinking in the past from prior measure developers have been -- it truly is two different thought patterns. It's

selecting the right antibiotic and the appropriate dosing and then the timing of the antibiotic.

The person that chooses the antibiotic is not always the one that gives it so you are really looking almost at two different entities. Jeff can certainly order it but the anesthesiologist may not give it on time. You're exactly right. If one fails and the other, there is a med breakdown but really the construct is it hits two different phases.

DR. J. JACOBS: It's a process metric and these are two different processes, both of which are required to be successful. Tracking the two as two separate processes made sense and that is, I think, why it was done that way in the past.

CO-CHAIR KOHR: Playing the devil's advocate. I'm sorry. I agree that if one person orders the antibiotic but the person who is going to give it is really supposed to be your double check to check that

it's the appropriate dose before they give it, just like the nurse does at the bedside is supposed to double check it.

So you're still checking if the process works by looking at them combined. The anesthesiologist really should be not just giving the drug that the surgeon ordered if the surgeon orders it. Usually it's the anesthesiologist who orders it, at least in our institution, but they are supposed to double check that it's the appropriate dose that they are giving on time. That's my only comment.

Mark, you had another comment?

DR. HOYER: I was just thinking again what we talked about yesterday is that it's two processes, indeed, but if there is a mistake made, it's easy to track where it occurred. It wouldn't be very difficult.

Whether it's pharmacy, whether it's nursing, whether it's delivery of a medication to patient bedside, whatever, it

would be very easy to find out if it didn't meet the standard. It would not be very difficult to sort out where the mistake occurred or where the error would have occurred.

CO-CHAIR KOHR: John.

DR. MAYER: I think in some ways this is similar to one of the earlier issues that we discussed which is what are we testing. Are we testing individual position compliance or performance or are we testing programmatic performance?

For this, if you combine the measures, you're evaluating programmatic performance which is can you order the right antibiotic in the right dose and can you give it on time. It doesn't seem to me any reason not to combine this into a single measure.

The only reason I can imagine is if somebody actually thought that this was somehow going to get linked to payment and then your payment is subject to stuff that you

can't control, then it sort of has the inherent unfairness aspect to it. I think a little bit goes to what are we trying to measure here.

Are we trying to measure programmatic performance or are we trying to measure individual components of the program performance. My own sense would be it ought to be programmatic but I don't know. Maybe there is some different perspective that we should be thinking about.

DR. HOYER: The other thing is the data comes from the same spot. It's electronically retrievable quite easily. It's very feasible and that was the point. I mean, it would be in the same data location and that was why we thought as well that it would be so easy to combine into one.

DR. MAYER: It's not a question of that. It's a question of what are the implications likely to be and what are we trying to measure.

DR. J. JACOBS: Exactly. That's what I brought up before when I mentioned when it's been used by the Physician's Quality Reporting Initiative, PQRI. It's separate metrics for those reasons. If we combine them, then we eliminate the ability to do an application like that in the future.

CO-CHAIR KOHR: Darryl.

DR. GRAY: The only other thing is that, for example, No. 11 actually talks about appropriate antibiotics whereas the other things are sort of more mechanistic in terms of timing and making sure that for whatever antibiotic is chosen that the dose is appropriate for the weight of the child.

Since No. 11 is actually dealing with selection of individual antibiotics, then there may be shifts that occur over time as different antibiotics become in or out of the selected group that makes things different --

I agree certainly that from a programmatic sampling you really want to

bundle all three components of the decision and the delivery but that, if one of these is likely to change, I don't know whether or not mechanistically that complicates matters if you've done them together. It may not.

DR. MAYER: As long as it's appropriate.

DR. GRAY: Yes.

DR. M. JACOBS: I don't think we have a very strong feeling about which of these various choices the NQF would ultimately make in terms of how to implement these. I think part of the reason that they are separated in the proposal is slightly different intent.

As Jeff said, we followed the model of the NQF endorsed adult cardiac surgery and measures of which one of these is essentially a direct reproduction, which is the timing of administration which goes to the efficacy of the drug.

