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 cardiomediastinal 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 cardiotomy,
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 A1c. 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 quality 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 someway 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 A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

2 12:30 p.m.

3 CO-CHAIR KOHR: So, Mark, why

4 don't you go ahead and get started presenting

5 the next measure. There's two people from our

6 group that are gone who are intimate with

7 those. Sylvia is the only one who would need

8 to get caught up.

9 DR. HOYER: Are you all set?

10 CO-CHAIR KOHR: I'm all set.

11 DR. HOYER: Okay. Sounds great.

12 Thank you. So this is measure No. 6,

13 "Availability of an institutional pediatric

14 Extracorporeal Life Support, or ECLS, program

15 for pediatric and congenital cardiac surgery

16 patients."

17 The numerator statement is whether

18 or not a facility or institution has an ECLS

19 program for pediatric and congenital cardiac

20 surgery. Again, the information, as with the

21 other measures, will be tracked at one and

22 four-year time intervals.

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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