

THE NATIONAL QUALITY FORUM

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PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE

NATIONAL VOLUNTARY STANDARDS FOR PEDIATRIC  
CARDIAC SURGERY

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OUTCOME MEASURES REVIEW WORKGROUP

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WEDNESDAY  
OCTOBER 21, 2009

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The Outcome Measures Review  
Workgroup of the Pediatric Cardiac Surgery  
Steering Committee met in Congressional A in  
the Hyatt Regency Washington Hotel, 400 New  
Jersey Ave, N.W., Washington, D.C., at 11:00  
a.m., Howard Jeffries, Co-Chair, presiding.

MEMBERS PRESENT:

HOWARD JEFFRIES, MD, MPH, MBA, Co-Chair  
PATRICIA A. GALVIN, RN, BSN, CNOR  
ALLEN J. HINKLE, MD  
SYLVIA LOPEZ, MD

CONSTANTINE MAVROUDIS, MD  
JOHN E. MAYER, MD

NQF STAFF PRESENT:

LISA HINES

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Adjourn

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

2 OUTCOME MEASURES REVIEW BREAKOUT WORKGROUP

3 11:06 a.m.

4 CO-CHAIR JEFFRIES: So, I guess at  
5 first just we'll talk about how we want to do  
6 the documentation. One person can do it. We  
7 can have the secondary do it for each of the  
8 measures as we go through it.

9 DR. MAVROUDIS: Are we going to  
10 take all the measures one at a time?

11 CO-CHAIR JEFFRIES: We are going  
12 to go one by one.

13 DR. MAVROUDIS: Are we starting  
14 with Number 1?

15 CO-CHAIR JEFFRIES: No, we're  
16 starting with 13. We have 10 measures, 13 to  
17 21.

18 DR. JENKINS: No, actually we're  
19 starting with 12. That's the whole procedure  
20 checklist.

21 CO-CHAIR JEFFRIES: 12, you're  
22 right. I'm sorry.

1 DR. MAVROUDIS: Well, if you have  
2 one person doing the minutes for consistency  
3 sake, it probably makes a lot of sense. I  
4 don't know if anyone would volunteer to do it.

5 CO-CHAIR JEFFRIES: Does anybody  
6 volunteer?

7 I mean I agree, I think, for  
8 consistency, but it might be just easier to  
9 have secondary do it just so that one person  
10 isn't labored -- if that's okay.

11 DR. JENKINS: Yes.

12 DR. MAVROUDIS: If I may stick my  
13 nose in here a little bit, and that is I've  
14 never seen these before up until a couple of  
15 days ago, these indicators, and I really think  
16 that the process is excellent. These are  
17 really good indicators.

18 Jeff, congratulations. You and  
19 your team have done a marvelous job. It just  
20 seems like every question I had, I just read  
21 the next sentence and it answered it.

22 So, I just wanted to mention that.

1 DR. J. JACOBS: Thank you.

2 CO-CHAIR JEFFRIES: So, the first  
3 measure, I think, is Number 12. The  
4 procedural time out.

5 Patricia, you're the primary on  
6 that?

7 MS. GALVIN: I am the primary.

8 CO-CHAIR JEFFRIES: -- and, Gus,  
9 you're the secondary.

10 DR. MAVROUDIS: Yes, I wrote  
11 something down.

12 CO-CHAIR JEFFRIES: Do you mind  
13 keeping the -- tracking the --

14 MS. GALVIN: The notes.

15 CO-CHAIR JEFFRIES: The notes.

16 DR. MAVROUDIS: You know  
17 something? I'm happy to do it and I'm happy  
18 to type it. I have no idea where to put it.

19 CO-CHAIR JEFFRIES: Yes. We're  
20 going to --

21 DR. MAYER: I mean I don't mind  
22 doing this.

1 DR. MAVROUDIS: Are you sure? I'm  
2 happy to do it, John. I just don't --

3 DR. MAYER: Well, what I'm worried  
4 about is just passing the thing around --

5 MS. GALVIN: Okay. So, this  
6 measure is the use of an expanded pre-  
7 procedural and post-procedural time out. The  
8 use of the expanded pre-procedural and post-  
9 procedural time out would include the  
10 following elements: the conventional pre-  
11 procedure time out which includes  
12 identification of the patient, operative site,  
13 procedure and history of any allergies.

14 A pre-procedural briefing where  
15 the surgeon shares with all the members of the  
16 operating room team the essential elements of  
17 the plan, including diagnosis, plan procedure,  
18 outline of essentials of anesthesia and bypass  
19 strategies, anticipated or planned implants or  
20 device applications, and anticipated  
21 challenges.

22 The post-procedural debriefing is

1 where the surgeon succinctly reviews with all  
2 members of the operating room team the  
3 essential elements of the operative plan  
4 identifying both successful and opportunities  
5 for improvement.

6           This debriefing should take place  
7 prior to the patient leaving the operating  
8 room, or its equivalent, and may be followed  
9 by a more in-depth dialog involving team  
10 members at a later time.

11           The actual briefing in the  
12 operating room is intentionally, importantly  
13 brief in recognition that period of transition  
14 may be a time of instability and vulnerability  
15 for the patient.

16           A briefing or handoff protocol at  
17 the time of transfer or arrival to the  
18 intensive care unit at the end of the  
19 operation involving the anesthesiologist,  
20 surgeon, physician, staff on the intensive  
21 care unit, including critical care and  
22 cardiology and nursing.

1           So, whether or not the facility  
2 implements an expanded pre-procedural and  
3 post-procedural time out for all patients  
4 undergoing pediatric and congenital heart  
5 surgery, the time out includes the following  
6 elements: The conventional pre-procedural  
7 time out -- actually, that's pretty much what  
8 it says in the first statement.

9           So, to open for discussion just on  
10 that piece, the WHO time out has become sort  
11 of the standard or a template that has been  
12 used in different settings and I don't know if  
13 that is what was used in the development of  
14 this concept here.

15           DR. J. JACOBS: What we wanted to  
16 do is actually expand on that so that the  
17 standard time out that JCAHO requires that is  
18 from WHO and that is used really in every  
19 hospital in the country, that's number one on  
20 the list of four.

21           MS. GALVIN: Okay.

22           DR. J. JACOBS: And then numbers



1 two, three and four are elements that our  
2 group thought are also important process  
3 elements to really provide good quality care.

4           And there's a substantial amount  
5 of peer-reviewed literature that supports  
6 that. Marc De Laval from Great Ormond Street  
7 has written a lot about the importance of  
8 having pre-procedural briefings and post-  
9 procedural debriefings with the operating room  
10 team.

11           And then Alan Goldman from Great  
12 Ormond Street has written a fair amount about  
13 handoff protocols, which is a very vulnerable  
14 time for the patient when the patient gets in  
15 the ICU and the responsibility for the care of  
16 that patient shifts from the surgeon and  
17 anesthesiologist to the intensive care unit  
18 team.

19           So, the source of this number one  
20 is the -- Element Number 1 of this comes from  
21 JCAHO and the standard time out. Element  
22 Number 2 and Number 3 come from research done

1 by Marc De Laval and others supporting the  
2 pre-procedural and post-procedural team  
3 debriefings.

4 And Element Number 4 comes from  
5 peer-review literature about the importance of  
6 having a structured process for the handoff in  
7 the ICU.

8 DR. MAVROUDIS: If I may. If I  
9 may.

10 MS. GALVIN: Yes.

11 DR. MAVROUDIS: When I saw this  
12 yesterday, I implemented a couple of these  
13 things in our time out that we did in the  
14 operating room, which I thought was a great  
15 idea.

16 And as I was doing it, I realized  
17 that it is -- as it indicated to say yes or  
18 no, that it was done or not done as an  
19 indicator, requires a rather complex -- a  
20 number of things that have to be done just to  
21 say yes.

22 And then if you miss one, does

1 that mean yes plus or no negative? You know  
2 what I mean?

3 MS. GALVIN: Yes.

4 DR. MAVROUDIS: And so I think  
5 that it is cumbersome in its inclusionary  
6 criteria here on how much -- for instance,  
7 when the child is unstable and you don't do  
8 the post-procedural briefing, who makes that  
9 decision? How does that get reported?

10 So, I think that a time out, an  
11 expanded time out to include anticipated  
12 challenges, the bypass strategy, I think  
13 that's excellent. That's easily -- that can  
14 be measured.

15 I'm not sure about how to deal  
16 with the post-procedural debriefing, although  
17 I started doing it and I think it's a good  
18 idea. I'd like to see it more didactic so  
19 that the person who is looking at this, who is  
20 observing this to mark whether he did or he  
21 didn't do it, will have clear-cut elements and  
22 not that many so that they can really put that

1 together.

2 DR. J. JACOBS: I think that's an  
3 excellent point. An analogous situation could  
4 be the adult cardiac surgery indicator of  
5 whether or not one uses an internal mammary  
6 artery.

7 So, when a program tracks whether  
8 or not they use this internal mammary artery,  
9 there's some patients where it would be a  
10 disaster to use an internal mammary artery and  
11 there's a list of known reasons why.

12 If the patient is a diabetic with  
13 a previous sternal problem or if the patient  
14 has problems with a subclavian artery, meaning  
15 that the internal mammary is not going to be  
16 good. So, there's reasons you would not use  
17 the internal mammary artery.

18 So, the indicator is tracked in a  
19 way that in situations where it's inapplicable  
20 that can be accounted for.

21 And very similarly here if a  
22 patient is very unstable and requires the full

1 attention of the team just to get them out of  
2 the operating room alive, you don't want to be  
3 standing there talking about well, how did  
4 their case go.

5           So, I think the same way we can  
6 track mammary usage and have appropriate  
7 exclusions, this could be tracked with  
8 appropriate exclusions also.

9           MS. GALVIN: In the tracking note,  
10 would it be expected that all elements are  
11 included?

12           I think that's where it might get  
13 into a little bit of difficulty.

14           DR. J. JACOBS: I think if this  
15 were to get implemented, the way I would  
16 envision implementing it in the database is  
17 that there's going to be database fields for  
18 all the structure and process metrics here.

19           And there's going to be four check  
20 boxes here, which there's going to be a check  
21 box for each of the four elements. And the  
22 database manager will enter yes or no for

1 whether each of those four elements was done.

2 And if one answers no, there's a list of

3 acceptable reasons why it wasn't done.

4 There's no acceptable reason why

5 Number 1 wasn't done, ever.

6 MS. GALVIN: Right.

7 DR. J. JACOBS: There's

8 potentially some acceptable reasons why Number

9 2 isn't done, patients getting CPR and you

10 just go to get to work. And there's

11 potentially some acceptable reasons why Number

12 3 isn't done.

13 So, if the database could track

14 each of the four elements with a yes or a no,

15 and if no, you have the opportunity to say why

16 it wasn't done with the acceptable reasons,

17 patient instability.

18 MS. GALVIN: So, one of --

19 actually, you're right. I mean you could say

20 you did one, two, three and four, however,

21 Number 3 has a lot of information in there.

22 So, what this is saying is that

1 there is identification of the operative plan,  
2 that if there's any implants -- I'm sorry.  
3 Number 2. If there's any implants, any  
4 devices, pump requirements and so on that are  
5 not often included in a time out.

6 So, if you have a pre-procedural  
7 briefing where the surgeon just says we're  
8 doing an ASD closure, does that count as  
9 meeting Number 2, or is there a way to capture  
10 that all of the elements in that particular  
11 section were included?

12 Do you see what I'm saying?

13 DR. J. JACOBS: Well, the  
14 definition is going to require that it was a  
15 proper pre-procedural briefing.

16 And the other thing I would say  
17 about this whole concept is that this is, in  
18 a way, an opportunity that we as a group have  
19 a way to change practice.

20 MS. GALVIN: Yes.

21 DR. J. JACOBS: And not just, you  
22 know, if we just listed Number 1 as the only

1 one that is a conventional pre-procedural time  
2 out, well, then every hospital in the country  
3 that has JCAHO certification is going to  
4 qualify automatically.

5 So, that's not going to  
6 differentiate anything.

7 MS. GALVIN: Right.

8 DR. J. JACOBS: But if we put two,  
9 three and four in here if we all as a group  
10 decide when the discussion is over that these  
11 are truly important concepts and practices, we  
12 implement those, then not only are we creating  
13 a quality indicator, we hope to potentially  
14 change the practice.