I think in the adult population

there is also evidence related to the duration of the course. That, I think, is another adult measure. There is not evidence in the pediatric population on which to base such a measure so we didn't include that.

So one measure essentially mimics the applicable evidence-based issues from the adult NQF measures and the other measure is specifically related to the pediatric population. In other words, in adults barring the presence of renal failure, you simply can't go wrong with a single dose for every one of a given drug but it's a uniquely important process in pediatrics to have it weight based. It was really in relation to the precedent and the adult database and the difference of intent of the two measures, we separated them. If it's preferable to combine them, your choice.

MS. HINES: And I think that the split is not limited to the STS adult cardiac surgery measures. The SCIP measures overall

were split and I think, again, just to be able to make the distinction between the two actions for data collection and reporting. We don't have a preference if you want to put something together but that's just the history.

CO-CHAIR KOHR: Mark, did you want to say something?

DR. HOYER: I'm not sure it's worth saying but after what Darryl said, it's not specifically stated selection of the correct antibiotic. Then you start thinking about what you do as nurses as well, right?

Was it the five things? Correct patient, correct dose, correct antibiotic or correct medicine, correct time, and correct site or whatever, route of administration -- whatever it is. You literally ferret out all those things. I'm just throwing that out as something that would be really separating all of those aspects of appropriate administration of any drug.

CO-CHAIR KOHR: I guess my question is, it seems to me we've been talking about these measures as focusing on the program rather than an individual provider. It seems like this is such a different focus than what we've been looking on because I agree with John. I think this goes together.

It looks at the program and is there a problem with this, versus an individual step a provider does. I guess I still don't understand the rationale. I know what you're saying about following that and there are two different actions, but they seem so tied in terms of -- if you link them with outcomes -- that it's hard for me to get my hands around why timing would just be looked at separately.

DR. MAYER: I don't know the answer to this but maybe Jeff or Marshall does, is whether or not this is actually going to have any payment implications. That's what I was talking about, the risk that one

provider would be at risk for actions that he can't control. If that's the case, if there is a payment implication, and I just don't know those PQRI measures well enough, then I think there would be a rationale for separating them.

DR. J. JACOBS: John is absolutely right. We don't know what will be adopted in the next version of PQRI but PQRI, or the next version, which may be a more aggressive version of pay for performance. The current PQRI, the cardiac surgery indicators came directly from the National Quality Forum-endorsed pediatric cardiac surgery indicators and separating them out was necessary for that to happen.

What we do here today has far-reaching implications and multiple domains. One of those domains is that if the federal government is going to tie reimbursement to performance, ideally the performance metrics that they use are also the performance metrics

that we endorse rather than another committee in Congress deciding what the performance measure should be.

So therefore, by keeping them separate one allows for this process to eventually be utilized by the federal government should they choose to do so.

CO-CHAIR KOHR: Correct me if I'm wrong -- because, Marshall, you mentioned this but maybe I misunderstood -- does the adult counterpart to this look at the number of doses as well because there is data to support that or is it just the single dose? We are just looking at a single dose. Maybe I misunderstood. I thought they looked at the whole -- is that wrong?

DR. J. JACOBS: Several adult metrics exist related to antibiotics, some of which revolve around the timing of the dose, some of which revolve around the dose itself, and some of which revolve around how long the antibiotics are continued.

We did not include in ours how long the antibiotics were continued because the evidence base does not exist in pediatrics for that as opposed to adults where there is multiple peer review publications that provide an evidence base for the length of using the antibiotics.

The other thing to keep in mind is that STS has proposed that outcome measures are reflective of a team sport and they are at the hospital level but process measures can be tracked at the provider level and that is what allows the process measures to then be adopted by the government rather than having to create their own. I think based on all of those, I think, there are several compelling strong reasons to keep these as two separate metrics.

MS. HINES: And I actually did the cardiac surgery measures for the individual positions working with Fred Edwards. We took the endorsed facility level and they were able to break out and unroll to the individual

position level. I think looking at feasibility that's what you really are looking for, an individual physician level that can roll up to a hospital and vice versa.

If CMS looks at us to come up with measures as we did in that project, the first thing that we went to was to go to the facility levels and say can these work at an individual level and they could because of the split so it is something to then consider.

