

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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Adjourn

1 P-R-O-C-E-E-D-I-N-G-S

2 8:07 a.m.

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

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

14 DR. LOPEZ: Good morning. Mr.  
15 Chairman and members of the Steering  
16 Committee, Workgroup B met yesterday to  
17 discuss outcome measures and one of those was  
18 013, mediastinitis after pediatric and  
19 congenital heart surgery.

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

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

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

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

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

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

1 following signs or symptoms with no other  
2 recognized cause, fever, hypothermia, apnea,  
3 bradycardia, or sternal instability and at  
4 least one of the following, peritoneal  
5 mediastinal drainage, organisms cultured for  
6 mediastinal blood, drainage, or tissue, and a  
7 widening of the cardiomeastinal silhouette.

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

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

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

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

9 CO-CHAIR JEFFRIES: Thank you.

10 Any comments from either group?

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

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

22 There's a list of operations in

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

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

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

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



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

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

12 DR. GRAY: Yes. Thanks.

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

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

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

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

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

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

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

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

19           There is no stratification or risk  
20   adjustment specified.

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

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

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

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

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

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

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

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

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

1 may have been later.

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

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

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

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

4 CO-CHAIR JEFFRIES: Right.

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

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

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

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

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

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

22 Dr. Jacobs?

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

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

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

14 CO-CHAIR JEFFRIES: So the  
15 language was confirmed.

16 DR. J. JACOBS: Right.

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

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



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

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

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

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

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

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

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

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

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

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

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

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

1 required dialysis prior to surgery.

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

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

12           CO-CHAIR JEFFRIES: Any  
13 discussion?

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

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

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

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

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

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

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

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

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

1 occur has high value to be noted.

2 CO-CHAIR JEFFRIES: Dr. Mavroudis.

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

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

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

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

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



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

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

16 CO-CHAIR JEFFRIES: Jeff.

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

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

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

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

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

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

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

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

22 For some of the same reasons that

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

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

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

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

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

11           CO-CHAIR JEFFRIES: Yes.

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

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

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

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

11           DR. HINKLE: I would just like to  
12 clarify and make sure my point was clear that  
13 it was purely from the public reporting  
14 perspective. From my perspective, I think,  
15 the public does understand the difference  
16 between 1 and 4 percent mortality.

17 Fortunately, you know, the healthcare system  
18 has advanced so significantly in this country  
19 they do understand that.

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

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

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

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

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

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

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

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

22           DR. M. JACOBS: Howard, I want to



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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 well demonstrated in New York State.

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

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

20           CO-CHAIR JEFFRIES: Lisa.

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

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

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

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

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

1 discuss that in our group yesterday.

2 Certainly that would add an N.

3 Just don't forget that's coming up, too. I

4 would assume that those are for quality

5 improvement purposes broken down by the

6 individual measures within them.

7 DR. MAYER: I mean, every one of

8 these things that is on here is tracked in the

9 STS database so we are collecting the

10 information. Part of the process is the

11 information is collected and fed back. I

12 think from our perspective that is what drives

13 improvement as much as anything else.

14 There is no more powerful

15 motivator than seeing how you or your

16 institution compares to your peers around the

17 country. That is the whole basis for which

18 the databases were constructed which they have

19 been shown to actually yield the results that

20 we are hoping.

21 You look in the adult world the

22 expected mortality is doing this and the

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

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

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

22 The problem with that, of course,



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

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

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

15 DR. MAYER: Right.

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

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

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

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

18 CO-CHAIR JEFFRIES: Dr. Jacobs.

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

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

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

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

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

1 out how frequently each of the subcomponent  
2 complications occurred.

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

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

17           CO-CHAIR JEFFRIES: Yes, Dr. Gray.

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

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

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

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

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

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

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

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

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

1 get used.

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22           MS. HINES: But I think because we

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

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

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

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

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

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

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

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

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

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

1 kind of gives you both in a nutshell.

2 CO-CHAIR JEFFRIES: Just one last  
3 comment.

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

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

22 MS. HINES: Darryl, it's been like



1 20 to 30 percent -- 20 to 30 cases because  
2 then you get into confidentiality issues in  
3 other reporting systems.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

19 (Off-mic comment.)

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

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

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

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

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

22 The denominator is the number of



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

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

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

1 discussion the subgroup recommended to put  
2 forward this measure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 CO-CHAIR JEFFRIES: Open it up for  
12 discussion.

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

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

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

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

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

22 Based on a limited experience in a

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

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

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

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

1 mitral valve falls apart or whatever.

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

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

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



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

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

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

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

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

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

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

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

1 change in the title.

2           The way the complications are  
3 coded in the STS database are unplanned re-  
4 operation during this admission or unplanned  
5 catheter intervention during this admission.

6 If the title of the measure that we are  
7 proposing were amended to unplanned cardiac  
8 intervention during this admission, which  
9 would be inclusive of re-operations and  
10 catheter interventions, it would exclude  
11 planned re-operations. It would include the  
12 catheter interventions and it would address  
13 the vagary of the title. I think all three  
14 points would be satisfied by a title change.

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

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

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

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

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

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

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

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

7 CO-CHAIR JEFFRIES: Is that title  
8 okay?

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

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

1 intervention.

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

4 DR. J. JACOBS: Yes.

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

12 DR. GHANAYEM: As separate  
13 measures.

14 MS. HINES: Yes.

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

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

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

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

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

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

1 this measure.

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

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

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

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

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

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

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

1 Zero votes for no.

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

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

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

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

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

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



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

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

13           CO-CHAIR JEFFRIES: Any discussion  
14 on this measure?

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

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

1 MS. HINES: Okay.

2 CO-CHAIR JEFFRIES: And one other  
3 difference. Correct me if I'm wrong here but  
4 you have to survive to be counted in 20. With  
5 the other ones if you die you would still be -  
6 -

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

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

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

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

8 CO-CHAIR JEFFRIES: Dr. Gray.

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

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

22 DR. GRAY: I'm talking about the

1 denominator does not necessarily exclude  
2 patients who died.

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

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

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

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

17 CO-CHAIR JEFFRIES: Thank you.

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

22 MS. HINES: And just as a matter

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

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

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

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

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

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

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

19 MS. HINES: That's cool. Thanks.

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

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

6           We're a few minutes early so why  
7 don't we take our break a little early and  
8 then when we come back we'll start on the  
9 process measures. We'll start up at 10:00?  
10 Or do we need to open it for public comment  
11 now? Wait until 10:00? Okay. We'll come at  
12 10:00 for public comment and then we'll start  
13 on process measures after that. Okay. Or we  
14 can come back in five minutes and start on  
15 process measures. Okay.

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

19           CO-CHAIR KOHR: Okay. We will go  
20 ahead and get started on the process  
21 instruction measures. We are going to go to  
22 02 because Darryl is the primary for 01 and

1 I'm the primary reviewer.

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

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

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



1 means in terms of information being provided  
2 to the public.

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

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

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

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

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

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

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

1 should happen.

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

9           DR. MAVROUDIS: May I?

10          CO-CHAIR KOHR: Yes.

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

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

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

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

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

18 CO-CHAIR KOHR: John.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

22 I gave the example yesterday I

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

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

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

22           We can wordsmith this in a way

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

7 CO-CHAIR KOHR: Is there anymore  
8 discussion?

9 Mark.

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

12 CO-CHAIR KOHR: Oh.

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

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

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

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

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

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

3 CO-CHAIR KOHR: I think Mark was  
4 first.

5 Did you have something you wanted  
6 to say?

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

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

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

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

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

15           CO-CHAIR KOHR: John.

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

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

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

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

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

1 improvement I would say.