15 MS. GALVIN: Well, I think they're  
16 important. Don't get me wrong. I'm just  
17 wondering in some settings --

18 DR. MAVROUDIS: How do you  
19 measure?

20 MS. GALVIN: How do you measure it  
21 and how do you -- how are you sure that all of  
22 those little elements are included, all of the



1 --

2 DR. MAVROUDIS: I got dinged. I  
3 got dinged, for instance, because I did the  
4 time out and then I told a story before I made  
5 the incision. And the story lasted more than  
6 a minute and I should have made the incision  
7 one minute after the time out, but that's a  
8 measurable thing, right?

9 MS. GALVIN: Yes.

10 DR. MAVROUDIS: And so I think  
11 what you're getting at is how are we going to  
12 do that for this, right?

13 MS. GALVIN: Yes. Right.

14 DR. HINKLE: I assume there will  
15 be a development process, a developing  
16 checklist for both of these pre and post-  
17 procedure that will evolve over time.

18 And then the nature of that will  
19 be kind of what Jeff, I think, was alluding to  
20 and that leads to the opportunity for quality  
21 improvement.

22 DR. J. JACOBS: Yes.

1 DR. HINKLE: But you got to get to  
2 the first place first which is what are the  
3 standards for pre-procedural -- I mean there  
4 may be new ones that are developed and to get  
5 some kind of -- eventually it would evolve, I  
6 would think, to a checklist.

7 Like we have in anesthesia, you  
8 know, there's a checkoff list before you start  
9 --

10 DR. J. JACOBS: Like what airplane  
11 pilots do.

12 DR. HINKLE: Right. It's the same  
13 -- so, that's how I looked at this as the  
14 process.

15 MS. GALVIN: I guess compliance is  
16 sort of what, as nurses, we struggle with,  
17 that everybody is on the same page.

18 We have a lot of residents in our  
19 programs. And in fact in our institution,  
20 they do the time out, but they may not have  
21 the answers to all of these.

22 DR. MAVROUDIS: Well, your points

1 are probably the most important ones here  
2 because the nurses are going to be doing this.

3 MS. GALVIN: Yes.

4 DR. MAVROUDIS: They're going to  
5 be the ones who are going to have to  
6 understand the process and put it into the  
7 system.

8 MS. GALVIN: Yes.

9 DR. MAVROUDIS: So, if you have  
10 some objections to this, we ought to --

11 MS. GALVIN: It's not an  
12 objection. It's just more of a clarification  
13 because yes, I know the diagnosis, I know the  
14 plan procedure, but I can't say that we're  
15 going to use X, Y or Z valve, that we're going  
16 to need these grafts in the room, that there's  
17 going to be some issues, it's a re-op  
18 sternotomy.

19 I mean that's not for a nurse to  
20 say.

21 DR. J. JACOBS: Right. So, our  
22 thoughts were that before you cut a kid open,

1 that's a discussion the surgeon should have  
2 with the nurse.

3 MS. GALVIN: Right.

4 DR. J. JACOBS: If I'm going to  
5 cut somebody open and put in an aortic valve -  
6 -

7 DR. MAVROUDIS: Operate on them.

8 DR. J. JACOBS: If I'm going to  
9 operate on somebody, yes, and put in an aortic  
10 valve -- well taken -- and put in an aortic  
11 valve, it's probably a good idea that before  
12 I make my incision that I make sure that the  
13 nurse has the aortic valve that I need  
14 somewhere in the room or at least in the  
15 hospital.

16 MS. GALVIN: I would agree.

17 DR. J. JACOBS: Because if you  
18 start that case and you do the standard time  
19 out, this is John Smith, date of birth is  
20 this, allergies are this, having an aortic  
21 valve replacement, great, you keep going, you  
22 get going, you dissect everything out. Okay,

1 I need a 17 millimeter -

2 MS. GALVIN: St. Jude valve or  
3 whatever.

4 DR. J. JACOBS: I need a 15-  
5 millimeter St. Jude valve. Oh, we don't have  
6 one.

7 MS. GALVIN: Right.

8 DR. J. JACOBS: So, that's the  
9 kind of thing that we were trying to get at  
10 here where I'm doing the redo sternotomy and  
11 I like bilateral rule-tract retractors set up  
12 to help me do -- to elevate the sternum when  
13 I do it.

14 And to be honest, if I have to do  
15 a redo sternotomy and the rule-tracts aren't  
16 in the hospital, it's not going to be a good  
17 deal for anybody because I haven't done a redo  
18 sternotomy without the rule-tract retractors  
19 for a long time.

20 MS. GALVIN: Yes.

21 DR. J. JACOBS: So, there's little  
22 things that you want to make sure are there

1 before you make your incision.

2 MS. GALVIN: Right. And I think --

3 DR. MAYER: Does this get to the --  
4 just from a mechanic standpoint here, does  
5 this get to the usability?

6 Is this where we -- I mean I don't  
7 think there's been much discussion yet about  
8 how important this is.

9 It sounds like everybody agrees  
10 it's important, right?

11 MS. GALVIN: It's important.

12 DR. MAYER: And it's that there's  
13 at least some data to suggest that this is  
14 likely to be beneficial, so it's  
15 scientifically acceptable.

16 So, now we're down into the  
17 usability/feasibility discussion.

18 DR. MAVROUDIS: So, what's the  
19 difference between the two?

20 DR. MAYER: Between usability and  
21 feasibility?

22 I think usability has -- at least

1 if I infer correctly from what was said  
2 earlier, it's more like how could somebody  
3 from the outside looking in use the  
4 information.

5 I think actually what we're  
6 talking about here is mostly feasibility about  
7 how we would actually implement this and  
8 devise a checklist or do something like that.  
9 Is that --

10 MS. GALVIN: How cumbersome the  
11 process might be and would it prevent someone  
12 from completing the process because it is  
13 cumbersome.

14 DR. MAYER: Right. But then  
15 usability is --

16 DR. MAVROUDIS: That's what we're  
17 getting at now that there may be too many  
18 issues here in order to make --

19 DR. J. JACOBS: If I put my other  
20 hat on as the database guy, what I would do is  
21 I would have on the database form in the same  
22 little place where you have diagnosis,

1 procedure, bypass time, arrest time, did you  
2 do Number 1, Number 2, Number 3 and Number 4,  
3 yes or no and check it. And you check those  
4 four things.

5           And if you put the little mouse  
6 over what those are, the actual definition  
7 pops up. And yes, at some point somebody is  
8 going to have to make a judgment call whether  
9 or not it's met the definition, but that's  
10 true of almost any database field.

11           And I think then it's just a  
12 matter of checking four boxes and making a  
13 judgment call that it was actually done.

14           CO-CHAIR JEFFRIES: So, just  
15 thinking of sort of the charge that the group  
16 has which is to go through the elements which  
17 are importance and then scientific  
18 acceptability --

19           DR. MAVROUDIS: What did you say?  
20 Scientific what?

21           CO-CHAIR JEFFRIES: Acceptability.

22           DR. MAVROUDIS: Oh.



1 CO-CHAIR JEFFRIES: So, let's  
2 please go through importance because that --  
3 if you read through the valuation criteria if  
4 it's not important, we stop right there.

5 So, let's go through the elements  
6 that are listed here. And I think you would -  
7 - just go through it just in that fashion.

8 I think a lot of this discussion  
9 has been great. A lot of the talk is about  
10 feasibility. But before we get to that, let's  
11 go through the importance first.

12 MS. GALVIN: So, the importance  
13 from this conversation, I'm assuming everybody  
14 agrees that this is an important thing to have  
15 in place specific for cardiac surgery.

16 DR. HINKLE: Well, can I just make  
17 one comment and ask a question, I guess?

18 MS. GALVIN: Sure.

19 DR. HINKLE: I see the importance  
20 from the cardiac care suite improving the  
21 process of care. The importance to the  
22 public, I think I'm there too.

1                   So, in other words, this would be  
2 reported out to the public potentially and  
3 they would look and say wow, a hundred  
4 percent.

5                   It's like the airline's on-time  
6 arrival. You go a hundred percent time outs  
7 achieved.

8                   And so I think that, to me, is how  
9 I looked at both of these. There's a public  
10 side and then there's an improvement side. I  
11 think it does both, but I don't know if I can  
12 answer the public looking for cardiac surgery  
13 if they're going to go -- I mean I don't know  
14 how important this is ultimately to the  
15 patient who is going to be selecting unless  
16 you go into some database and making a  
17 selection of where they're going to go have  
18 their cardiac surgery.

19                   I think it's an important element.  
20 So, I do, you know, my vote on this -- my view  
21 on this is definitely it's in the importance -  
22 - it cuts through the importance criteria.

1 MS. GALVIN: Yes.

2 CO-CHAIR JEFFRIES: I think this  
3 is one of those areas where the public  
4 probably expects us to do this.

5 DR. HINKLE: Yes. Okay.

6 CO-CHAIR JEFFRIES: The fact that  
7 we don't do it is shocking to them sort of  
8 like you expect the pilot to know how they're  
9 going to land the plane.

10 DR. HINKLE: Right. Right. Okay.

11 MS. GALVIN: Right.

12 DR. HINKLE: Do the checklist  
13 before they take off.

14 DR. J. JACOBS: People go in and  
15 operate and they've got the heart dissected  
16 out, and they find out the valve that they  
17 need isn't there.

18 And you're right. That is  
19 shocking to the public. Because if the plane  
20 took off and you found that you didn't have  
21 wheels on it to land --

22 DR. MAVROUDIS: Shocking to

1 anybody.

2 DR. J. JACOBS: But it happens,  
3 and it happens all the time. So, that's what  
4 this is.

5 DR. MAVROUDIS: Again, if I may, I  
6 would ask the -- I want to go back to what you  
7 wanted to do, and that is to go by stages.

8 What stage are we at now?

9 MS. GALVIN: So, we're still on  
10 importance, right?

11 DR. HINKLE: I think we went  
12 through that.

13 MS. GALVIN: Do we vote?

14 DR. MAVROUDIS: Are we all saying  
15 it's important?

16 DR. HINKLE: Yes.

17 DR. MAVROUDIS: I should go to the  
18 process and read just to satisfy my -- I think  
19 that three is going to be difficult to use.  
20 And I'm not sure that's the venue either.

21 I'm not sure that when we're about  
22 ready to move the patient over and everybody's

1 got their things that they're doing, is the  
2 time to stop and say how do did we do, guys  
3 and girls? Did we do okay? How did you do?  
4 How did I do?

5 DR. HINKLE: Yes. Increase in the  
6 pressures and there's so much going on that --

7 DR. MAVROUDIS: Yes. I'm not sure  
8 that's the venue. I think it's the venue  
9 before you do the operation, everybody is you  
10 haven't done it yet. It's not started,  
11 basically.

12 Although, the anesthesiologist has  
13 done their work and so forth. So, I'm not  
14 sure how that's going to play and how that's  
15 going to be enforceable because there may be  
16 a lot of times people will say well, we don't  
17 have enough time, the patient is too unstable,  
18 click unstable.

19 MS. GALVIN: Well, actually what  
20 we did to make this work was we took it out of  
21 the operating room and brought it to the  
22 bedside in the ICU.

1           We consider that a post-procedural  
2   debriefing that includes all of the important  
3   people. The operating room nurse goes up and  
4   stays with the patient, the anesthesiologist  
5   and resident go up, the residents are there.

6           Then there's a time that the nurse  
7   needs to get the patient settled, but there's  
8   no discussions that start until that person is  
9   ready to take this report, and then the whole  
10  thing is gone through.

11           DR. MAVROUDIS: And who is  
12  responsible for doing that? Is it going to be  
13  the resident, the attending? Does it have to  
14  be the attending and so forth? Who does that?

15           MS. GALVIN: We have both,  
16  actually. I mean sometimes it's the  
17  attending, sometimes it's the resident.

18           DR. MAVROUDIS: Okay.

19           DR. J. JACOBS: I mean what we  
20  were looking at when we wrote this, that for  
21  Number 3 it was members of the surgical team  
22  and members of the nursing team and profusion

1 team in the OR.

2 MS. GALVIN: Yes.

3 DR. J. JACOBS: And then Number 4  
4 is members of the anesthesia and surgical team  
5 with the ICU hand-over team. So, it's two  
6 different groups of people.