CO-CHAIR KOHR: Is there any other discussion? Okay. We'll move forward with voting on the measure. Those in favor of recommendation for time-limited endorsement please raise your hand. 12 out of 12. Okay.

Schonay, do you want to present your -- I know we talked about it but just a brief overview. We need to vote on it.

MS. BARNETT-JONES: PCS-011-09, the measure counts for the percent of patients undergoing pediatric cardiac surgery with a body weight appropriate for prophylactic

antibiotics. The subcommittee discussed this measure and determined that body weight is not independent of timing and dosage which are the central theme from PCS-010-09 which we just discussed.

Based on that, do you want to put the questions back on the floor? Since the recommendation from the committee was to combine and now that seems not to be the case so let's put it back on the floor for questions.

CO-CHAIR KOHR: Any discussion about this measure? Okay. So we'll go ahead and move forward with the vote. Those in favor of recommendation for time-limited endorsement please raise your hand. 12 out of 12. Okay. We're done.

MS. HINES: Through this discussion over the last couple of days we have had some research recommendations that have come to light adding risk adjustment to some of the measures. I certainly think this

last discussion of kind of an overall picture of medication could be a recommendation as well, listed as a research recommendation. If there is anything else that came up in discussions that we should note, we would like to hear them.

DR. GRAY: I'm wondering so, for example, with this is there -- when you say it's research -- is there any potential thought of adding another measure that would actually combine them? I guess you don't necessarily want to do that.

In a sense it almost turns it into a composite measure which I guess would be one way of addressing that the sort of programmatic thought would be -- if you turn it into an all-or-none composite, then that basically achieves the same purpose that would be achieved by having the two measures combined.

I'm not sure if that is a way of getting around that. Therefore, you don't

necessarily -- well, if you want to have an additional measure that actually is a composite, that would be a mechanism for doing that. I don't know if we necessarily want to go as far as that. We certainly don't need to make a recommendation now to do that. I'm not necessarily suggesting that.

MS. HINES: And the research recommendations, I'll let you know, kind of become the field for measure developers to look to see what are the measures that need to be developed. Where are there gaps and where are there tweaks that need to be made.

While we certainly don't make promises that everything that ends up in the research list becomes a measure, it is kind of a first stop for most folks to go and look and say what's been noted.

The other composite-type thing that we heard were some of the structure measures when you were talking about rounds and the conferences and those type of things.

I'm not sure if you would like that listed as a potential future measure.

DR. M. JACOBS: May I respond with a comment to the suggestion about composite measures? I think as a quality assessment program or project matures, I think composite measures become an incredibly useful tool.

But I think there was a very important discussion held around the survival free of significant morbid complications measure that we had proposed. It was appropriately recognized that was in the absence of an aggregate or the absence of any one element of the aggregate and was not referred to as a composite measure.

The STS congenital database is working in a research perspective to develop composite morbidity measures. I think from the viewpoint of a statistician, the challenge of a composite measure is appropriate and valid weighting of the elements of a composite so that one knows how to score compliance or

performance when some of the issues are fulfilled or present and some are not fulfilled or absent.

If one chooses to lump and aggregate measures, if you truly want to consider it a composite, then there has to be some implicit, preferably evidence-based method of weighting the contribution of the components.

It's really for that reason that we separated some of these things that are clearly associated thematically and clinically but are not yet able to be associated as a composite from an evidence-based statistical standpoint and it's a great research proposal because it's exactly what we're working on for the future but there hasn't been enough analysis of data to achieve that yet.

DR. GHANAYEM: Marshall, I completely agree but don't you think that some of these structure measures that we talked about are already incredibly challenging in

terms of measuring the true impact on them? Because they are not being track in the thoroughness that you need to decide whether there is an impact.

I think that does hold true for some of the measures but I don't think it holds true for all the structure measures where we are just talking about the conferences, particularly. Because I don't know how you can analyze that statistically.

DR. M. JACOBS: Which is why those are related to structure and descriptive, I think, rather than process which infers that you can eventually draw outcome conclusions from the analysis.