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

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

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



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

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

12 DR. MAYER: This is a structure  
13 measure.

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

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

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

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

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

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

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

5 CO-CHAIR KOHR: John.

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

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

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

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

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

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

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

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

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

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

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

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

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

7 DR. GHANAYEM: That is the post-  
8 operative.

9 MS. HINES: Yes.

10 CO-CHAIR KOHR: Allen.

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

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

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

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

9 Is there any other discussion? I  
10 think that --

11 Go ahead, Lisa.

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

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

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

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

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

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

22           They do not have multidisciplinary



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

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

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

22           DR. J. JACOBS: I'm submitting it

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

6 CO-CHAIR KOHR: Okay.

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

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

17 DR. MAVROUDIS: You don't.

18 CO-CHAIR KOHR: -- my  
19 conference --

20 DR. MAVROUDIS: You don't.

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

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

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

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

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

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

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

17 CO-CHAIR KOHR: John.

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

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

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

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

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

1 a reasonable example.

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

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

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

1 thing.

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

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

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

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

22 However, then if one program had a

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

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

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

20 CO-CHAIR KOHR: Yes, Lisa.

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



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

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

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

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

22 DR. HOYER: Then there's

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

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

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

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

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

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

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

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

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

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

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

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

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

19           Darryl.

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

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

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

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

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

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

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

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

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

20 Operator, are you there?

21 OPERATOR: Yes, ma'am.

22 MS. WILBON: Is there anyone on

1 the audience line?

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

4 MS. WILBON: Okay. Thank you.

5 OPERATOR: You're welcome.

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

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

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

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

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

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

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



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

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

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

22           The usability was certainly felt

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

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

13           CO-CHAIR KOHR: Any discussion?

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

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

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

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

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

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

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

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

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

19 CO-CHAIR KOHR: Any other  
20 comments?

21 John.

22 DR. MAYER: Well, only that I

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

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

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

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

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

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

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

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

1 participation is based on the STS database.

2 Yes, Dr. Mavroudis.

3 DR. MAVROUDIS: No, I'm voting.

4 CO-CHAIR KOHR: Oh, okay. Please  
5 raise your hand if you're in support. We have  
6 12 out of 12. Thank you. So we'll go ahead  
7 with 03 which is Nancy's.

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

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

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

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

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

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



1 listed in here.

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

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

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

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

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

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

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

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

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

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

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

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

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

4 DR. GHANAYEM: On a daily basis.

5 DR. J. JACOBS: Pardon?

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

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

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

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

16 DR. GHANAYEM: Sure.

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

1 team does.

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

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

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

1 nurse, and the respiratory therapist on every  
2 patient.

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

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

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

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

12 DR. GHANAYEM: That is not what  
13 this says.

14 DR. J. JACOBS: Suggest a  
15 revision.

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

18 DR. J. JACOBS: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

17 DR. J. JACOBS: Daily patient care  
18 discussion.

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

1 Multidisciplinary to me is more than one.

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

5 DR. HOYER: Right.

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

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

13 CO-CHAIR KOHR: Right.

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

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

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

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

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

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

21 DR. J. JACOBS: I agree  
22 completely.

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

4 DR. J. JACOBS: Multidisciplinary  
5 rounds --

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

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

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

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

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

19 MS. BARNETT-JONES: Understood.

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

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

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

8 DR. J. JACOBS: Oh, yes.

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

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

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

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

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

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

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

13 MS. BARNETT-JONES: I agree with  
14 that.

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

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

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

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

11 DR. J. JACOBS: I like that.

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

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

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

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

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

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

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

22 DR. J. JACOBS: Right.



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

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

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

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

22 DR. MAYER: I think the reality of

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

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

7 DR. MAYER: Surgeons have to go to  
8 the operating room and anesthesiologists have  
9 to go to the operating room and the  
10 pharmacists may not work, you know, 6:00 to  
11 4:00 or something like that. Not everybody is  
12 as nutso as the docs who work 12, 14, 16-hour  
13 days.

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

22 DR. GHANAYEM: Yes.

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

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

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

19 CO-CHAIR KOHR: Go ahead.

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

22 CO-CHAIR KOHR: I did. I wrote it

1 down already.

2 DR. J. JACOBS: Excellent.

3 MS. BARNETT-JONES: I'm sorry.

4 Not to be a stickler but if we put, "Family

5 participation is welcomed and encouraged,"

6 instead of saying, "To include the family as

7 a member of the healthcare team," I think it

8 makes a much stronger statement.

9 DR. J. JACOBS: I agree with that.

10 DR. HOYER: With all due respect

11 again, I mean, I would have to take a little

12 issue with that because the family will not

13 always be there. We happen to know that.

14 Sometimes given the level of

15 people's education there are certain things

16 that are difficult to talk about in rounds

17 with the entire group and the family because

18 it's a different type of discussion that's had

19 with the family there as compared to when the

20 healthcare professionals are there.

21 DR. J. JACOBS: We could say,

22 "Inclusion of the family as a member of the

1 healthcare team is welcomed and encouraged."

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

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

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

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

22 CO-CHAIR KOHR: Absolutely. I

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

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

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

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

6 CO-CHAIR KOHR: Absolutely. Any  
7 other discussion?

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

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

1 and just making that clear.

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

9           CO-CHAIR KOHR: John.

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

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



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

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

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

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

1 as a structural measure.

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

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

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

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

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

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

22 Okay. So we'll go ahead and move

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

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

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

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

1 operations.

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

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

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

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

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

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

16           I'll open it up for other comment.

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

1 an M&M is.

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

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

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

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

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

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

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

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

1 undergoing surgery for pediatric and  
2 congenital heart disease.

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

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



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

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

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

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

22           The term peer review, you're

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

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

15 CO-CHAIR KOHR: Thank you.

16 Allen.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 DR. J. JACOBS: Quarterly.

1 CO-CHAIR KOHR: Quarterly?

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

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

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

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

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

1 peer review conference. That's all.

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

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

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

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

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



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

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

17 CO-CHAIR KOHR: John.

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

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

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

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

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

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

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

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

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

1 is about is the clinical judgment.

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

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

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

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

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

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

5 DR. MAYER: Not Florida.

6 DR. HINKLE: What was that? Not  
7 Florida?

8 DR. MAYER: Not Florida.

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

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

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

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

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

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

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

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

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

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

22 I think it's beyond the scope of

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

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

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

22 Okay. "Regularly scheduled -- and



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

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

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

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

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

7 The next measure is going to be  
8 presented by Mark.

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

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

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

21 DR. M. JACOBS: Thank you.

22 DR. HOYER: Okay. Thank you.

1 I'll do measure No. 6.

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

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

8 DR. GRAY: I said Howard.

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

11 DR. GRAY: Sorry.

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

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

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

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

22 Do people need to check out

1 because we can take a break real quick? Okay.

2 Why don't we do that before, Mark, you

3 present. I know you're all ready and anxious.

4 (Whereupon, the above-entitled

5 matter went off the record at 11:47 a.m. and

6 resumed at 12:30 p.m.)

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

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

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

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

1 life saving and have been proven to be such.

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

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

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

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

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

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



1 heart surgeries are currently being done.

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

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

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

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

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

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

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

22           CO-CHAIR KOHR: Any discussion?

1 Okay. We'll proceed with the vote. Recommend  
2 for time-limited endorsement. All those in  
3 favor please raise your hand. Okay. We have  
4 11 out of 11.

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

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

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

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

22 The numerator statement is the

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

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

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

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

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

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

1 DR. HINKLE: I have a question.

2 CO-CHAIR KOHR: Allen.

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

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

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

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

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

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

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

17 Is there any other comments?

18 Okay. So we'll move forward for --

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

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

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

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

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



1 340 which is about pediatric heart surgeon  
2 volume?