7 MS. GALVIN: Yes.

8 DR. J. JACOBS: And that's why we  
9 separated those things out because it's not  
10 universal that both groups of people are all  
11 in the same place at the same time because the  
12 first group may not be in the ICU. They may  
13 be setting up for the next case.

14 MS. GALVIN: Yes.

15 DR. MAVROUDIS: If you're  
16 monitoring this in the operating room, when  
17 are you going to be satisfied that all of this  
18 stuff was done?

19 Suppose I tell you oh, it was  
20 done, but suppose you don't agree?

21 MS. GALVIN: Right. I think that  
22 using that WHO framework, I think what they

1 wanted or the goal of that debriefing in the  
2 operating room was, was there anything that  
3 could have been done better in this venue in  
4 the operating room?

5           Something went wrong. Could  
6 something have been done better? And the  
7 debriefing of the transition of care happened  
8 at the bedside.

9           What we aren't good about is that  
10 in the operating room, discussing how the  
11 procedure itself went, what could have been  
12 done differently, what went wrong, what can we  
13 do better the next time.

14           DR. MAVROUDIS: There's a list of  
15 arguments right there.

16           MS. GALVIN: Yes.

17           DR. MAVROUDIS: You made me give  
18 blood, I didn't want to give it, what's wrong  
19 with you, you didn't read the literature, how  
20 stupid. I mean I can see all that developing.

21           DR. J. JACOBS: Better to talk  
22 about it though than just to walk away.



1 DR. MAVROUDIS: It may very well  
2 be, but it breeds for confrontation under  
3 those circumstances.

4 CO-CHAIR JEFFRIES: I think these  
5 discussions sort of allow us to get really at  
6 two, which is understanding the -- if the  
7 measure is well defined and precisely  
8 specified, which I think is what you're  
9 getting at.

10 MS. GALVIN: Yes.

11 CO-CHAIR JEFFRIES: I think what  
12 we can do is come up with some recommendations  
13 either in this group or in the Committee for  
14 some language changes which may make it a  
15 little more clear.

16 Maybe it's -- from what you're  
17 saying, it's not taking out the meeting in the  
18 operating room or something.

19 DR. MAVROUDIS: No, I think it's a  
20 good idea. I'm getting stuck, and I think  
21 appropriately so, on who is going to observe  
22 this, who is going to say you did or didn't do

1 it. That's all.

2 DR. MAYER: But, I mean presumably  
3 you're going to just put it into your --  
4 you're going to put it in as part of your  
5 database entry, right?

6 So, and then how you work that out  
7 locally depends on your local environment and  
8 whether it's the operating room nurse or the  
9 profusionist or the whatever.

10 But I do think the -- I do think  
11 probably the key to the whole thing is the  
12 escapes which is we're having trouble, Stage  
13 1 is too much drug, I don't think we ought to  
14 stop, let's get to the -- that's got to be a  
15 legitimate -- that's got to be a legitimate  
16 escape so that people don't feel like they  
17 have committed some terrible sin by omitting  
18 this.

19 It's a judgment call.

20 DR. MAVROUDIS: And this is where  
21 your idea about clicking on it gives you --

22 DR. J. JACOBS: Yes. I mean it's

1 the same way they track a mammary artery.  
2 Yes, we did it or no, we did not because we  
3 didn't want to, not good. No, we did not  
4 because the patient has subclavian artery  
5 stenosis and you can't use the mammary because  
6 there is no blood in it.

7 So, here you would say yes, we did  
8 it or no, we did not because of hemodynamic  
9 instability of the patient.

10 DR. LOPEZ: If Number 3 --

11 DR. J. JACOBS: It's for a  
12 legitimate reason.

13 DR. LOPEZ: If Number 3 were done  
14 in a concise and efficient manner, how much  
15 time do you envision a debriefing taking?

16 DR. J. JACOBS: If the case went  
17 well, 20 seconds. If the case didn't go well,  
18 you'd say a couple of minutes and we'll come  
19 back and talk about it later.

20 I couldn't see spending more than  
21 two minutes on this. But it's just to get in  
22 the habit of instead of putting that last

1 stitch in and going and eating lunch, putting  
2 that last stitch in, looking at the nurse.

3 I mean it seems like the very  
4 obvious thing that you put your last stitch  
5 in, you look at the nurse who has helped you  
6 for the last four hours, and you talk to her  
7 before you leave.

8 It seems like it should happen all  
9 the time. But you know what? It doesn't.  
10 And there's plenty of surgeons who put that  
11 last stitch in and they're out of there and  
12 they don't say anything to anybody.

13 And so this could take if it's a  
14 perfect case, 30 seconds. Thanks a lot,  
15 everything went well, see you next case.

16 In a case where you had a problem,  
17 well, this didn't go so well and we probably  
18 can't talk about it now, but let's have a  
19 meeting tomorrow and we'll talk about it at  
20 lunch. And we'll go over and figure out why  
21 we didn't have that valve here or why the  
22 retractor is --

1 DR. MAVROUDIS: No one has said --  
2 no one is indicating that's not a good idea.  
3 It's a great idea. Just how it's going to be  
4 judged, that's all we're talking about.

5 DR. HINKLE: Yes, and the reality  
6 gets in, I mean you don't expect to conduct a  
7 quality improvement session during this  
8 moment. It's just to say we had this quick  
9 debrief.

10 But I agree with you. It's going  
11 to get into a potential here for emotional --  
12 I mean I can remember when starting the case  
13 there was an accidental cut through the RV  
14 outlet graft.

15 Well, you got to at that point,  
16 everyone's got to focus and get the job done.  
17 And then at the end, that needs to be talked  
18 about.

19 But I think what you're suggesting  
20 here that's all at the end of that case, that  
21 all you would say is well, we got to talk  
22 about what happened here at a later time.

1 That's a debrief.

2 DR. J. JACOBS: Or maybe you did  
3 talk about it if the opportunity exists, but  
4 you don't just move on to the next thing  
5 without even --

6 DR. HINKLE: Yes, you recognize --  
7 you say well, something happened here. And  
8 I'm just thinking back to some cases where --  
9 but I can see where you don't want to get into  
10 a blame situation at this moment, I guess is  
11 the way I would look at it.

12 I think what you're saying is just  
13 have a check -- just have a -- most things  
14 maybe it will only be 15 seconds because it's  
15 so urgent to move the patient to a -- and so  
16 you could still check the box that you had  
17 that debrief.

18 DR. MAYER: Yes, I think --

19 DR. HINKLE: And recognize the  
20 severity of --

21 DR. MAYER: -- what's written here  
22 actually sort of covers it. The actual

1 debriefing in the operating room is  
2 intentionally and importantly brief in  
3 recognition of the fact that periods of  
4 transition may be times of instability or  
5 vulnerability to the patient.

6 DR. MAVROUDIS: Well, we should  
7 just keep that then.

8 CO-CHAIR JEFFRIES: So, Jeff,  
9 questions about the numerator. Is the  
10 intensive enumerator a yes-no, or is it number  
11 of patients that it's done on over -- so, if  
12 it is number of patients, the way that I've  
13 seen a lot of these type of measures come out  
14 is it's an all or nothing.

15 So if all four are done, then you  
16 get a yes. If you miss one, then you get a  
17 no.

18 DR. J. JACOBS: I think I would  
19 agree with that.

20 And what I would do is on the  
21 database, we track all four individually. But  
22 then for the quality indicator you did all

1 four, yes. You forgot to do one, it's a no.

2 CO-CHAIR JEFFRIES: So, it's meant  
3 to be a rating system.

4 DR. J. JACOBS: Yes. And it's a  
5 rate with the denominator being the number of  
6 -- the denominator is actually defined in one  
7 of the metrics they're talking about over  
8 there.

9 DR. MAVROUDIS: In all of them.

10 DR. J. JACOBS: Right.

11 DR. HINKLE: Yes.

12 CO-CHAIR JEFFRIES: So, I would  
13 think we need to change a little language on  
14 the numerator because it says whether or not.  
15 And I think it's probably whether or not by  
16 patient.

17 DR. J. JACOBS: Yes. I think the  
18 two things I've noticed that would need to be  
19 changed is that it's got to be all or none by  
20 patient, and that we have to specify  
21 acceptable forms of noncompliance or, as John  
22 said, escapes, which I don't think we



1 specified in enough detail in this document.

2           So, that's the two things I think  
3 if we could -- the way I would sum it up is  
4 the two things this discussion led to so far  
5 that needs to be changed is that there needs  
6 to be documentation of escapes.

7           There's probably no escapes for  
8 Number 1, but there's probably legitimate  
9 escapes for 2 and 3. Probably no escapes for  
10 Number 4.

11           And then we should change it so  
12 that it's an all or none phenomena so it's a  
13 rating.

14           CO-CHAIR JEFFRIES: And my only  
15 comments on 4 is there are some centers that -  
16 - it gets to the floor and not to the ICU.

17           DR. J. JACOBS: But still even if  
18 you go to the floor, you should have to have  
19 some type of a handoff of --

20           CO-CHAIR JEFFRIES: We just need  
21 to -- just the language, it says ICU. So, I  
22 would just say ICU or wherever the patient --

1 DR. J. JACOBS: There's actually  
2 language we can use in here too. In here, the  
3 Anesthesiology Society defined the period of  
4 anesthetic care, and they defined it until  
5 they turn over care to somebody else.

6 Then they have sentences that say  
7 when that was in the recovery room and how  
8 that applies when it's in the ICU. So, the  
9 verbiage can be applied here so that it would  
10 cover the recovery room or whatever.

11 So, that's a good idea too. I  
12 would agree with all three of those  
13 suggestions.

14 MS. GALVIN: Okay. So, I don't  
15 have that in front of me, so what is the next  
16 --

17 CO-CHAIR JEFFRIES: The next thing  
18 is measure number two -- reliability.

19 MS. GALVIN: So, I guess in the  
20 area of reliability, if the data collection is  
21 as, you know, if we do sort of look at it from  
22 a simplistic yes-no, then the data should be

1 reliable.

2           We still have a concern about the  
3 elements when you say yes, that all of those  
4 elements were included.

5           But the data should -- and other  
6 studies have supported the use of a checklist  
7 to reduce errors. So that, to me, it seems a  
8 reliable measure.

9           Anybody else have anything to add?

10           CO-CHAIR JEFFRIES: I mean the one  
11 question I have, and I think it's a question  
12 for several of the measures, is there's a  
13 statement in the forms that were submitted  
14 that said reliability, validity testing -- and  
15 so how we could get around that.

16           DR. MAYER: Well, some of them, I  
17 mean there is an escape at least in some of  
18 the stuff I read that said they have face  
19 validity. I think that was the term that was  
20 used.

21           Then I don't know that we need to  
22 necessarily say here's the references of how

1 many we'll require and things like that.

2 I think there are other situations  
3 where clearly we don't know. Right? I mean  
4 we don't have -- we're not sure that it has  
5 validity or -- and I think we'll just have to  
6 recognize that, I mean that's all we can do.

7 I think one of the later ones is  
8 the composite measure of absence of any of the  
9 above. Well, I mean it sort of has face  
10 validity that if you avoid those  
11 complications, it's likely you're going to  
12 have better quality of your outcomes. Right?

13 But do we know that those are  
14 exactly the right ones or maybe there should  
15 be another one in there or something like  
16 that. Have we studied that?

17 The answer is no, but clinical  
18 impression is, is that those are the important  
19 ones to measure.

20 I mean that's the way I'm  
21 interpreting it. Is that where you're --

22 CO-CHAIR JEFFRIES: That's

1 reasonable for validity. Because again I  
2 think with face validity, we sort of have  
3 pulling out from --

4 DR. MAYER: Right.

5 CO-CHAIR JEFFRIES: -- having  
6 things be numerically presented to you.

7 DR. MAYER: Right.

8 CO-CHAIR JEFFRIES: For  
9 reliability, I mean I think that's unknown.

10 DR. MAYER: Right.

11 CO-CHAIR JEFFRIES: I mean I think  
12 that's the question. We don't know about the  
13 repeatability of these results from, again,  
14 center to center, time to time, whether or not  
15 over time we will see improvements because of  
16 changes that are made.