MS. NUGENT: One of the goals that was mentioned yesterday was in regards to quality of care was -- a parent definitely cares if they are bringing their child home from the hospital but is that child going to be able to graduate from college, have a family. I know we are early on in the

tracking but I hope that there are measures that are being thought of or developed that can track over a period of time. Maybe we do have them. I just want to put that on the record.

DR. J. JACOBS: I think what you're talking about is of huge, massive importance and there has been a substantial effort by the STS to create a platform where the database can be used to facilitate longitudinal follow-up over time and answer those questions for adult cardiac surgery, for adult thoracic surgery, and for pediatric and congenital heart surgery.

It's been a process to get to the point where that can be done because we have to find a way to do it without violating the regulations associated with HIPAA because longitudinal follow-up means knowing somebody's identification and unique identifiers but we have worked out ways to do that.

We have implemented strategies within our database. The STS adult cardiac database has been collecting unique identifiers since January 1, 2008, the thoracic database since January 1, 2009, and the pediatric database will start collecting them in about six weeks on January 1, 2010.

Those unique identifiers allow one to track how a patient is doing over time, whether they're alive, whether they're dead, and what their functional status is, what interventions they've required, and what medications they might need over time. All the pieces are in place to start doing that.

We now have data back from the STS adult cardiac database from those analyses and we have been able to link close to 100,000 coronary bypass operations to the Social Security Death Master File and find out their life status one year after the operation.

That's something we've never been able to do with the STS database and we are

going to be able to do that with the pediatric database really soon. Once we have that data then we can be able to propose quality metrics based upon that data.

I think that is priority number one for us, to be quite honest. That initiative combined with the public reporting initiative of the STS database is really two of the areas that we are most aggressively working on right now.

MS. HINES: How about from a parent perspective, what don't we have that you would like to see?

MS. BARNETT-JONES: I feel quite relieved today to just have had, number one, been able to participate and, number two, to have brought the family perspective to that and to have the family included in rounds. For me that is very, very critical as I've mentioned before.

I think Lisa is very much on point in terms of going forward, you know, what

should we expect. So many times I hear from my medical team, Olivia's medical team, my medical team as well, that pediatric research and so forth lags 10 years behind that of the adult world.

I hear that a lot and to be able to at least have some concrete measures so that I know in 10 years when she gets to be a teenager there will be something in place that we can start to look at from a lifestyle what her life expectancy can continue to be.

Again, without putting these types of measures in place to be able to track that and have some data, not only for her but for all the children who, you know, are in that same position coming behind, again, we are drawing the line in the sand. I'm very pleased that we are drawing such a high line and high bar to measure against. I'm pleased with that so far.

CO-CHAIR KOHR: John.

DR. MAYER: Jeff didn't say

specifically, although I know he knows it so I'll just say it for him. One of the other efforts is not only to link to the Social Security Death Master File or National Death Index or any of the other things so we can find out whether patients are still alive or dead.

Also in parallel with that there is a major effort now to link with unique patient identifier information the emerging American College of Cardiology pediatric cardiology database which is sort of in its final formative stages with the STS data.

So that, as those patients are being seen in follow-up one year, five years, 10 years after an operation that we might have done when the child was a newborn or something like that, there will be that longitudinal follow-up.

That is one of the major, I would say from a 30,000 foot level, the major effort that the STS is making in its database effort

-- is to convert it from just being a 30-day outcome or hospital discharge mortality, morbidity database and really turn it into a longitudinal database.

I mean, I think it makes sense clinically, biologically. I think it makes sense from a public policy perspective. We have invested a fair amount of time and effort in making sure that happens. I can tell you this.

I don't know who, if anyone, in here is a privacy advocate, but I'll tell you there are some major roadblocks that have been thrown up. There has been a lot of mis- and disinformation about this. I think we've got the mechanisms to do this now so you can sort of strip off the identifier when the data -- this is my simple-minded way of conceiving of it.

The data comes into our data warehouse and the unique identifier information gets stripped off but can

ultimately be linked back so the only way that any data in the database gets out is that the patient is in the database. That's the only thing that could potentially ever be findable without hacking into the Duke warehouse.