3 DR. J. JACOBS: The difference is  
4 that this metric states that the volume needs  
5 to be classified through counting cases that  
6 are coded through a clinical database. The  
7 previous AHRQ metric classifies counting  
8 volumes through administrative database. In  
9 the packet we provided several references  
10 showing that counts coming from those  
11 administrative databases can be inaccurate.

12 Specifically three references that  
13 have been published in the peer review  
14 literature, one that shows that a case count  
15 from the ICD-9 codes showed a large amount of  
16 inaccuracy compared to a review of the  
17 clinical database, a second that started  
18 reviewing a clinical database and showed that  
19 it had a large inaccuracy with the ICD-9 codes  
20 that were actually coded, and a third done by  
21 CDC which concluded that outcomes analysis  
22 based on purely administrative coding is prone

1 to substantial misclassification. The  
2 difference between this and the previously  
3 endorsed metric is that it requires the volume  
4 to come from a clinical database.

5 CO-CHAIR JEFFRIES: So how does  
6 NQF deal with two measures that for all  
7 intents and purposes look similar, though they  
8 do come from different sources?

9 MS. HINES: I would think there  
10 are differences in the codes, too, as I recall  
11 from what the AHRQ measure has and some of the  
12 stratifiers. I know Kathy was talking  
13 yesterday about the use of the RACHS in the  
14 AHRQ measures.

15 Darryl, you may know more.

16 CO-CHAIR JEFFRIES: There's a  
17 volume measure and a mortality measure. The  
18 RACHS stratification is within the mortality  
19 measure and not in the volume which is PID-7  
20 or one is 6 and one is 7.

21 DR. GRAY: One of the things is  
22 that Jeff Marshall and some others have been

1 having conference calls for about a year and  
2 a half trying to actually develop a crosswalk  
3 between the STS and ICD-9 diagnosis and  
4 procedure code specifically to address in part  
5 --

6 Well, hopefully we'll actually get  
7 to do a concordance study looking at  
8 individual patients but first just to document  
9 the overlap or occasional gaps between the  
10 ICD-9 and STS codes to identify the fact that,  
11 for example, there is no specific ICD-9  
12 procedure code for Norwood so you end up  
13 having to figure out a combination of  
14 diagnosis and procedure codes that actually  
15 capture those.

16 In part we are actually trying to  
17 make sure that we can actually have a way that  
18 if you are using a database that is based, for  
19 example, on ICD-9 diagnosis and procedure  
20 codes that you can actually compare that to  
21 something like, for example, STS, and make  
22 sure that you are actually capturing the exact

1 same distribution of diagnosis and procedure  
2 so that is part of what we're doing.

3 CO-CHAIR KOHR: John.

4 DR. MAYER: I think there is one  
5 other intrinsic problem with the  
6 administrative claims database and that is the  
7 data that are being acquired for that purpose  
8 are being acquired primarily so that the  
9 hospitals can get paid for what services they  
10 are providing.

11 So there is always a little bit of  
12 risk when you start using data that was  
13 acquired for one purpose and try to use it for  
14 another purpose. I think the references that  
15 were cited here are all in the pediatric realm  
16 where there seems to be a nontrivial  
17 discrepancy between the administrative claims  
18 data and so-called clinical data. It's not  
19 confined to congenital heart surgery.

20 In Massachusetts we had a little  
21 bit of a natural experiment where as part of  
22 changing what institutions were allowed to do

1 adult heart surgery in Massachusetts under a  
2 certificate of need process there was a  
3 requirement that all institutions in the state  
4 participate in both the STS cardiac surgery  
5 database as well as the interventional cath  
6 database.

7           The hospitals at the same time  
8 were continuing to have to report all of their  
9 claims data to the Department of Public Health  
10 as part of how they sort of keep track of what  
11 is going on and it had some payment  
12 implications and some other things.

13           So, you have two concurrent  
14 patient populations that, for all intents and  
15 purposes, should have been exactly the same  
16 patients. Yet, if you compare just the  
17 denominators -- so how many patients were  
18 classified as having isolated coronary artery  
19 bypass in these two data sets, there's a 27  
20 percent difference in the denominator.

21           The caveat here is that the STS  
22 data was all audited so it was quite clear --

1 this was in circulation the last year or so or  
2 maybe two years -- it's quite clear that the  
3 administrative claims data has got some at  
4 least potential pitfalls.

5 Remember who is actually putting  
6 the data in. Right? It's not the clinicians  
7 that are putting the data in for diagnosis and  
8 procedure in the hospital database. It's the  
9 people in medical records and I've been down  
10 there and I've talked to those folks.

11 It would be unreasonable to expect  
12 that they would have the same level of  
13 sophistication and understanding what might  
14 appear to be subtle but, in fact, are very  
15 real and really important clinical  
16 differences. I'm worried if we are just  
17 relying on administrative claims databases.

18 I think that is part of the reason  
19 why there is as much emphasis as there has  
20 been from at least the professional side in  
21 trying to encourage and expand the development  
22 of clinical databases where the data are

1 actually being captured and reviewed at all by  
2 the clinical staff as opposed to the hospital  
3 building staff.

4 CO-CHAIR KOHR: Lisa.

5 MS. HINES: I think my bigger  
6 question would be, and I understand having to  
7 have volumes set for denominators but is that  
8 public reporting? All of our other volume  
9 measures have been tied to mortality. A  
10 number in and of itself, as was said here,  
11 doesn't indicate quality.

12 However, you know, volume and  
13 mortality as the next two can be paired up.  
14 They match up nicely with their mortality  
15 counterparts. Certainly that adds value and  
16 context for public reporting by others.

17 I'm not sure that a volume measure  
18 like this in and of itself has a purpose for  
19 setting the denominator is something that  
20 would be good for public reporting out of  
21 context, I guess. It has no tie to quality.

22 DR. J. JACOBS: I think, first of

1 all, there is already an NQF endorsed  
2 indicator for reporting pure volume out of  
3 administrative databases. And we felt that  
4 that if that is going to exist there should be  
5 a parallel one coming out of clinical  
6 databases which we think will be a more  
7 accurate volume count.

8 MS. HINES: The AHRQ is tied to  
9 mortality and it's a paired measure. One  
10 can't be reported without the other as NQF  
11 endorsement.

12 DR. J. JACOBS: Second of all, we  
13 feel quite strongly that reporting of  
14 mortality without any complexity  
15 stratification should not be done. In other  
16 words, one should not ever report pediatric  
17 heart surgery outcome with the numerator the  
18 number of patients who have died the  
19 denominator just the number of cases done.

20 That's why we don't want to tie  
21 this to a mortality measure. But we do think  
22 it's important to know the overall number of



1 cases done at a program for a variety of other  
2 reasons.

3           It's hard to even begin to assess  
4 what the scope of a program's worth is or the  
5 quality without knowing how many cases they  
6 do. If that is not tracked, it's impossible  
7 to know how many cases are missed with the  
8 other complexity stratification tools.

9           I think just because we don't want  
10 to stratify -- I'm sorry, just because we  
11 don't want to report mortality based on this  
12 indicator as a subsequent outcome indicator  
13 doesn't eliminate the need for reporting this  
14 indicator in and of itself as a structural  
15 assessment.

16           CO-CHAIR KOHR: Mark.

17           DR. HOYER: I just have a question  
18 for Lisa to clarify that a little bit. I'm  
19 trying to figure out how one would publicly  
20 report the information of the outcomes without  
21 the denominator.