17 DR. HINKLE: I would just make a  
18 comment that in all of medicine that's  
19 practiced, probably only less than 50 percent  
20 is evidence-based. Then it goes to consensus.

21 Consensus sometimes then moves to  
22 evidence over time.

1 DR. JENKINS: An alternative  
2 measurement strategy for this is that most  
3 hospitals are measuring pathogens as part of  
4 their transmission requirement.

5 Many are actually using  
6 observation actually so one could actually not  
7 use the check box at all, but actually measure  
8 implementation of it.

9 DR. MAYER: I think the question  
10 is going to be the feasibility and how much,  
11 you know, do we necessarily want to add  
12 another 20 boxes to check or something like  
13 that.

14 I mean or mandate that that be  
15 used, which we do have to keep in mind that  
16 this is going to have some impact. What we're  
17 proposing and recommending is not going to be  
18 without impact on how we take care of  
19 patients.

20 And some of the things if we get -  
21 - this is definitely one where the enemy of  
22 good is better. I mean if we get to too much

1 data collection, we're going to distract  
2 people from taking care of the patients.

3 DR. J. JACOBS: I don't think this  
4 is going to be all that cumbersome. I mean  
5 right now we're collecting about 250 fields  
6 for every operation. Four yes-no check boxes  
7 on top of that isn't going to be a deal  
8 buster. So, I think it's pretty feasible from  
9 that point of view.

10 Kathy's idea is a very interesting  
11 idea about a way to validate what's going to  
12 be collected in the database externally. And  
13 once we collect these fields within the  
14 database, it's going to use the internal QI  
15 process from time to time to check out whether  
16 or not it's not just four boxes being checked  
17 routinely, but whether it's actually  
18 happening.

19 But I don't think that that really  
20 would change the way you would write this.  
21 That's just another way to validate or file  
22 within the hospital.

1 DR. JENKINS: The other loophole I  
2 saw in the process that they could approve  
3 something, but make you come back --

4 MS. HINES: And that's what all of  
5 these measures will become. And, Jeff, I  
6 think on the forms that were submitted where  
7 you state there was no reliability and  
8 validity testing probably thinking in pilot  
9 testing or in a national kind of setting, but  
10 certainly there was data behind choosing  
11 elements of the measures.

12 DR. J. JACOBS: And that's why I  
13 brought all these materials, is because  
14 there's hundreds of peer review publications  
15 that support these 20 metrics.

16 MS. HINES: Right. But just to --

17 DR. J. JACOBS: That question read  
18 was there formal reliability and validity  
19 testing done.

20 To be quite honest, I don't know  
21 what a formal reliability or validity test is,  
22 but I know that we use the stuff in the



1 database and we use it to track outcomes. And  
2 some of the stuff we used in the database for  
3 ten or 15 years.

4 MS. HINES: Right. And I just  
5 wanted to make that clear point because  
6 certainly there was no reliability or validity  
7 testing which I think Howard was trying to get  
8 to.

9 It wouldn't meet scientific  
10 acceptability. But there is data and I think  
11 it was just the way our form is constructed  
12 for our time out.

13 So, any additional testing or  
14 additional information gleaned from the book  
15 you probably --

16 DR. J. JACOBS: But in those forms  
17 and other places, all the references that are  
18 --

19 DR. JENKINS: But there's no data  
20 in the book about the checklists and --

21 DR. J. JACOBS: No, but there's  
22 other published papers which we went through

1 by Marc De Laval and by Alan Goldman, that  
2 talks about implementing these strategies.  
3 And those are referenced in this particular  
4 packet for this metric, because I know  
5 Marshall Jacobs put together all those  
6 publications for that.

7           So, did the STS database do  
8 validity testing of this? No. But is there  
9 peer review literature that supports it?  
10 Absolutely. Those peer review publications  
11 are listed in the materials in --

12           DR. JENKINS: What they're looking  
13 for is if you got -- let's suppose Austin did  
14 80 percent and Tampa did 90 percent. What  
15 does that mean?

16           Does that mean we forgot to check  
17 off the boxes, does that mean we interpreted  
18 how to check off the boxes differently, does  
19 that mean really that Tampa's performance is  
20 10 percent better than Austin? That's what  
21 they're looking at.

22           How would you really know? If

1 you're going to put that out in a public  
2 report card, you're saying that you believe  
3 that 90 is better than 80 and it -- I think  
4 that's what they're looking at.

5 DR. J. JACOBS: Yes, but it might  
6 be that some of that data never existed.  
7 There's no data that would ever be created to  
8 tell a guy jumping out of an airplane that  
9 it's a good idea to wear a parachute. Right?

10 DR. JENKINS: You can incorporate  
11 it as a structural element Jeff.

12 DR. J. JACOBS: That's basically  
13 what we're doing.

14 DR. JENKINS: I think that's what  
15 you want.

16 DR. J. JACOBS: Yes.

17 MS. HINES: And I'm just trying to  
18 tease it out and get clarity because those are  
19 the type of questions that the CSAC is going  
20 to look for.

21 If they look at a form to, as you  
22 all know, and see no reliability and validity,

1 it's going to be well, why did you even  
2 discuss this?

3 So, I'm just bringing the points  
4 out for discussion and --

5 DR. J. JACOBS: So, the answer is  
6 that there's piles of peer review literature  
7 that support it and the references are in the  
8 packet. That's the best way I can answer it.

9 MS. HINES: No, no no. That's  
10 fine. I'm just trying to make sure that we  
11 fairly represent it and have the discussion  
12 point --

13 MR. HARDER: And that's your  
14 homework if you get time-limited endorsement.

15 MS. HINES: Is to kind of --

16 DR. JENKINS: And is it limited to  
17 a year?

18 MR. HARDER: Two years.

19 MS. HINES: Two years.

20 The thing to consider with  
21 feasibility, too, that is often brought up, it  
22 may be 20 more elements, but the outcome of

1 those 20 elements, I mean they're truly not  
2 looking just at we don't want more burden, but  
3 does that outweigh the good? Does the burden  
4 outweigh the good?

5           So again, if it's not being done  
6 and equipment is not in the room when it  
7 should be, things like that, I think that  
8 would totally justify the 20 extra questions  
9 just from your standpoint.

10           DR. J. JACOBS: The trick is for  
11 this, you know, I've been thinking about so  
12 then we go back and over the next two years we  
13 try to do this reliability testing, but we're  
14 trying to prevent some pretty rare things.

15           How we're going to document, I  
16 guess that's a discussion for another time,  
17 but it's going to be tricky.

18           DR. MAYER: Well, you know, but  
19 there are some -

20           DR. J. JACOBS: No, I know. But if  
21 you can't - I understand you say that's your  
22 homework, but if you came back and said all

1 right, we want to have reliability and  
2 validity testing to demonstrate that it's a  
3 good idea to wear a parachute when you're  
4 jumping out of an airplane, well, where are  
5 you going to get the data on outcomes of  
6 people who didn't?

7                   So, I mean that's taking this  
8 argument to an extreme, but I think it applies  
9 to what we're talking about here just a little  
10 less extreme.

11                   MS. HINES: Well, and I think with  
12 what I'm seeing other STS - I talked to Dave  
13 Shahian. He's filled out a ton of these forms  
14 and stuff and I think he'll be very helpful  
15 and kind of -

16                   DR. J. JACOBS: I had dinner with  
17 Dave Shahian 48 hours ago in Vienna and we  
18 talked about - that's exactly what we talked  
19 about. He was sitting - me, him and his wife  
20 in this restaurant, and we spent two hours  
21 talking about these forms.

22                   So, I agree. That's the right guy

1 to talk to.

2 CO-CHAIR JEFFRIES: So, from a  
3 feasibility, just looking through the  
4 statements here, this is a little different  
5 because this is new. It's not something which  
6 currently exists in the data record.

7 And I think that's something  
8 you're really getting at, John.

9 Are we ready to discuss about  
10 recommending this or is there more discussion  
11 that we need to have?

12 DR. MAVROUDIS: If you need a  
13 motion, then I make a motion that we recommend  
14 it.

15 DR. HINKLE: Second.

16 CO-CHAIR JEFFRIES: Is there any  
17 dissension?

18 All right. So, we'll move on to  
19 the next one which is 13, mediastinitis.

20 DR. LOPEZ: I've got that one.  
21 Number 13, mediastinitis, that was PS3 in  
22 congenital heart surgery. The measure is the

1 rate of mediastinitis versus re-exploration  
2 after pediatric or congenital open heart  
3 surgery. It includes the following diagnosis  
4 of post-operative mediastinitis to meet the  
5 following criteria.

6           Criteria 1, a patient has  
7 organisms cultured for mediastinal fluid or  
8 tissue that is obtained during the surgical  
9 operation or by needle aspiration.

10           Number 2, the patient has evidence  
11 of mediastinitis by histopathologic  
12 examination or visualize evidence of  
13 mediastinitis seen during surgical operation.

14           Number 3, the patient has at least  
15 one of the following numbered signs or  
16 symptoms with no other recognized cause. That  
17 is fever, chest pain, sternal instability and  
18 at least one of the following: purulent  
19 mediastinal drainage, organisms cultured from  
20 mediastinal blood, drainage or tissue, or the  
21 widening of the cardiomeastinal silhouette.

22           Number 4, a patient is less than a



1 year of age and has at least one of the  
2 following: Signs or symptoms with no other  
3 recognized cause, fever, hypothermia, apnea,  
4 bradycardia or sternal instability, and at  
5 least one of the following features, purulent  
6 mediastinal drainage, organisms cultured from  
7 mediastinal blood, drainage or tissue, or  
8 widening of the cardiomediastinal silhouette.

9           Infections of the sternum, that is  
10 osteomyelitis, should be classified as  
11 mediastinitis.

12           Sternal instability that is not  
13 associated with a wound infection or  
14 mediastinitis, is not mediastinitis.

15           The time interval begins upon  
16 admission to the operating room. Ends 30 days  
17 post-op or until the time of discharge,  
18 whichever is longer.

19           DR. MAVROUDIS: So, if I got this  
20 right, no positive culture, no mediastinitis,  
21 right?

22           You need a positive culture.

1 DR. LOPEZ: Well, no.

2 PARTICIPANT: There could be a  
3 positive blood culture, right? As opposed to  
4 -

5 DR. LOPEZ: Yes. Mediastinal  
6 fluid. This is mediastinal blood, drainage or  
7 -

8 DR. MAVROUDIS: Oh, okay. I'm  
9 sorry. I misheard.

10 DR. LOPEZ: But you could also just  
11 have purulent drainage or widening of the  
12 cardiomediastinal --

13 DR. MAVROUDIS: So, I thought that  
14 - I don't have it in front of me.

15 DR. HINKLE: It doesn't say.

16 DR. J. JACOBS: This definition is  
17 on Page 254 of this big blue book. And it's  
18 the CDC definition. So, this is a definition  
19 that's developed by the Center for Disease  
20 Control.

21 There's a manuscript in this book  
22 that's first authored by Howell Walters from

1 Children's Hospital in Detroit. Then it goes  
2 into the rationale for incorporating this  
3 definition and the STS database's compared to  
4 other definitions that are out there. And  
5 it's basically the CDC definition which is  
6 harmonious with the definition in the STS  
7 adult cardiac database.

8           And all the definitions and the  
9 rationale behind it in this chapter here.

10           DR. MAYER: Okay. So, we can't  
11 rewrite the definition of mediastinitis

12           DR. J. JACOBS: Right. I think  
13 that's probably beyond - well, I think that's  
14 beyond the scope of our task here.

15           I mean there's a group of people  
16 that spent two years working on incorporating  
17 this into the STS database and there is good  
18 science behind it.

19           DR. MAVROUDIS: This is pretty  
20 straightforward. All I wanted was a  
21 clarification, and I got it. This is pretty  
22 straightforward. I don't see any problem with

1 it.

2 DR. LOPEZ: Yes, the blood culture,  
3 I guess, doesn't play a part in the  
4 definition.

5 DR. HINKLE: It could, but it's not  
6 sine qua non, I guess.

7 DR. MAVROUDIS: What else do you  
8 have there?

9 DR. LOPEZ: Do you know how they  
10 define fever in infants less than a year of  
11 age and apnea?

12 I mean in the neonatal literature,  
13 there is a precise definition for apnea. I'm  
14 just wondering how STS is defining it.