You know, in the broader perspective, and I'm saying this a little bit to get it on the record here, too, is this, like almost everything else we do, is not without its problems and its unintended consequences and, I think, sometimes I would argue over-the-top issue about privacy can bring its own set of difficulties in understanding what long-term outcomes are, as a for instance.

I think, you know, there are a lot of things that have these sort of, as I say, unintended consequences and I think we should have to be thinking about those going forward and not just look at it from one perspective.

MS. BARNETT-JONES: Absolutely. I think you are very much on point with that.

I think our overall goal is positive outcomes and that is what we are all striving for.

There absolutely are some best practices that can be gleaned and as we go forward be able to apply some of those best practices to institutions across the country so that we can repeat the things that work and those things that don't work or that we need to go back and rework, we put them back into the process and do that.

Like I said, I think we have set a very high bar. I absolutely understand HIPAA and the issues associated with HIPAA but from a family's perspective, when you are kind of in the trenches, what you are looking for is what does this mean? What does this mean long-term? Will this child have a childhood? At the end of the day will they walk out of here? Will they be able to play and color and laugh and go to the zoo?

They sound kind of trivial on one respect but not being able to do that and when

that opportunity is not there you do understand the value of having those opportunities. So I absolutely agree that the challenges are there but I think that the benefits far outweigh those challenges.

DR. MAYER: This doesn't have to be on the record. I think it's been extremely valuable to have you here. I think your perspective for me, personally, and, I think, for the whole process has really been very valuable so I'm glad you took the time and effort to be here.

MS. BARNETT-JONES: Thank you.

MS. WILBON: We do actually have one more opportunity for public comment. I'm not sure that anyone is there.

Operator, can you hear me? Are you there? Operator?

OPERATOR: There are no questions at this time.

MS. WILBON: Okay. Thank you. Is there anyone on the line?

OPERATOR: No, ma'am.

MS. WILBON: Okay. Thank you.

Actually just a couple logistical things. Before you guys pack up, if you could remember to give us back your USB port whether or not you had the opportunity to save the updated measure evaluation forms. Again, if you weren't able to complete it, that's fine. We'll send out a reminder e-mail so that the primary reviewers can get that back to us.

I'm trying to think if there is anything logistical I can think of. Oh, yes. I think I mentioned a few times we'll be compiling all the information. We've got transcripts to go through, we've got audio to go through so it may take us some time to get everything compiled and back to you out for review but that will be part of the process to e-mail the pertinent points back out so you guys have the opportunity to add anything we may have missed and then that will go out for public comment.

We will also have a follow-up conference call to resolve any extra issues. We'll be communicating with the Jacobses to make sure that we get all the recommendations and come up with a process so they can submit that information back to us and we'll have a follow-up conference call and we'll get that information back out to you for your final review and then we'll have a final conference call, or another conference call to discuss those changes and make sure you have a final approval on what was resubmitted.

Then, again, that will go out for public comment and then we'll have another conference call to discuss the public's comments on your decisions here and your recommendations for the measures that were proposed. That is kind of what's on the horizon.

If anyone has any questions, Tina and I and Sarah will be available pretty much anytime so feel free to e-mail us. I think we

would just like to thank everyone for participating. I think we had some really good discussions and we are really excited about putting these measures out, especially them being some of the -- well, in addition to AHRQ's two measures but having a little bit more robust portfolio for the pediatric cardiac surgery community. Thank you, everyone.

MS. HINES: And don't forget measure 21, I know the developers have already reached out to try to get that and see what we can do about coming up with a modified measure. Just as a point of reference. If that, for whatever reason doesn't work out, we still have 21 that we would need to discuss and vote on, the freestanding measure from Boston so we'll keep you posted on that.

CO-CHAIR KOHR: On behalf of Howard and I, we really appreciate all of your input in giving up these two days and coming here to really hash out these measures. I

think we've had a really fruitful two days and I'm real excited about this.

CO-CHAIR JEFFRIES: I agree with what she said.

(Whereupon, at 1:36 p.m. the meeting was adjourned.)

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