22           I'm foreseeing that somebody has -

1 - if you can't report the number of cases that  
2 were done and you were simply reporting, let's  
3 say, a percentage, I could see that maybe, but  
4 if you reported one death at one institution  
5 and they did two cases that year, that's 50  
6 percent.

7           That's not too good. If you just  
8 said one and an institution that did 500 cases  
9 has 20 deaths or 10 or whatever, it seems that  
10 would be very misleading information so I just  
11 don't know. I'm just curious is it possible  
12 that you can't -- they have to be inextricably  
13 linked I would think.

14           MS. HINES: And I'm agreeing with  
15 what you're saying. We have always linked a  
16 volume measure with a mortality measure in our  
17 current endorsed measures. However, there is  
18 no mortality counterpart to this specific  
19 measure.

20           It's going to be a nine and it's  
21 going to be 8 links to 18, I think, and 9  
22 links to 19 so that question is answered but

1 just a general volume. I'm not saying it  
2 can't go forward. I'm just saying this  
3 historically --

4 DR. HOYER: But the complication  
5 rates that we talked about before, too, in the  
6 outcomes measures all of those three,  
7 mediastinitis, stroke, renal failure, would  
8 have to be also tied to something with total  
9 volume. Would it not?

10 DR. J. JACOBS: Exactly.

11 DR. HOYER: Right. That's the way  
12 this ties in.

13 DR. J. JACOBS: That is the  
14 denominator for the four free-standing  
15 morbidity measures for which, to date, there  
16 is not complexity stratification tools  
17 developed.

18 In order to report mediastinitis  
19 rate, stroke rate, pacemaker rate, renal  
20 failure rate, and rate of re-operations, five  
21 of them actually, this is the denominator for  
22 those. In other words, those would just show

1 up as a percentage without a denominator.  
2 That is kind of part of the whole object for  
3 being a structural measure.

4 MS. HINES: I am just thinking  
5 paired making sure that they get reported  
6 together or something but that's different.  
7 Thank you.

8 CO-CHAIR KOHR: Darryl.

9 DR. GRAY: So, Lisa, you're saying  
10 that they -- Lisa Hines, that is, you're  
11 saying that 6 and 7 as they are now, I mean,  
12 they still do get reported. They get reported  
13 late but they get reported nonetheless.  
14 Right?

15 MS. HINES: Your PDI?

16 DR. GRAY: Yes.

17 MS. HINES: PDI-6 and 7.

18 DR. GRAY: I'm sorry. Right.

19 MS. HINES: The AHRQ measure. Yes.  
20 They do get reported. They do get reported as  
21 a paired measure.

22 DR. GRAY: I would think in order

1 to be able to put those numbers into context  
2 even though they have been accepted it  
3 actually really is important to actually have,  
4 to the degree possible, the parallel volume  
5 measure from STS for people to be able to, for  
6 example, look at those instances until, God  
7 willing, we ever actually get to do this  
8 concordance study to look at how accurate the  
9 administrative data actually are.

10           Until we do that it will really be  
11 important for people to actually have the STS  
12 numbers which probably are better to be able  
13 to -- the volume numbers to actually be able  
14 to interpret that.

15           CO-CHAIR KOHR: Any other  
16 discussion? Okay. We'll move forward with  
17 the vote. So please raise your hand if you  
18 are in support of recommendation for time-  
19 limited endorsement. That's 12 out of 12.

20           Okay. We'll move forward with the  
21 next measure. Darryl.

22           DR. GRAY: In the interest of time

1 I'll just say briefly this allows for the risk  
2 stratification to be included for what was  
3 done in measure 7. There's not much else to  
4 say about it. Just a point of clarification,  
5 I guess.

6           The document -- in a couple of  
7 cases it makes reference to risk adjustment  
8 and it's actually risk stratification because  
9 you're not doing any adjustment to the volumes  
10 as a function of risk categories. Beyond that  
11 there's not much to say about it, just that  
12 it's obviously not specifically endorsing any  
13 specific risk stratification scheme but just  
14 is allowing for one to be used.

15           CO-CHAIR KOHR: Any discussion?

16           DR. HOYER: Just to beat the  
17 obvious. It does say it's stratified by  
18 complexity and I think the complexity  
19 stratification versus risk stratification is  
20 a better descriptor.

21           CO-CHAIR KOHR: So are you  
22 recommending a change? No?

1 DR. HOYER: That's the way the  
2 newer version was. I think when we had our  
3 conference call there were some suggestions  
4 made to change it already so it already said  
5 that.

6 CO-CHAIR KOHR: Okay. All right.

7 DR. HOYER: The current version  
8 does say complexity.

9 CO-CHAIR KOHR: Yes.

10 DR. HOYER: I mean, obviously the  
11 complexity stratification is driven in part by  
12 perception to the difference in risk but it is  
13 still a complexity stratification so, yes,  
14 just make sure that the language always does  
15 refer to that.

16 CO-CHAIR KOHR: Any further  
17 discussion? Okay. We'll move forward with a  
18 vote. Those in support of recommendation with  
19 time-limited endorsement please raise your  
20 hand. Okay, 12 out of 12. We'll move forward  
21 with the next measure.

22 Nancy.

1 DR. GHANAYEM: The next measure is  
2 the operative mortality for the six benchmark  
3 operations that we spoke about, I believe, in  
4 measure 19. They have a surgical volume of  
5 the operative mortality. I'm sorry. I pulled  
6 up the wrong one. This is the surgical volume  
7 for those six pediatric and congenital heart  
8 operations that were, I think, reviewed when  
9 Allen did his review.

10 I think there wasn't much more  
11 that I would add on top of the discussion we  
12 had earlier. I think we need to have the  
13 volumes to be able to look at the operative  
14 mortality to provide the denominator. I think  
15 it needs to be done.

16 CO-CHAIR KOHR: Okay. It's open  
17 for discussion. Any comments?

18 MS. HINES: Just a point for the  
19 group. As we've said, the other measures,  
20 volume and mortality, have been reported as a  
21 pair. Would you want these to be reported as  
22 a pair?



1 DR. GHANAYEM: It makes sense to  
2 me but I have a very simplified view on the  
3 whole process so I don't have the knowledge or  
4 the foundation that all of you have in terms  
5 of why not do it that way.

6 DR. HOYER: So the question is: is  
7 there any other reason that you would need  
8 that volume for those six benchmark  
9 procedures. If you don't, then they could be  
10 theoretically paired is what I'm hearing you  
11 say.

12 You're having the volume for the  
13 six benchmark procedures and then you're going  
14 to see how many of those benchmark procedures  
15 that you do so that's an numerator. Those  
16 seem to be linked without really being useful  
17 by themselves in any other regard whereas the  
18 volume overall was different. That could be  
19 used differently for many, many different  
20 numerators. This seems like this one is tied.  
21 Again, I'm simple thinking, too.

22 MS. HINES: And it would be like 8

1 and 18 the one that you just discussed and 9  
2 and 19.

3 DR. GHANAYEM: Jeff, maybe you can  
4 shed a little bit more light on that.

5 DR. J. JACOBS: Again, when we  
6 submitted them separately we were just  
7 following the model used by the STS adult  
8 cardiac metrics where volume is a structural  
9 metric and mortality is an outcome metric so  
10 we were just following what has already been  
11 done.

12 I think it's important to know  
13 both because the percentage of mortality isn't  
14 so good without knowing the number of patients  
15 involved. And also that then allows one to  
16 calculate confidence intervals. Just knowing  
17 a percentage without the denominator you can't  
18 do confidence intervals then either.

19 MS. HINES: I would just want to  
20 make sure that may be a recommendation down  
21 the line that the two be reported together and  
22 would like to be able to say that the group

1 felt that was viable that they should be  
2 reported together to show context.