15 CO-CHAIR JEFFRIES: It would be the  
16 same.

17 DR. LOPEZ: It would be the same as  
18 the pediatric literature?

19 CO-CHAIR JEFFRIES: The apnea would  
20 be the same definition. Fever is most  
21 subjective.

22 DR. LOPEZ: Yes.

1 CO-CHAIR JEFFRIES: That's some  
2 sort of institution.

3 Well, where I worked it's anywhere  
4 from 38.2 to 38.9. So, I guess it depends on  
5 where you work.

6 DR. LOPEZ: Okay.

7 CO-CHAIR JEFFRIES: But apnea is,  
8 if I remember correctly, it's 20. So, 20 or  
9 30 seconds.

10 DR. LOPEZ: It's usually 20 in the  
11 pediatric literature.

12 CO-CHAIR JEFFRIES: Yes. And I  
13 think that would be similar.

14 DR. LOPEZ: Okay.

15 DR. MAVROUDIS: I don't see how you  
16 could argue with any part of this. It's a  
17 great indicator.

18 CO-CHAIR JEFFRIES: So, from an  
19 importance point of view

20 DR. LOPEZ: Yes, importance. It is  
21 important. And scientific acceptability.

22 CO-CHAIR JEFFRIES: So, Jeff, one

1 of the things of importance is demonstrating  
2 variation.

3 Have you seen that when you're  
4 looking through the STS data set, that there  
5 is variation across centers?

6 DR. MAVROUDIS: You mean what you  
7 call them on -

8 DR. MAYER: No, no.

9 DR. HINKLE: The outcomes. The  
10 outcomes.

11 They did mention that you - there  
12 was some mention in some of the mortality  
13 measures about variation across the STS  
14 database, but I assume -

15 DR. MAVROUDIS: Oh, I see.

16 DR. HINKLE: - assume all of these  
17 could have if you have the data there.

18 PARTICIPANT: I don't know that  
19 we've looked, have we?

20 DR. J. JACOBS: Well, what I can  
21 tell you is that we have not published any  
22 papers that show the variation of race,

1 mediastinitis or stroke or any of those things  
2 we're about to talk about.

3           But from working with the data in  
4 the STS database, there's no doubt that  
5 different hospitals just looking at the data,  
6 different hospitals have different -

7           DR. MAVROUDIS: Different hospitals  
8 report differently.

9           DR. J. JACOBS: Report different  
10 rates of mediastinitis.

11           Now, the actual, formal study of  
12 that had not been done, but it could be done.

13           DR. HINKLE: But I think you raise  
14 one point I was going to raise when we get to  
15 the mortality ones, which are probably  
16 relevant here. The whole issue of quality  
17 improvement is to decrease variation over  
18 time.

19           So, capturing that is important  
20 somewhere in, maybe in all of these measures,  
21 I'm not sure, but I mean generally trying to  
22 get to a new move, the whole process may be to

1 a new place, but then decrease the variation  
2 around it so that the outcome is more highly  
3 predictable.

4 DR. MAVROUDIS: Is there anything  
5 there that calls for taking into account  
6 gastrostomy, tracheostomy?

7 DR. JENKINS: Risk adjustment.  
8 You're looking at risk adjustment?

9 DR. MAVROUDIS: Yes, I am.

10 DR. J. JACOBS: Right. So, nobody  
11 that I know of has done a risk adjustment  
12 specifically for mediastinitis and created a  
13 tool to do that.

14 DR. MAVROUDIS: Right. So, what I  
15 mean is all I'm saying is that if we do  
16 measure this, the only way I guess that we  
17 could get this is to look at the database and  
18 see if there's tracheostomy and gastrostomy.

19 DR. J. JACOBS: And those are all  
20 variables that are tracked in the database.

21 DR. MAVROUDIS: Right.

22 DR. JENKINS: You could do it by



1 exclusion.

2 DR. HINKLE: Yes. Are you  
3 suggesting those would be exclusions in the -

4 DR. MAVROUDIS: I don't know if I'm  
5 suggesting that. What do you think?

6 DR. HINKLE: I don't know either.  
7 I would think that a proximity of a trach -

8 DR. MAVROUDIS: And the  
9 gastrostomy.

10 DR. HINKLE: - and the gastrostomy,  
11 probably - I don't know the answer, but I can  
12 see why you're raising the -

13 DR. MAVROUDIS: I think that that  
14 is a reasonable exclusion in my mind, because  
15 the chances mediastinitis in most patients is  
16 extremely high. 20 percent, 15 percent,  
17 something like that.

18 DR. HINKLE: Well, I don't know.  
19 But I mean it would actually before we start  
20 making this up, we ought to have the data.

21 I mean I'd rather include it and  
22 then we can figure out how to deal with it,

1 you know, and maybe that's another project is  
2 to try to risk adjust for mediastinitis and  
3 the presence of a preexisting trach and  
4 gastrostomy, you know.

5 I mean I think we're still in the  
6 developmental stage here. That's what I was  
7 sort of getting at before. Cast the net  
8 widely, then you figure out what -

9 (Simultaneous speakers.)

10 DR. MAVROUDIS: Right.

11 DR. MAYER: But I mean the issue is  
12 this is an important -

13 CO-CHAIR JEFFRIES: But the point  
14 is -

15 DR. MAYER: This is an important  
16 thing.

17 DR. MAVROUDIS: But that makes it  
18 even more important because the next thing is  
19 what are the issues that are associated.

20 DR. HINKLE: yes. Once you look at  
21 that variation, you can understand that -

22 DR. MAVROUDIS: Right.

1 DR. HINKLE: Exactly. The more  
2 complex and the higher volume sidebars.

3 MS. HINES: And remember you have -  
4 one of the things that you need to do is come  
5 up with research recommendations as well as -

6 DR. MAVROUDIS: Well, here's one of  
7 them, right?

8 Yes, those are not easy to come  
9 by, those things. So, we've got one. Good.

10 CO-CHAIR JEFFRIES: Kathy, did you  
11 have a comment?

12 DR. JENKINS: Well, I just thought  
13 that if that was such an unanswered question,  
14 it would question the scientific integrity  
15 that when we go forward with exclusions at  
16 this point, feel more confident about the  
17 measure and then do that research later to see  
18 if we can expand it.

19 Because it might go further in  
20 this process, I think that question about risk  
21 adjustment sitting in the background.

22 DR. MAYER: I'm not sure I totally

1 follow what you said, Kathy. I mean what  
2 you're saying is we ought to collect all the  
3 data and then figure out how to risk adjust it  
4 once we see what it looks like?

5 DR. JENKINS: I -

6 DR. MAYER: Is that -

7 DR. JENKINS: I'm new to the NQF  
8 process, so I thought there was sort of a  
9 formal proposal of an actual measure that was  
10 going to get endorsed.

11 So, this is an excellent measure  
12 that has a lot of the features that will make  
13 it need not very little controversy except for  
14 this risk adjustment problem since you don't  
15 have the data already.

16 So, I was just suggesting that  
17 conversion of the measures is a place to start  
18 so that you can get it through without the  
19 factor of risk adjustment or -

20 DR. J. JACOBS: I think that's an  
21 excellent point.

22 DR. JENKINS: - do it by category

1 with your categories to get around.

2 DR. J. JACOBS: I think that's an  
3 excellent point because we could start making  
4 a list of things that should be excluded like  
5 tracheostomy, gastrostomy, enterostomy,  
6 colostomy, whatever.

7 But if we had to say well, where's  
8 the data, we're doing that based on well,  
9 that's what we think is a risk, and it is a  
10 risk. But a better way is let's just track  
11 mediastinitis and then we could very easily  
12 study from the database.

13 DR. MAYER: But you're not  
14 proposing any of those things as an exclusion,  
15 right

16 DR. J. JACOBS: No, I'm not. No.  
17 I'm just saying -

18 DR. HINKLE: I think we're all  
19 saying the same thing.

20 DR. J. JACOBS: I don't think that  
21 the argument on the table is that we want to  
22 put those in as exclusions now. We want to

1 put - let's capture - we'll get to  
2 mediastinitis and let's study what a risk -

3 DR. MAYER: Right.

4 DR. JENKINS: But then that means -  
5 but if the centers have different variation in  
6 rates, are you adjusting them for quality  
7 difference or could it just be a case mix?

8 DR. HINKLE: Right. Could be a  
9 case mix. I think I would just say that it's  
10 proven that it's a trach, then you hope  
11 there's a quality improvement initiative to  
12 prevent it from happening.

13 I mean I don't know if it's silver  
14 trachs or something that would -

15 DR. JENKINS: I agree it's all  
16 important.

17 DR. HINKLE: - drive the -

18 DR. JENKINS: I'm not suggesting  
19 that trachs aren't important.

20 DR. HINKLE: No, I know you're not.

21 DR. JENKINS: I'm trying to make it  
22 into a performance measure without the -

1 CO-CHAIR JEFFRIES: And I think  
2 you're indicating that one of the rationales  
3 that you use are a basket of measures and you  
4 can't look at just one measure for a sample.  
5 But this measure and also looking at the case  
6 mix suggested measure will help you get some  
7 understanding.

8 At least you understand what case  
9 mix that institution holds. So, it makes some  
10 sense of some of these are good measures which  
11 aren't case mix suggested.

12 DR. JENKINS: The mediastinitis  
13 project is an excellent project.

14 DR. MAYER: Well, we're not under  
15 any gun here to publicly report for at least  
16 a few years, right? Didn't I hear that?  
17 Somebody say that? I mean I think we got time  
18 to figure this stuff out a little bit, you  
19 know.

20 DR. JENKINS: But it did say that  
21 you had to believe that these measures are  
22 ineligible to be performance measures now.

1 DR. MAYER: Then we should toss the  
2 whole lot of them out.

3 DR. J. JACOBS: No, I think they  
4 are, I mean as far as they spent two years  
5 developing their performance measures.

6 DR. MAVROUDIS: It's okay the way  
7 it is. It's okay the way it is. What you're  
8 saying is this is the incidence. You're not  
9 saying that this is the incidence in clean  
10 ones, it's just the incidence in all of them.

11 That's it, right? That's the  
12 definition right there.

13 DR. MAYER: I think what I'm - you  
14 can correct me if I'm wrong or if I'm  
15 mishearing this, because I don't want to get  
16 us down any garden paths here, but I think  
17 there's a recognition that we're going to  
18 propose a measure now, but we're gong to come  
19 back and revisit it in two years and refine  
20 it, right?

21 I mean this is an iterative  
22 process, not that we have - we've got stuff



1 perfectly established and all we're trying to  
2 do is figure out if you're adhering to the  
3 perfectly established ironclad evidence.

4 MS. HINES: Right.

5 DR. MAYER: Do I understand that  
6 right?

7 MS. HINES: Because I mean as you  
8 go back and you start looking at testing  
9 results, we've had stroke measures that had  
10 stroke/atrial fib flutter. Well, you start  
11 doing testing and you realize that - or TIEs.  
12 You realize TIEs are noise. So, they take it  
13 out and they refine it and just leave it as  
14 strokes.

15 So, that's part of the testing  
16 that you will find those things and make the  
17 revisions and the data will lock them in.

18 DR. MAYER: All right.

19 DR. HINKLE: I mean at NCQA, that's  
20 the same process.

21 DR. JENKINS: Intended use. So,  
22 does the intended use of the measure include

1 both public reporting and quality improvement?

2 Yes. If no, do not submit.

3 DR. HINKLE: When, right.

4 DR. JENKINS: If not, will you  
5 finish in 24 months?

6 DR. MAYER: I think the operative  
7 word there is "Intended," right?

8 DR. HINKLE: Yes. Right.

9 MS. HINES: And the quality  
10 improvement versus the public reporting. I  
11 mean we truly did just used to look at quality  
12 improvement in metrics. We won't endorse just  
13 quality improvement. It has to be used.

14 And as you say, there's a timeline  
15 to public reporting, but it has to -

16 CO-CHAIR JEFFRIES: Can you give me  
17 an example of a metric that you did endorse  
18 that would suggest a quality improvement  
19 metric?

20 MS. HINES: In the old days. In  
21 the old days.

22 CO-CHAIR JEFFRIES: Can you give me

1 an example of one?

2 MS. HINES: Oh, sure. Home health,  
3 we just - there were some original measures  
4 that came through that said improvement and  
5 ability to do upper body dressing.