3 CO-CHAIR KOHR: Any further  
4 discussion?

5 Allen.

6 DR. HINKLE: Really just a  
7 question not about this particular measure but  
8 maybe to the experts here whether they are  
9 ever entertaining like a coefficient of  
10 variation or some other metric to get at  
11 variation within any of these measures. Maybe  
12 I should ask at the end of the meeting. It's  
13 not relevant to this particular --

14 CO-CHAIR KOHR: Yes, let's finish  
15 the measures first. Is that all right?

16 DR. HINKLE: Okay.

17 CO-CHAIR KOHR: Okay. Any further  
18 discussion on this measure? Okay. We'll move  
19 forward on voting. Recommendation for time-  
20 limited endorsement with a condition of  
21 pairing 8 with 18.

22 DR. GHANAYEM: I think we should

1 condition it but I think it should be endorsed  
2 regardless of whether it's paired or not so I  
3 don't want to affect the endorsement by  
4 putting a condition on the endorsement.

5 MS. HINES: You can vote and we  
6 can just put in the narrative what the  
7 suggestion would be.

8 CO-CHAIR KOHR: Okay. Let's  
9 rephrase that. Recommend for time-limited  
10 endorsement. Those who are in support please  
11 raise your hand. Okay, 12 out of 12.

12 We'll move forward with the next  
13 measure. The next measure is timing of the  
14 antibiotic in administration for pediatric and  
15 congenital cardiac surgery. It is focused on  
16 the patient receiving prophylactic antibiotics  
17 within an hour of surgical incision or two  
18 hours if they are receiving Vancomycin.

19 It has appropriate exclusion  
20 criteria. The discussion that our group had -  
21 - and, Schonay, you can add to this -- was  
22 that this measure should be combined with No.

1 11 because if you don't give the appropriate  
2 dose of the antibiotic it doesn't matter what  
3 time you give it it's not going to be  
4 effective. That was basically our main  
5 comment about this measure.

6 I will open it up for discussion.

7 DR. HOYER: You said it both ways.  
8 You enter the data in the same spot. You put  
9 the time and you put the dose and so,  
10 therefore, we thought --

11 CO-CHAIR KOHR: It would be easy  
12 to capture this data together.

13 DR. HOYER: -- this was a little  
14 bit of a nuance in separating those two  
15 things. You can't really have one without the  
16 other

17 CO-CHAIR KOHR: I thought you were  
18 going to say something else.

19 Okay. Any other discussion.

20 MS. WILBON: I just had a quick  
21 question and clarification from your  
22 discussion yesterday. Did you want the

1 measures to be paired or you wanted them to be  
2 combined into one measure?

3 CO-CHAIR KOHR: Combined into one  
4 measure.

5 MS. WILBON: Okay. I just wanted  
6 to clarify that.

7 CO-CHAIR KOHR: Yes.

8 DR. J. JACOBS: That is also fine  
9 by me but, again, if I remember right, there  
10 are some antibiotic measures that are in the  
11 adult cardiac proposal that were separated out  
12 for some reason and we were just trying to be  
13 consistent with what the National Quality  
14 Forum has done in the past and clearly they  
15 did have a reason for separating out the  
16 antibiotic proposal into two metrics.

17 That is the reason it has then  
18 been carried out at other levels where those  
19 metrics were then adopted into PQRI as two  
20 separate metrics. So if we are going to be  
21 consistent with what NQF has done in the past  
22 and then what the federal government has done

1 by applying NQF metrics in the past, we would  
2 have to keep these as two separate measures.

3 If we combine them, we are doing  
4 something different and breaking precedent,  
5 which, to be honest, I have no strong feelings  
6 either way but we were just trying to follow  
7 what has already been done by several groups.

8 CO-CHAIR KOHR: Can you provide  
9 the rationale for that because, if you don't  
10 give the appropriate dose, it doesn't matter  
11 if you give it on time. I know I keep saying  
12 that. I've said it like five times.

13 DR. GHANAYEM: When you get one  
14 wrong, you've got it wrong.

15 CO-CHAIR KOHR: Yes. That's  
16 right.

17 DR. GHANAYEM: One wrong is both  
18 wrong.

19 MS. HINES: I don't disagree and I  
20 think the thinking in the past from prior  
21 measure developers have been -- it truly is  
22 two different thought patterns. It's

1 selecting the right antibiotic and the  
2 appropriate dosing and then the timing of the  
3 antibiotic.

4           The person that chooses the  
5 antibiotic is not always the one that gives it  
6 so you are really looking almost at two  
7 different entities. Jeff can certainly order  
8 it but the anesthesiologist may not give it on  
9 time. You're exactly right. If one fails and  
10 the other, there is a med breakdown but really  
11 the construct is it hits two different phases.

12           DR. J. JACOBS: It's a process  
13 metric and these are two different processes,  
14 both of which are required to be successful.  
15 Tracking the two as two separate processes  
16 made sense and that is, I think, why it was  
17 done that way in the past.

18           CO-CHAIR KOHR: Playing the  
19 devil's advocate. I'm sorry. I agree that if  
20 one person orders the antibiotic but the  
21 person who is going to give it is really  
22 supposed to be your double check to check that



1 it's the appropriate dose before they give it,  
2 just like the nurse does at the bedside is  
3 supposed to double check it.

4           So you're still checking if the  
5 process works by looking at them combined.  
6 The anesthesiologist really should be not just  
7 giving the drug that the surgeon ordered if  
8 the surgeon orders it. Usually it's the  
9 anesthesiologist who orders it, at least in  
10 our institution, but they are supposed to  
11 double check that it's the appropriate dose  
12 that they are giving on time. That's my only  
13 comment.

14           Mark, you had another comment?

15           DR. HOYER: I was just thinking  
16 again what we talked about yesterday is that  
17 it's two processes, indeed, but if there is a  
18 mistake made, it's easy to track where it  
19 occurred. It wouldn't be very difficult.

20           Whether it's pharmacy, whether  
21 it's nursing, whether it's delivery of a  
22 medication to patient bedside, whatever, it

1 would be very easy to find out if it didn't  
2 meet the standard. It would not be very  
3 difficult to sort out where the mistake  
4 occurred or where the error would have  
5 occurred.

6 CO-CHAIR KOHR: John.

7 DR. MAYER: I think in some ways  
8 this is similar to one of the earlier issues  
9 that we discussed which is what are we  
10 testing. Are we testing individual position  
11 compliance or performance or are we testing  
12 programmatic performance?

13 For this, if you combine the  
14 measures, you're evaluating programmatic  
15 performance which is can you order the right  
16 antibiotic in the right dose and can you give  
17 it on time. It doesn't seem to me any reason  
18 not to combine this into a single measure.

19 The only reason I can imagine is  
20 if somebody actually thought that this was  
21 somehow going to get linked to payment and  
22 then your payment is subject to stuff that you

1 can't control, then it sort of has the  
2 inherent unfairness aspect to it. I think a  
3 little bit goes to what are we trying to  
4 measure here.

5           Are we trying to measure  
6 programmatic performance or are we trying to  
7 measure individual components of the program  
8 performance. My own sense would be it ought  
9 to be programmatic but I don't know. Maybe  
10 there is some different perspective that we  
11 should be thinking about.

12           DR. HOYER: The other thing is the  
13 data comes from the same spot. It's  
14 electronically retrievable quite easily. It's  
15 very feasible and that was the point. I mean,  
16 it would be in the same data location and that  
17 was why we thought as well that it would be so  
18 easy to combine into one.

19           DR. MAYER: It's not a question of  
20 that. It's a question of what are the  
21 implications likely to be and what are we  
22 trying to measure.

1 DR. J. JACOBS: Exactly. That's  
2 what I brought up before when I mentioned when  
3 it's been used by the Physician's Quality  
4 Reporting Initiative, PQRI. It's separate  
5 metrics for those reasons. If we combine  
6 them, then we eliminate the ability to do an  
7 application like that in the future.

8 CO-CHAIR KOHR: Darryl.

9 DR. GRAY: The only other thing is  
10 that, for example, No. 11 actually talks about  
11 appropriate antibiotics whereas the other  
12 things are sort of more mechanistic in terms  
13 of timing and making sure that for whatever  
14 antibiotic is chosen that the dose is  
15 appropriate for the weight of the child.

16 Since No. 11 is actually dealing  
17 with selection of individual antibiotics, then  
18 there may be shifts that occur over time as  
19 different antibiotics become in or out of the  
20 selected group that makes things different --

21 I agree certainly that from a  
22 programmatic sampling you really want to

1 bundle all three components of the decision  
2 and the delivery but that, if one of these is  
3 likely to change, I don't know whether or not  
4 mechanistically that complicates matters if  
5 you've done them together. It may not.

6 DR. MAYER: As long as it's  
7 appropriate.

8 DR. GRAY: Yes.

9 DR. M. JACOBS: I don't think we  
10 have a very strong feeling about which of  
11 these various choices the NQF would ultimately  
12 make in terms of how to implement these. I  
13 think part of the reason that they are  
14 separated in the proposal is slightly  
15 different intent.

16 As Jeff said, we followed the  
17 model of the NQF endorsed adult cardiac  
18 surgery and measures of which one of these is  
19 essentially a direct reproduction, which is  
20 the timing of administration which goes to the  
21 efficacy of the drug.

22 I think in the adult population

1 there is also evidence related to the duration  
2 of the course. That, I think, is another  
3 adult measure. There is not evidence in the  
4 pediatric population on which to base such a  
5 measure so we didn't include that.

6           So one measure essentially mimics  
7 the applicable evidence-based issues from the  
8 adult NQF measures and the other measure is  
9 specifically related to the pediatric  
10 population. In other words, in adults barring  
11 the presence of renal failure, you simply  
12 can't go wrong with a single dose for every  
13 one of a given drug but it's a uniquely  
14 important process in pediatrics to have it  
15 weight based. It was really in relation to  
16 the precedent and the adult database and the  
17 difference of intent of the two measures, we  
18 separated them. If it's preferable to combine  
19 them, your choice.

20           MS. HINES: And I think that the  
21 split is not limited to the STS adult cardiac  
22 surgery measures. The SCIP measures overall

1 were split and I think, again, just to be able  
2 to make the distinction between the two  
3 actions for data collection and reporting. We  
4 don't have a preference if you want to put  
5 something together but that's just the  
6 history.

7 CO-CHAIR KOHR: Mark, did you want  
8 to say something?

9 DR. HOYER: I'm not sure it's  
10 worth saying but after what Darryl said, it's  
11 not specifically stated selection of the  
12 correct antibiotic. Then you start thinking  
13 about what you do as nurses as well, right?

14 Was it the five things? Correct  
15 patient, correct dose, correct antibiotic or  
16 correct medicine, correct time, and correct  
17 site or whatever, route of administration --  
18 whatever it is. You literally ferret out all  
19 those things. I'm just throwing that out as  
20 something that would be really separating all  
21 of those aspects of appropriate administration  
22 of any drug.

1                   CO-CHAIR KOHR: I guess my  
2 question is, it seems to me we've been talking  
3 about these measures as focusing on the  
4 program rather than an individual provider.  
5 It seems like this is such a different focus  
6 than what we've been looking on because I  
7 agree with John. I think this goes together.

8                   It looks at the program and is  
9 there a problem with this, versus an  
10 individual step a provider does. I guess I  
11 still don't understand the rationale. I know  
12 what you're saying about following that and  
13 there are two different actions, but they seem  
14 so tied in terms of -- if you link them with  
15 outcomes -- that it's hard for me to get my  
16 hands around why timing would just be looked  
17 at separately.

18                  DR. MAYER: I don't know the  
19 answer to this but maybe Jeff or Marshall  
20 does, is whether or not this is actually going  
21 to have any payment implications. That's what  
22 I was talking about, the risk that one



1 provider would be at risk for actions that he  
2 can't control. If that's the case, if there  
3 is a payment implication, and I just don't  
4 know those PQRI measures well enough, then I  
5 think there would be a rationale for  
6 separating them.

7 DR. J. JACOBS: John is absolutely  
8 right. We don't know what will be adopted in  
9 the next version of PQRI but PQRI, or the next  
10 version, which may be a more aggressive  
11 version of pay for performance. The current  
12 PQRI, the cardiac surgery indicators came  
13 directly from the National Quality Forum-  
14 endorsed pediatric cardiac surgery indicators  
15 and separating them out was necessary for that  
16 to happen.

17 What we do here today has far-  
18 reaching implications and multiple domains.  
19 One of those domains is that if the federal  
20 government is going to tie reimbursement to  
21 performance, ideally the performance metrics  
22 that they use are also the performance metrics

1 that we endorse rather than another committee  
2 in Congress deciding what the performance  
3 measure should be.

4 So therefore, by keeping them  
5 separate one allows for this process to  
6 eventually be utilized by the federal  
7 government should they choose to do so.

8 CO-CHAIR KOHR: Correct me if I'm  
9 wrong -- because, Marshall, you mentioned this  
10 but maybe I misunderstood -- does the adult  
11 counterpart to this look at the number of  
12 doses as well because there is data to support  
13 that or is it just the single dose? We are  
14 just looking at a single dose. Maybe I  
15 misunderstood. I thought they looked at the  
16 whole -- is that wrong?

17 DR. J. JACOBS: Several adult  
18 metrics exist related to antibiotics, some of  
19 which revolve around the timing of the dose,  
20 some of which revolve around the dose itself,  
21 and some of which revolve around how long the  
22 antibiotics are continued.

1                   We did not include in ours how  
2 long the antibiotics were continued because  
3 the evidence base does not exist in pediatrics  
4 for that as opposed to adults where there is  
5 multiple peer review publications that provide  
6 an evidence base for the length of using the  
7 antibiotics.

8                   The other thing to keep in mind is  
9 that STS has proposed that outcome measures  
10 are reflective of a team sport and they are at  
11 the hospital level but process measures can be  
12 tracked at the provider level and that is what  
13 allows the process measures to then be adopted  
14 by the government rather than having to create  
15 their own. I think based on all of those, I  
16 think, there are several compelling strong  
17 reasons to keep these as two separate metrics.

18                   MS. HINES: And I actually did the  
19 cardiac surgery measures for the individual  
20 positions working with Fred Edwards. We took  
21 the endorsed facility level and they were able  
22 to break out and unroll to the individual

1 position level. I think looking at  
2 feasibility that's what you really are looking  
3 for, an individual physician level that can  
4 roll up to a hospital and vice versa.

5           If CMS looks at us to come up with  
6 measures as we did in that project, the first  
7 thing that we went to was to go to the  
8 facility levels and say can these work at an  
9 individual level and they could because of the  
10 split so it is something to then consider.

11           CO-CHAIR KOHR: Is there any other  
12 discussion? Okay. We'll move forward with  
13 voting on the measure. Those in favor of  
14 recommendation for time-limited endorsement  
15 please raise your hand. 12 out of 12. Okay.

16           Schonay, do you want to present  
17 your -- I know we talked about it but just a  
18 brief overview. We need to vote on it.