6 It may be perfectly relevant as a  
7 quality improvement measure, you know,  
8 certainly within a larger set. Do you want it  
9 for public reporting? No.

10 So, it's great to know so that you  
11 can prepare, but you really didn't want that  
12 to be published on a website, what does that  
13 mean to the consumers, what does that really  
14 show when we had broader functional status  
15 measures that weren't all encompassing.

16 So, that's the closest thing that  
17 comes to mind.

18 CO-CHAIR JEFFRIES: So, we went  
19 through the importance and the scientific  
20 acceptability.

21 Any other elements of discussion  
22 there?

1 DR. MAYER: Well, only what we just  
2 said. STS will need to develop new statistic  
3 models for associated variable - for variables  
4 associated with this complication.

5 DR. J. JACOBS: Such as severity of  
6 disease or anatomic problems like tracheostomy  
7 or gastrostomy.

8 DR. MAYER: Or immune deficiency or  
9 -

10 DR. J. JACOBS: But none of that  
11 prevents this from being something that should  
12 be part of this bucket of metrics, in my mind.

13 DR. MAYER: Right.

14 CO-CHAIR JEFFRIES: And usability.  
15 It seemed that there was an adult measure, but  
16 it's been pretty focused on damages.

17 DR. LOPEZ: Right.

18 CO-CHAIR JEFFRIES: And then any  
19 comments about feasibility?

20 DR. MAYER: I think it's pretty  
21 easily trackable.

22 CO-CHAIR JEFFRIES: Actually in

1 Washington State starting in, I think it's  
2 January, there's going to be a public  
3 reporting measure of a cardiac surgical  
4 nature. Cardiac surgery. Washington State.

5 DR. JENKINS: In kids too?

6 CO-CHAIR JEFFRIES: Everything.

7 Yes, kids and adults.

8 DR. HINKLE: And hospital  
9 infections are becoming a requirement. A lot  
10 of Department of Public Health, State  
11 Department of Health.

12 CO-CHAIR JEFFRIES: Okay. So, our  
13 recommendation?

14 DR. MAVROUDIS: I move it.

15 CO-CHAIR JEFFRIES: All right. So,  
16 the next measure is 14, which is stroke after  
17 pediatric cardiac surgery.

18 The measure is the rate of new  
19 onset stroke rate after pediatric and general  
20 heart surgery.

21 The numerator is the number of  
22 patients who undergo pediatric and general

1 heart surgery and develop postoperative  
2 stroke/CVAs defined by the following  
3 definition.

4           The rude definition of stroke is  
5 any confirmed neurological deficit of abrupt  
6 onset caused by a disturbance in blood flow to  
7 the brain or when the neurologic deficit does  
8 not resolve in 24 hours. And the temporal  
9 elements incorporated in the definition allow  
10 for a distinction between stroke and a  
11 transient ischemic attack wherein there is a  
12 temporary loss of neurologic function  
13 resulting from a temporary alteration in  
14 cerebral blood flow, but not resulting in  
15 permanent brain injury and with symptoms of  
16 that resolve within 24 hours. A RIND or  
17 reversible ischemic neurologic deficit is a  
18 sub-type of stroke with a neurologic function  
19 and symptoms resolve within 72 hours.

20           The numerator is - excuse me. The  
21 denominator is patients who undergo pediatric  
22 and general heart operations. And the

1 exclusions are operations which are not of the  
2 above type.

3 DR. J. JACOBS: So, that definition  
4 is out of the chapter that's on - I think it's  
5 on Page 234 in this book. And the definition  
6 is on Page 237.

7 This chapter was authored by a  
8 group of cardiologists and cardiac surgeons  
9 with substantial input from neurology. And  
10 Dan Link is the pediatric neurologist at  
11 Children's Hospital in Philadelphia who is  
12 very involved in stroke research.

13 The definition must harmonize with  
14 the definitions used for stroke in the STS  
15 adult cardiac database along with the American  
16 College of Cardiology, NCDR.

17 So, by using that definition we're  
18 going to call a stroke the same thing, and ACC  
19 NCDR call a stroke the same thing, STS adult  
20 cardiac database called a stroke. Plus,  
21 that's harmonized with the definition used by  
22 several neurologists and scientists.

1           So, the strengths and weaknesses  
2 of that definition and the arguments for and  
3 for not using it and the reason why it was  
4 ultimately chosen are spelled out in great  
5 detail in this paper.

6           I think based on that definition  
7 it's pretty trackable. It's pretty important.  
8 And the science behind it is in the paper.  
9 That's just like the last one. Just like  
10 there's a tracheostomy is probably a pre-  
11 operative risk factor. For mediastinitis  
12 there's probably certain variables that are  
13 preoperative risk factors for stroke.

14           And the next step is going to be  
15 the same exact thing, just like we can use  
16 this to study what's high and low risk, we can  
17 use this the same way with the STS database to  
18 say which variables are associated with more  
19 or less strokes.

20           CO-CHAIR JEFFRIES: Right. I mean  
21 I think you have started on that discussion in  
22 the data that you submitted and the range for



1 stroke after an ASD was only one percent.

2 Again, it indicates some sort of  
3 complexity adjustment.

4 DR. J. JACOBS: No doubt.

5 CO-CHAIR JEFFRIES: Is something  
6 you should consider. But I think that that is  
7 going to be similar for all of these.

8 DR. J. JACOBS: Yes.

9 CO-CHAIR JEFFRIES: I mean if all  
10 you do is ASDs, you're going to have a low  
11 incidence of most of these complications.

12 Jeff, I have one question,  
13 enumerator question. So, the definition talks  
14 about the difference between an RIND -

15 DR. J. JACOBS: Right.

16 CO-CHAIR JEFFRIES: - and a  
17 stroke. So in the numerator, are you  
18 including RINDs?

19 DR. J. JACOBS: Yes. We - that was  
20 the hardest part of this whole paper. And the  
21 average - the most common definition utilized  
22 by neurologists, say that a reversible

1 ischemic neurologic deficit is some type of a  
2 stroke.

3                   So, therefore, yes, we are because  
4 they say it's a type of stroke.

5                   CO-CHAIR JEFFRIES: Adults use 72  
6 hours after CABG.

7                   DR. J. JACOBS: No.

8                   CO-CHAIR JEFFRIES: I think they  
9 did. I have to look, but I think that's what  
10 I remember seeing.

11                   DR. J. JACOBS: The STS definition  
12 -

13                   CO-CHAIR JEFFRIES: Well, in the  
14 NQF measure.

15                   DR. J. JACOBS: This whole thing  
16 with stroke and reversible ischemic neurologic  
17 deficit is quite a topic, discussed topics.

18                   CO-CHAIR JEFFRIES: The adult  
19 measure was after 72 hours. Postoperative  
20 neurologic deficit which has been greater than  
21 72 hours.

22                   DR. J. JACOBS: That's very

1 interesting because the STS definition of a  
2 stroke is greater than 24 hours. So, then  
3 they're tracking a stroke exclusive of the  
4 subtype of stroke defines neurologic deficit  
5 in that metric.

6 CO-CHAIR JEFFRIES: Right.

7 DR. J. JACOBS: So, I think we  
8 could do it either way.

9 DR. HINKLE: Well, it may be in the  
10 adult, the prevalence of carotid artery  
11 disease, TIEs. I mean there's probably a  
12 difference from that perspective, I would  
13 think, that might lead to more branching.

14 So, the data is probably dictating  
15 a difference already in 72 versus -

16 CO-CHAIR JEFFRIES: It's also, I  
17 guess, in some ways, what is important to the  
18 person who's being impacted, I guess.

19 DR. HINKLE: Yes.

20 CO-CHAIR JEFFRIES: If you have a  
21 deficit that resolves in three days or is  
22 resolved in one day, it's not going to.

1 DR. J. JACOBS: So, why 72 and not  
2 96? We're dichotomizing it between this  
3 variable, right?

4 CO-CHAIR JEFFRIES: Exactly.

5 DR. J. JACOBS: I certainly don't  
6 feel strongly either way. If the adult metric  
7 is 72 hours, what they're doing then is  
8 they're tracking in the STS database, a stroke  
9 as defined as greater than 24 hours. And  
10 they're just defining whether that stroke was  
11 a reversible ischemic neurologic deficit and  
12 excluding those. And this metric now tracks  
13 strokes inclusive of reversible ischemic  
14 neurologic deficits.

15 And I think this metric could be  
16 written to be harmonious with the adult  
17 database and say a stroke with symptoms that  
18 last more than 72 hours, I think that we would  
19 have no problem with that.

20 DR. MAVROUDIS: Except you don't  
21 really know where the big symptoms of a child  
22 is a seizure and it gets treated. If you

1 don't treat it, then you know that it persists  
2 and you may have some issues whether it  
3 persists or it doesn't persist.

4           And a stroke - I mean and a  
5 procedure after an operation is no small  
6 matter. And so clearly this is a very  
7 important metric without question.

8           DR. J. JACOBS: Yes.

9           DR. MAVROUDIS: And then the other  
10 subtypes here as I think you're basing it  
11 mostly on physical examination, aren't you?  
12 Because if you do EEGs on every kid, every  
13 child, you're going to get some spikes there  
14 that you won't see when grandma seizures, that  
15 it looks like a seizure on the EEG and then  
16 you treat it.

17           And so then we really don't know  
18 what the - and then the problem with that is  
19 not everybody does EEGs across the board.

20           And so, this is becoming a little  
21 bit more difficult especially since some  
22 people are actually getting CT scans before

1 and after. And then your stroke rate may be  
2 30 percent if you look for it, and two percent  
3 if you don't.

4 So if I've got this right here,  
5 you and all the colleagues decided that this  
6 is going to be on physical exam, right?

7 DR. J. JACOBS: Right.

8 DR. MAVROUDIS: And then supported  
9 by something else.

10 DR. J. JACOBS: Right. In other  
11 words, if you have a finding on CT scan with  
12 a normal physical exam, that's not going to  
13 count for this.

14 DR. MAVROUDIS: Right. Right.

15 DR. J. JACOBS: And what that does  
16 is it creates a level playing field for  
17 variations in institutional practice between  
18 CT scanning everybody who has heart surgery  
19 and nobody.

20 DR. MAVROUDIS: So, you've already  
21 thought about that, clearly.

22 DR. J. JACOBS: Yes. And quite a

1 bit of this paper talks about that.

2 DR. MAVROUDIS: So, the point is  
3 that we're talking about physical exam or  
4 other signs associated with stroke like  
5 seizure and so forth and so on, right?

6 DR. J. JACOBS: Right.

7 DR. JENKINS: Physical exam by a  
8 neurologist or a pediatric neurologist?

9 DR. J. JACOBS: We said any  
10 confirmed neurologic deficit. We didn't get  
11 into that detail about who does the physical  
12 exam.

13 DR. JENKINS: I'm just thinking of  
14 FET babies and global injury and anesthesia  
15 and -

16 DR. MAVROUDIS: But, I mean, that's  
17 a good one though. Confirmed, right? So, in  
18 your hospital, the confirmation might be  
19 different than my hospital, but it's  
20 confirmed.

21 DR. MAYER: So, can I -

22 DR. J. JACOBS: Yes, let's -

1 DR. MAYER: Can I just make sure I  
2 understand what's in this neurologic injury or  
3 stroke definition?

4 Are patients who seize going to be  
5 counted here?

6 DR. J. JACOBS: Yes.

7 DR. MAYER: Because it's sort of in  
8 the chapter, it's in the controversies. What  
9 section is it? The way I read it, it's on -

10 DR. HINKLE: I mean the measure is  
11 titled "Stroke or Cerebrovascular Accident."

12 DR. J. JACOBS: If the answer is in  
13 this chapter. I don't want to -

14 DR. MAYER: Is it? Maybe I misread  
15 it.

16 DR. J. JACOBS: On Page 237, Number  
17 9.

18 CO-CHAIR JEFFRIES: I don't think a  
19 seizure in and of itself implies neurologic  
20 deficit.

21 DR. HINKLE: It says - the  
22 definition says rate of new onset of stroke or



1 cerebrovascular accident. It doesn't say  
2 anything about seizures. Seizures could be a  
3 secondary manifestation of a stroke, but -

4 DR. MAVROUDIS: Seizures mean  
5 something down the road, doesn't it?

6 DR. MAYER: Most likely. But not  
7 always.

8 DR. HINKLE: Right.

9 DR. MAYER: But just forget that  
10 part. Is it in or out, the seizure -

11 DR. J. JACOBS: If you have a  
12 seizure without any confirmed neurologic  
13 deficit, it's out. If you have a seizure with  
14 confirmed neurologic deficit, it's in.