19           MS. BARNETT-JONES: PCS-011-09,  
20 the measure counts for the percent of patients  
21 undergoing pediatric cardiac surgery with a  
22 body weight appropriate for prophylactic

1 antibiotics. The subcommittee discussed this  
2 measure and determined that body weight is not  
3 independent of timing and dosage which are the  
4 central theme from PCS-010-09 which we just  
5 discussed.

6           Based on that, do you want to put  
7 the questions back on the floor? Since the  
8 recommendation from the committee was to  
9 combine and now that seems not to be the case  
10 so let's put it back on the floor for  
11 questions.

12           CO-CHAIR KOHR: Any discussion  
13 about this measure? Okay. So we'll go ahead  
14 and move forward with the vote. Those in  
15 favor of recommendation for time-limited  
16 endorsement please raise your hand. 12 out of  
17 12. Okay. We're done.

18           MS. HINES: Through this  
19 discussion over the last couple of days we  
20 have had some research recommendations that  
21 have come to light adding risk adjustment to  
22 some of the measures. I certainly think this

1 last discussion of kind of an overall picture  
2 of medication could be a recommendation as  
3 well, listed as a research recommendation. If  
4 there is anything else that came up in  
5 discussions that we should note, we would like  
6 to hear them.

7 DR. GRAY: I'm wondering so, for  
8 example, with this is there -- when you say  
9 it's research -- is there any potential  
10 thought of adding another measure that would  
11 actually combine them? I guess you don't  
12 necessarily want to do that.

13 In a sense it almost turns it into  
14 a composite measure which I guess would be one  
15 way of addressing that the sort of  
16 programmatic thought would be -- if you turn  
17 it into an all-or-none composite, then that  
18 basically achieves the same purpose that would  
19 be achieved by having the two measures  
20 combined.

21 I'm not sure if that is a way of  
22 getting around that. Therefore, you don't

1 necessarily -- well, if you want to have an  
2 additional measure that actually is a  
3 composite, that would be a mechanism for doing  
4 that. I don't know if we necessarily want to  
5 go as far as that. We certainly don't need to  
6 make a recommendation now to do that. I'm not  
7 necessarily suggesting that.

8 MS. HINES: And the research  
9 recommendations, I'll let you know, kind of  
10 become the field for measure developers to  
11 look to see what are the measures that need to  
12 be developed. Where are there gaps and where  
13 are there tweaks that need to be made.

14 While we certainly don't make  
15 promises that everything that ends up in the  
16 research list becomes a measure, it is kind of  
17 a first stop for most folks to go and look and  
18 say what's been noted.

19 The other composite-type thing  
20 that we heard were some of the structure  
21 measures when you were talking about rounds  
22 and the conferences and those type of things.

1 I'm not sure if you would like that listed as  
2 a potential future measure.

3 DR. M. JACOBS: May I respond with  
4 a comment to the suggestion about composite  
5 measures? I think as a quality assessment  
6 program or project matures, I think composite  
7 measures become an incredibly useful tool.

8 But I think there was a very  
9 important discussion held around the survival  
10 free of significant morbid complications  
11 measure that we had proposed. It was  
12 appropriately recognized that was in the  
13 absence of an aggregate or the absence of any  
14 one element of the aggregate and was not  
15 referred to as a composite measure.

16 The STS congenital database is  
17 working in a research perspective to develop  
18 composite morbidity measures. I think from  
19 the viewpoint of a statistician, the challenge  
20 of a composite measure is appropriate and  
21 valid weighting of the elements of a composite  
22 so that one knows how to score compliance or



1 performance when some of the issues are  
2 fulfilled or present and some are not  
3 fulfilled or absent.

4           If one chooses to lump and  
5 aggregate measures, if you truly want to  
6 consider it a composite, then there has to be  
7 some implicit, preferably evidence-based  
8 method of weighting the contribution of the  
9 components.

10           It's really for that reason that  
11 we separated some of these things that are  
12 clearly associated thematically and clinically  
13 but are not yet able to be associated as a  
14 composite from an evidence-based statistical  
15 standpoint and it's a great research proposal  
16 because it's exactly what we're working on for  
17 the future but there hasn't been enough  
18 analysis of data to achieve that yet.

19           DR. GHANAYEM: Marshall, I  
20 completely agree but don't you think that some  
21 of these structure measures that we talked  
22 about are already incredibly challenging in

1 terms of measuring the true impact on them?  
2 Because they are not being track in the  
3 thoroughness that you need to decide whether  
4 there is an impact.

5 I think that does hold true for  
6 some of the measures but I don't think it  
7 holds true for all the structure measures  
8 where we are just talking about the  
9 conferences, particularly. Because I don't  
10 know how you can analyze that statistically.

11 DR. M. JACOBS: Which is why those  
12 are related to structure and descriptive, I  
13 think, rather than process which infers that  
14 you can eventually draw outcome conclusions  
15 from the analysis.

16 MS. NUGENT: One of the goals that  
17 was mentioned yesterday was in regards to  
18 quality of care was -- a parent definitely  
19 cares if they are bringing their child home  
20 from the hospital but is that child going to  
21 be able to graduate from college, have a  
22 family. I know we are early on in the

1 tracking but I hope that there are measures  
2 that are being thought of or developed that  
3 can track over a period of time. Maybe we do  
4 have them. I just want to put that on the  
5 record.

6 DR. J. JACOBS: I think what  
7 you're talking about is of huge, massive  
8 importance and there has been a substantial  
9 effort by the STS to create a platform where  
10 the database can be used to facilitate  
11 longitudinal follow-up over time and answer  
12 those questions for adult cardiac surgery, for  
13 adult thoracic surgery, and for pediatric and  
14 congenital heart surgery.

15 It's been a process to get to the  
16 point where that can be done because we have  
17 to find a way to do it without violating the  
18 regulations associated with HIPAA because  
19 longitudinal follow-up means knowing  
20 somebody's identification and unique  
21 identifiers but we have worked out ways to do  
22 that.

1                   We have implemented strategies  
2 within our database. The STS adult cardiac  
3 database has been collecting unique  
4 identifiers since January 1, 2008, the  
5 thoracic database since January 1, 2009, and  
6 the pediatric database will start collecting  
7 them in about six weeks on January 1, 2010.

8                   Those unique identifiers allow one  
9 to track how a patient is doing over time,  
10 whether they're alive, whether they're dead,  
11 and what their functional status is, what  
12 interventions they've required, and what  
13 medications they might need over time. All  
14 the pieces are in place to start doing that.

15                   We now have data back from the STS  
16 adult cardiac database from those analyses and  
17 we have been able to link close to 100,000  
18 coronary bypass operations to the Social  
19 Security Death Master File and find out their  
20 life status one year after the operation.

21                   That's something we've never been  
22 able to do with the STS database and we are

1 going to be able to do that with the pediatric  
2 database really soon. Once we have that data  
3 then we can be able to propose quality metrics  
4 based upon that data.

5 I think that is priority number  
6 one for us, to be quite honest. That  
7 initiative combined with the public reporting  
8 initiative of the STS database is really two  
9 of the areas that we are most aggressively  
10 working on right now.

11 MS. HINES: How about from a  
12 parent perspective, what don't we have that  
13 you would like to see?

14 MS. BARNETT-JONES: I feel quite  
15 relieved today to just have had, number one,  
16 been able to participate and, number two, to  
17 have brought the family perspective to that  
18 and to have the family included in rounds.  
19 For me that is very, very critical as I've  
20 mentioned before.

21 I think Lisa is very much on point  
22 in terms of going forward, you know, what

1 should we expect. So many times I hear from  
2 my medical team, Olivia's medical team, my  
3 medical team as well, that pediatric research  
4 and so forth lags 10 years behind that of the  
5 adult world.