15 DR. MAYER: Fine. Okay. So, the  
16 issue is the neurologic deficit, not the  
17 seizure.

18 DR. J. JACOBS: Right.

19 DR. MAYER: And then the neurologic  
20 deficit may be any of a variety of things -

21 DR. J. JACOBS: Right.

22 DR. MAYER: - from hemiparesis to

1    aphasia -

2                   DR. J. JACOBS: Yes.

3                   DR. MAYER: - to whatever, right?

4                   DR. J. JACOBS: Yes.

5                   DR. MAYER: Okay.

6                   DR. J. JACOBS: Yes.

7                   DR. JENKINS: Could it be global or  
8   not?

9                   DR. J. JACOBS: Yes.

10                  DR. JENKINS: Does it have to be  
11   focal?

12                  DR. J. JACOBS: It could be focal  
13   or global.

14                  DR. JENKINS: Global too.

15                  DR. J. JACOBS: Yes.

16                  DR. HINKLE: So, now you're  
17   confusing me a little bit because I'm going to  
18   protect my anesthesia colleagues which is, you  
19   know, there's a lot of regional anesthesia  
20   done now if there's a complication from a  
21   thoracic epidural, is that all excluded here?

22                  DR. J. JACOBS: You have to read

1 the whole definition.

2 DR. HINKLE: Okay.

3 DR. J. JACOBS: Stroke is any  
4 confirmed neurologic deficit of abrupt onset  
5 caused by a disturbance of blood flow to the  
6 brain.

7 DR. HINKLE: Right.

8 DR. J. JACOBS: So, if you have a  
9 neurologic deficit from - disturbance of blood  
10 flow to the brain -

11 DR. HINKLE: Great. Just checking.

12 DR. J. JACOBS: - when the  
13 neurologic deficit does not resolve within 24  
14 hours.

15 And this is a pretty power-packed  
16 six pages that really answers every question  
17 that's come up so far.

18 DR. JENKINS: And I just don't  
19 understand the 24 hours, and that's the type  
20 of patients who are often paralyzed. I just  
21 don't understand that.

22 DR. J. JACOBS: That's the

1 definition that the American Society -

2 DR. JENKINS: But in the context of  
3 pediatric heart surgery.

4 DR. HINKLE: Right. I was thinking  
5 of even other anesthetics that can cause  
6 myoclonus and things that look like seizures.  
7 It has to be a cerebrovascular - but to me,  
8 it's going to be confirmed on an MRI or  
9 something, I would guess. But I mean you raise  
10 a really good point. They're all on -

11 DR. JENKINS: If it's there at 72,  
12 I guess, not -

13 CO-CHAIR JEFFRIES: It's not saying  
14 it's 24 hours if you have a deficit, but it  
15 says you have a stroke that doesn't resolve  
16 within 24 hours and it becomes apparent -

17 DR. J. JACOBS: Right. Exactly.  
18 That's the answer -

19 DR. JENKINS: And if it was there  
20 at 24 and it resolved by a week.

21 CO-CHAIR JEFFRIES: You won't know.  
22 I mean some of them you won't know. I mean I

1 think you're right. There's going to be some  
2 things you won't know.

3 DR. J. JACOBS: But if you merge  
4 normal, there are things are okay, and then it  
5 should be counted as a stroke.

6 What you're missing -

7 DR. HINKLE: Plus, there's  
8 cognitive dysfunction.

9 DR. J. JACOBS: The incidence of -  
10 the amount of time that you're going to miss  
11 somebody who's been paralyzed and sedated for  
12 four days and they wake up normal, but they  
13 actually had a stroke that resolved after 61  
14 or 78 hours, that's probably not the most  
15 common scenario.

16 So, I don't think I would lose too  
17 much sleep over that one.

18 DR. MAYER: I mean this is a  
19 clinical definition, right?

20 DR. J. JACOBS: It is. And it's a  
21 clinical definition that was intensely  
22 wordsmithed with guys that are real experts in

1 this stuff.

2 I'm doing my best to claim what we  
3 came up with, but I'm certainly not the  
4 expert. I was a facilitator.

5 CO-CHAIR JEFFRIES: So, just the  
6 language about RIND and health risks, I'm  
7 confused.

8 DR. J. JACOBS: Well, what an RIND  
9 is, is some type of stroke. And it's one that  
10 is completely resolved in 72 hours.

11 So, the only question is if you  
12 wanted to make - the options we have as a  
13 group is to say we're going to harmonize with  
14 what the adult metric is which means we're  
15 going to say a stroke  
16 with symptoms that persist beyond 72 hours,  
17 which is okay, or we're going to do it with  
18 cutoff of 24.

19 I don't feel strongly about either  
20 one of those.

21 DR. MAVROUDIS: I think the way it  
22 is, is okay. I think our discussion was a

1 clarification of things. And if further  
2 clarification needs to be done, we can add a  
3 pop-up to it like you're talking about.

4 MS. HINES: Just a question because  
5 this measure is 18 and under. The adult  
6 measure started at over 20. What happened to  
7 the 19?

8 DR. J. JACOBS: This is an  
9 interesting question that the scope goes  
10 beyond just this group. The STS congenital  
11 heart surgery database has stratified patients  
12 into four age groups; neonates, infants,  
13 children and adults. And we've said that an  
14 adult is somebody who's over 18.

15 I recently learned that the CDC  
16 defines an adult as somebody who's over 21.

17 MR. HARDER: And that's what  
18 congress said.

19 DR. J. JACOBS: Right.

20 DR. JENKINS: And the FDA.

21 DR. MAYER: That must make it  
22 right.

1 (Laughter.)

2 PARTICIPANT: Maybe between the two  
3 measures, the adult measure -

4 MS. HINES: Define 16. That was  
5 the first one.

6 PARTICIPANT: I mean these are only  
7 - this is probably a handful of patients we're  
8 talking about.

9 MS. HINES: I'm sure. It's just  
10 somebody's got to look at it.

11 DR. J. JACOBS: But we've got to  
12 get this right.

13 (Off-the-record comments.)

14 DR. J. JACOBS: The ones it will  
15 turn out to be is if you're stabbed in the  
16 heart and you're 19, you don't have anywhere  
17 to go right now.

18 (Laughter.)

19 DR. J. JACOBS: So, we in our  
20 database, said a child is under 18, but I  
21 don't know that that might not be something  
22 down the road we might have to revise, but I



1 think we'd have to study it a little bit and  
2 find out what everybody else is saying.

3           And I think we came up with 18  
4 because that's kind of like an average  
5 compared to what we heard from different  
6 people.

7           Kathy just said the FDA is 16, CDC  
8 is 21, so I would think for now we should keep  
9 it at 18 with the possibility of potentially  
10 revising it down the road realizing that if  
11 you have an acquired cardiac lesion between 18  
12 and 20, there's no NQF metrics that are going  
13 to cover you.

14           MR. HARDER: But congress said,  
15 Jeff, the age is 21.

16           DR. J. JACOBS: Okay.

17           MR. HARDER: Just so you know. I  
18 know that for sure. Just so you know. And  
19 that's what the Impact Registry is going to be  
20 too. It's 21, just so you know.

21           DR. J. JACOBS: Right. And  
22 that's where I heard about this. The Impact

1 is doing 21.

2 MR. HARDER: That's because I  
3 raised the issue.

4 DR. J. JACOBS: Was this in Vegas?  
5 There was a meeting in Vegas where the impact  
6 guys were telling me about 21.

7 DR. HARDER: Yes.

8 DR. HINKLE: What is it in Europe?

9 DR. J. JACOBS: Well, you can drink  
10 beer in London when you're 12.

11 DR. HINKLE: I know that, but the  
12 definition that - there's an international  
13 database that might define it.

14 DR. J. JACOBS: No, no. In the STS  
15 and EACTS databases right now it's 18.

16 DR. HINKLE: It's 18.

17 DR. J. JACOBS: Everything in the  
18 STS database is done in the EACTS, and vice-  
19 versa. So, it's 18.

20 DR. HINKLE: Okay.

21 DR. J. JACOBS: But I was actually  
22 thinking that we might need to revisit the

1 issue because Impact is saying it's 21 based  
2 on what congress told the FDA.

3 DR. HINKLE: Okay.

4 DR. JENKINS: The Impact is  
5 ultimately going to hit adults.

6 DR. J. JACOBS: Right. But I know  
7 that we made the decision in Impact to make  
8 the cutoff between children and adults at 21.

9 And that's one of the few  
10 differences right now between Impact and STS  
11 database, and it might be that the STS  
12 database needs to make that change too.

13 It's really not that many  
14 patients, but it's something we need to  
15 revisit.

16 CO-CHAIR JEFFRIES: So, the only  
17 other comment I had here I think I already  
18 brought up, which is about the potential in  
19 the future to think about risk adjustment or  
20 complexity adjustment.

21 DR. J. JACOBS: And I think that's  
22 going to apply for every complication we're

1 tracking right now.

2 CO-CHAIR JEFFRIES: Okay.

3 DR. J. JACOBS: And it's probably  
4 most relevant for mediastinitis and stroke,  
5 but it's also going to be relevant for heart  
6 block and other things as well.

7 CO-CHAIR JEFFRIES: And is this  
8 like mediastinitis when you've looked at the  
9 data set in an unpublished manner? There's a  
10 variation among centers?

11 DR. J. JACOBS: Yes, I think there  
12 is for every one of these, but I don't have a  
13 reference that I can provide for that.

14 That's just me looking at the  
15 data.

16 CO-CHAIR JEFFRIES: Sure. I don't  
17 have any other comments.

18 DR. MAVROUDIS: I move.

19 CO-CHAIR JEFFRIES: So, why don't  
20 we -

21 PARTICIPANT: Second.

22 CO-CHAIR JEFFRIES: So, why don't

1 we break for lunch.

2 (Whereupon, the above-entitled  
3 matter went off the record at 12:23 p.m. and  
4 resumed at 1:12 p.m.)

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

2    1:12 p.m.

3           CO-CHAIR JEFFRIES: Why don't we  
4 skip 15. We'll just come back to that one.

5           DR. MAVROUDIS: I know. Let's go  
6 to the most controversial one. Just kidding.

7           CO-CHAIR JEFFRIES: So, that  
8 wouldn't be 16, but we'll go to 16. So, 16 is  
9 my measure as primary, and you're the  
10 secondary. And that is arrhythmia  
11 necessitating permanent pacemaker insertion.

12           So, the brief description is  
13 percentage of pediatric and congenital heart  
14 surgery patients with a new onset arrhythmia  
15 that requires postoperative permanent  
16 pacemaker insertion.

17           The numerator, a stated number of  
18 pediatric and congenital heart patients with  
19 new onset arrhythmia or prior insertion of a  
20 permanent pacemaker after heart surgery. And  
21 then there's some definitions. And that  
22 implantation and utilization of a permanent

1 pacemaker for treatment of any arrhythmia,  
2 including heart block.

3           And the time window is 30 days  
4 post-op or until time of discharge, whichever  
5 is longer. And the denominator is number of  
6 pediatric and general heart surgery operations  
7 with the exclusions, as we said before - well,  
8 actually the one other set of exclusions are  
9 patients with implanted pacemakers before  
10 surgery. And then the other set of exclusion  
11 are patients who don't have pediatric or  
12 congenital cardiac operations.

13           DR. MAVROUDIS: The only thing that  
14 I have to comment on is whether it was clear  
15 enough that this thing occurred, this  
16 occurrence, this arrhythmia occurred after  
17 open heart surgery or after any kind of  
18 surgery during that hospitalization.

19           I think it's fairly clear. The  
20 thing that we have to be careful of is that  
21 patients, and we talked about this before,  
22 that some patients come to the operating room

1 with an arrhythmia who will get pacemaker  
2 intentionally for that purpose. But I think  
3 this is clear that it eliminates those  
4 patients just by the wording.