6 I hear that a lot and to be able  
7 to at least have some concrete measures so  
8 that I know in 10 years when she gets to be a  
9 teenager there will be something in place that  
10 we can start to look at from a lifestyle what  
11 her life expectancy can continue to be.

12 Again, without putting these types  
13 of measures in place to be able to track that  
14 and have some data, not only for her but for  
15 all the children who, you know, are in that  
16 same position coming behind, again, we are  
17 drawing the line in the sand. I'm very  
18 pleased that we are drawing such a high line  
19 and high bar to measure against. I'm pleased  
20 with that so far.

21 CO-CHAIR KOHR: John.

22 DR. MAYER: Jeff didn't say

1 specifically, although I know he knows it so  
2 I'll just say it for him. One of the other  
3 efforts is not only to link to the Social  
4 Security Death Master File or National Death  
5 Index or any of the other things so we can  
6 find out whether patients are still alive or  
7 dead.

8           Also in parallel with that there  
9 is a major effort now to link with unique  
10 patient identifier information the emerging  
11 American College of Cardiology pediatric  
12 cardiology database which is sort of in its  
13 final formative stages with the STS data.

14           So that, as those patients are  
15 being seen in follow-up one year, five years,  
16 10 years after an operation that we might have  
17 done when the child was a newborn or something  
18 like that, there will be that longitudinal  
19 follow-up.

20           That is one of the major, I would  
21 say from a 30,000 foot level, the major effort  
22 that the STS is making in its database effort

1 -- is to convert it from just being a 30-day  
2 outcome or hospital discharge mortality,  
3 morbidity database and really turn it into a  
4 longitudinal database.

5 I mean, I think it makes sense  
6 clinically, biologically. I think it makes  
7 sense from a public policy perspective. We  
8 have invested a fair amount of time and effort  
9 in making sure that happens. I can tell you  
10 this.

11 I don't know who, if anyone, in  
12 here is a privacy advocate, but I'll tell you  
13 there are some major roadblocks that have been  
14 thrown up. There has been a lot of mis- and  
15 disinformation about this. I think we've got  
16 the mechanisms to do this now so you can sort  
17 of strip off the identifier when the data --  
18 this is my simple-minded way of conceiving of  
19 it.

20 The data comes into our data  
21 warehouse and the unique identifier  
22 information gets stripped off but can



1 ultimately be linked back so the only way that  
2 any data in the database gets out is that the  
3 patient is in the database. That's the only  
4 thing that could potentially ever be findable  
5 without hacking into the Duke warehouse.

6           You know, in the broader  
7 perspective, and I'm saying this a little bit  
8 to get it on the record here, too, is this,  
9 like almost everything else we do, is not  
10 without its problems and its unintended  
11 consequences and, I think, sometimes I would  
12 argue over-the-top issue about privacy can  
13 bring its own set of difficulties in  
14 understanding what long-term outcomes are, as  
15 a for instance.

16           I think, you know, there are a lot  
17 of things that have these sort of, as I say,  
18 unintended consequences and I think we should  
19 have to be thinking about those going forward  
20 and not just look at it from one perspective.

21           MS. BARNETT-JONES: Absolutely. I  
22 think you are very much on point with that.

1 I think our overall goal is positive outcomes  
2 and that is what we are all striving for.

3           There absolutely are some best  
4 practices that can be gleaned and as we go  
5 forward be able to apply some of those best  
6 practices to institutions across the country  
7 so that we can repeat the things that work and  
8 those things that don't work or that we need  
9 to go back and rework, we put them back into  
10 the process and do that.

11           Like I said, I think we have set a  
12 very high bar. I absolutely understand HIPAA  
13 and the issues associated with HIPAA but from  
14 a family's perspective, when you are kind of  
15 in the trenches, what you are looking for is  
16 what does this mean? What does this mean  
17 long-term? Will this child have a childhood?  
18 At the end of the day will they walk out of  
19 here? Will they be able to play and color and  
20 laugh and go to the zoo?

21           They sound kind of trivial on one  
22 respect but not being able to do that and when

1 that opportunity is not there you do  
2 understand the value of having those  
3 opportunities. So I absolutely agree that the  
4 challenges are there but I think that the  
5 benefits far outweigh those challenges.

6 DR. MAYER: This doesn't have to  
7 be on the record. I think it's been extremely  
8 valuable to have you here. I think your  
9 perspective for me, personally, and, I think,  
10 for the whole process has really been very  
11 valuable so I'm glad you took the time and  
12 effort to be here.

13 MS. BARNETT-JONES: Thank you.

14 MS. WILBON: We do actually have  
15 one more opportunity for public comment. I'm  
16 not sure that anyone is there.

17 Operator, can you hear me? Are  
18 you there? Operator?

19 OPERATOR: There are no questions  
20 at this time.

21 MS. WILBON: Okay. Thank you. Is  
22 there anyone on the line?

1 OPERATOR: No, ma'am.

2 MS. WILBON: Okay. Thank you.

3 Actually just a couple logistical  
4 things. Before you guys pack up, if you could  
5 remember to give us back your USB port whether  
6 or not you had the opportunity to save the  
7 updated measure evaluation forms. Again, if  
8 you weren't able to complete it, that's fine.  
9 We'll send out a reminder e-mail so that the  
10 primary reviewers can get that back to us.

11 I'm trying to think if there is  
12 anything logistical I can think of. Oh, yes.  
13 I think I mentioned a few times we'll be  
14 compiling all the information. We've got  
15 transcripts to go through, we've got audio to  
16 go through so it may take us some time to get  
17 everything compiled and back to you out for  
18 review but that will be part of the process to  
19 e-mail the pertinent points back out so you  
20 guys have the opportunity to add anything we  
21 may have missed and then that will go out for  
22 public comment.

1                   We will also have a follow-up  
2 conference call to resolve any extra issues.  
3 We'll be communicating with the Jacobses to  
4 make sure that we get all the recommendations  
5 and come up with a process so they can submit  
6 that information back to us and we'll have a  
7 follow-up conference call and we'll get that  
8 information back out to you for your final  
9 review and then we'll have a final conference  
10 call, or another conference call to discuss  
11 those changes and make sure you have a final  
12 approval on what was resubmitted.

13                   Then, again, that will go out for  
14 public comment and then we'll have another  
15 conference call to discuss the public's  
16 comments on your decisions here and your  
17 recommendations for the measures that were  
18 proposed. That is kind of what's on the  
19 horizon.

20                   If anyone has any questions, Tina  
21 and I and Sarah will be available pretty much  
22 anytime so feel free to e-mail us. I think we

1 would just like to thank everyone for  
2 participating. I think we had some really  
3 good discussions and we are really excited  
4 about putting these measures out, especially  
5 them being some of the -- well, in addition to  
6 AHRQ's two measures but having a little bit  
7 more robust portfolio for the pediatric  
8 cardiac surgery community. Thank you,  
9 everyone.

10 MS. HINES: And don't forget  
11 measure 21, I know the developers have already  
12 reached out to try to get that and see what we  
13 can do about coming up with a modified  
14 measure. Just as a point of reference. If  
15 that, for whatever reason doesn't work out, we  
16 still have 21 that we would need to discuss  
17 and vote on, the freestanding measure from  
18 Boston so we'll keep you posted on that.

19 CO-CHAIR KOHR: On behalf of  
20 Howard and I, we really appreciate all of your  
21 input in giving up these two days and coming  
22 here to really hash out these measures. I

1 think we've had a really fruitful two days and  
2 I'm real excited about this.

3 CO-CHAIR JEFFRIES: I agree with  
4 what she said.

5 (Whereupon, at 1:36 p.m. the  
6 meeting was adjourned.)

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