5           If it's not clear to everyone,  
6 then we should change the wording. I think  
7 it's clear to me.

8           DR. J. JACOBS: Where we said new  
9 onset arrhythmia.

10           DR. HINKLE: Yes, new onset.

11           DR. MAVROUDIS: Right.

12           CO-CHAIR JEFFRIES: And I think the  
13 exclusion for that has spelled that out.

14           DR. HINKLE: It does say begins on  
15 admission to the operating room. So, my only  
16 thought about it is I think that's fair, but  
17 I think it's rarely there could be arrhythmias  
18 from the anesthesia or that those would be  
19 self limited and not caused by the surgery  
20 necessarily. But surgery and anesthesia are  
21 together in this process, so -

22           DR. MAVROUDIS: I mean you can also



1 say that measuring pressures afterwards you  
2 put the needle to the wrong place and then -

3 DR. J. JACOBS: But you could have  
4 a stroke because of the way the anesthesia is  
5 being administered, also.

6 DR. HINKLE: Right.

7 DR. J. JACOBS: You can get  
8 mediastinitis if the anesthesiologist doesn't  
9 use good sterile technique.

10 So, this isn't to judge the  
11 performance of the surgeon. This is to judge  
12 the performance of the surgical team.

13 CO-CHAIR JEFFRIES: Absolutely.

14 DR. HINKLE: Yes. Right.

15 DR. MAVROUDIS: This is a very  
16 important issue, clearly, because it's an  
17 enduring complication. And the sad thing is  
18 that we really don't know the impact of  
19 pacemaker insertion in a two-year-old child  
20 for the rest of his or her life.

21 I mean there are some scattered  
22 reports about it, but we don't know what that

1 does to their lifestyle - not lifestyle, but  
2 for the longevity of that patient.

3 My guess is that it's  
4 significantly less. I would say on the order  
5 of ten to 15 years, but we're going to find  
6 out.

7 DR. JENKINS: Did you ask people  
8 about variation and indication for pacemaker?  
9 I mean, is it standardized?

10 DR. J. JACOBS: Yes, there is a  
11 variation when one would put in a pacemaker  
12 and when one would not. But the postoperative  
13 indications for putting in a pacemaker, I  
14 think, are a little bit tighter.

15 DR. JENKINS: My worry about this  
16 measure was potential unintended consequences.

17 DR. MAVROUDIS: Like what?

18 DR. JENKINS: Well, people chose  
19 not to put pacemakers -- to not to have  
20 pacemakers implanted and patients --

21 DR. MAVROUDIS: They'll go to hell.

22 DR. JENKINS: What?

1 DR. MAVROUDIS: They'll go to hell.

2 DR. JENKINS: They'll go to hell.

3 Okay. Could be, but the baby would have  
4 first.

5 DR. MAVROUDIS: No, that's what I'm  
6 saying. I mean if they're doing it because of  
7 that, then they're really missing out on why  
8 they became a physician.

9 DR. JENKINS: I'm with you, but I'm  
10 just saying that when you put P for measures  
11 out there, you do have to worry about  
12 unintended consequences.

13 And when you're not at iron-clad  
14 indication territory --

15 DR. J. JACOBS: But there are some  
16 things that are iron-clad indications, and  
17 that's the one we're trying to keep track of.  
18 I mean if you've got a little one with heart  
19 block after a VSD closure, you're going to get  
20 a pacemaker.

21 DR. JENKINS: But that's not what  
22 you're asking.

1 DR. J. JACOBS: Right.

2 (Simultaneous speakers.)

3 DR. J. JACOBS: There was a fair  
4 amount of discussion that went into that  
5 because the original written out version was  
6 the third degree. And then, in the final  
7 analysis, that's probably 90 percent of them.  
8 And the remaining ten percent, I guess you get  
9 sick sinus syndrome and other things.

10 But the reason it was left in  
11 after that postoperative sick sinus syndrome  
12 is also in some ways the manifestation of poor  
13 surgical technique.

14 DR. MAVROUDIS: As long as we're in  
15 good shape, Mr. Chairman, are we continuing or  
16 do we - can we make a motion or -

17 CO-CHAIR JEFFRIES: Well, let's  
18 just go through this.

19 DR. MAVROUDIS: Okay.

20 CO-CHAIR JEFFRIES: So, from an  
21 importance point of view --

22 DR. MAVROUDIS: Way important.

1 Highly important.

2 CO-CHAIR JEFFRIES: And again I  
3 think it's, you know, my comment was similar  
4 to the things you've already stated that we  
5 didn't have the -- I think there was some  
6 assumption there's variation.

7 I mean it was listed there was one  
8 to three percent incidence, but that there are  
9 variation across centers.

10 DR. J. JACOBS: Oh, there's no  
11 doubt.

12 CO-CHAIR JEFFRIES: And that  
13 there's opportunity for improvement.

14 DR. J. JACOBS: Yes, it should be  
15 zero patient. I mean I've had patients I've  
16 closed a VSD on and put a pacemaker in and -

17 DR. MAVROUDIS: I don't think it  
18 should be zero percent.

19 DR. J. JACOBS: In a perfect world.

20 DR. MAVROUDIS: It shouldn't be  
21 zero percent because the anatomy isn't as  
22 consistent. And that's why it shouldn't be

1 zero.

2 DR. J. JACOBS: Yes. But there's  
3 definitely variation.

4 DR. MAVROUDIS: You'd like it to be  
5 zero.

6 DR. J. JACOBS: You'd like it to be  
7 zero, but there's definitely variation.

8 CO-CHAIR JEFFRIES: And do you  
9 track pre-existing pacemakers currently in the  
10 STS data set?

11 DR. MAVROUDIS: If it's a pre-  
12 operative pacemaker -- if it's a pre-operative  
13 pacemaker, it's in the --

14 DR. MAYER: I think it's a pre-  
15 operative arrhythmia is what's in the current  
16 version right at this minute, and then --

17 DR. MAVROUDIS: Yes. The answer is  
18 yes.

19 CO-CHAIR JEFFRIES: So, if someone  
20 has a pacemaker, they would track pre-op  
21 arrhythmia.

22 DR. J. JACOBS: Yes.

1 CO-CHAIR JEFFRIES: But that  
2 doesn't necessarily mean it's a pacemaker.

3 DR. J. JACOBS: But they're not  
4 going to have -- if they have a pacemaker,  
5 their operation isn't going to include  
6 pacemaker implantation within 30 days of  
7 surgery because they've already got one.

8 Their operation might be a battery  
9 change or a lead change.

10 CO-CHAIR JEFFRIES: Okay. But  
11 that's a separate code.

12 DR. J. JACOBS: Separate code.

13 CO-CHAIR JEFFRIES: I don't have  
14 any other thing from what I've reviewed.

15 Do we need to have any more  
16 discussion about -

17 DR. HINKLE: Well, I would like -  
18 I'm going to ask a question that will clarify  
19 questions that I would have asked on all the  
20 others, you know?

21 CO-CHAIR JEFFRIES: Okay.

22 Dr. Hinkle: So, it has to do with

1 the code. The litany of CPT codes and ICD-9s,  
2 I guess.

3 So, the question to you is that  
4 we're in ICD-9 world, the United States.  
5 Congress has said on October the 20th, 2013  
6 we're going to go to ICD-10. You made some  
7 comment about ICD-11.

8 Europe, the rest of the world is  
9 all in ICD-10 now. That's a huge  
10 transformation that's going to take place.

11 So, I'm trying to understand the  
12 cross -- sounds like you guys already maybe  
13 have the ICD-9, ICD-10, 11 crosswalk done.  
14 I'm not sure, but the rest of the healthcare  
15 in the United States does not.

16 It's going to be like a Y2K issue,  
17 we think, going forward. So, my question has  
18 really to do with the timing and when this  
19 two-year window we're talking about, is it  
20 2011 and 2012?

21 You're talking about -- it won't  
22 even be because ICD-9 is not supposed to --



1 it's not mandated until October 20th, 2013  
2 right now at least. So, that's one of my -

3 DR. J. JACOBS: So, those are CPT  
4 codes there.

5 DR. HINKLE: Yes, I know, but -

6 DR. J. JACOBS: Which is a totally  
7 separate issue.

8 DR. HINKLE: Yes.

9 DR. J. JACOBS: And CPT gets  
10 updated every single year.

11 DR. HINKLE: Right.

12 DR. J. JACOBS: And these are  
13 reported based on a denominator and numerator  
14 CPT codes.

15 DR. HINKLE: Yes.

16 DR. J. JACOBS: But I don't think  
17 that really --

18 DR. HINKLE: Pertains to this one.

19 DR. J. JACOBS: Right.

20 DR. HINKLE: Maybe because I'm  
21 thinking --

22 DR. J. JACOBS: I don't think it

1 pertains to any of these.

2 DR. HINKLE: Oh, even when you get  
3 into the subsets of --

4 DR. J. JACOBS: I think everything  
5 here --

6 DR. HINKLE: -- cardiac mortality?

7 DR. J. JACOBS: This is all CPT  
8 code based, but --

9 DR. HINKLE: So, it's not --

10 DR. J. JACOBS: But to answer a  
11 couple of your questions about ICD-9, 10 and  
12 11, Europe has used ICD-10, you're correct,  
13 for over a decade. When I trained there in  
14 1995, we recorded in ICD-10. And the United  
15 States theoretically is maybe going to start  
16 doing that soon.

17 ICD-11 is just an idea. And  
18 there's an international committee in our --  
19 and members of our nomenclature committee sit  
20 on the international committee that's  
21 developing ICD-11, but that's not going to be  
22 implemented for, I would think, at least a

1 decade.

2           So, ICD-11 is a non-issue. It's a  
3 decade away from being functional. It's just  
4 a bunch of people sitting in a room putting  
5 ideas on paper right now.

6           DR. HINKLE: So, my question is  
7 really more do you see the ICD-10 conversion  
8 as it takes place, which may be very messy in  
9 America because every hospital has got to do  
10 it, the doctor, I mean everyone's got to --  
11 being messy, impinging your ability to measure  
12 this?

13           DR. J. JACOBS: No.

14           DR. HINKLE: No. Okay.

15           DR. J. JACOBS: No, because the  
16 numerators and the denominators are written  
17 based on CPT codes.

18           DR. HINKLE: Yes. Okay.

19           DR. J. JACOBS: The complexity  
20 stratification tools are all made based on  
21 procedures and the associated diagnosis of  
22 those procedures. And they can be cross-

1 mapped to any ICD system that exists pretty  
2 quickly.

3 DR. MAYER: When we entered in the  
4 codes into the STS database, your local  
5 version that you download then to the central  
6 database, you're not loading it by code  
7 numbers. You're loading it by STS code.

8 DR. HINKLE: Yes. Okay. So,  
9 you've got to crosswalk the STS from ICD-9, I  
10 assume.

11 DR. J. JACOBS: Yes, we do.

12 DR. HINKLE: So, there's going to  
13 be -- we're going to go from 25,000, roughly,  
14 ICD-9 codes to 160,000.

15 I've already done the crosswalk  
16 for pediatric surgical procedures to see what  
17 happens to them, and there's an expansion.  
18 There's more granularity and stuff and it's --  
19 I'm not trying to belabor the issue, but it's  
20 -- as I was looking through all of this stuff,  
21 it sort of was in the back of my mind.

22 I'm going like okay, we're all

1 going to be affected by it as we try to report  
2 publically.

3 DR. J. JACOBS: I think you're  
4 absolutely right. It's a huge issue. None of  
5 these metrics were written based on ICD-9.

6 DR. HINKLE: Okay. Yes. That  
7 sounds like you're going to be --

8 DR. HARDER: And just in general  
9 about registries, when you go in for a version  
10 upgrade and you change data elements, they go  
11 through a verification of remapping.

12 So, this is an exercise that  
13 normally happens in registry land, just so you  
14 know.

15 DR. HINKLE: Yes.

16 MR. HARDER: It's not like it's  
17 going to be something new.

18 DR. HINKLE: No, I'm aware of that.  
19 It's a huge project for us. Okay. I'm fine  
20 otherwise.

21 DR. MAVROUDIS: What was your  
22 concern? Was that leading up to the ICD-9s?

1 Is that what the issue was?

2 DR. HINKLE: The ICD-10 conversion.

3 DR. MAVROUDIS: Okay. All right.

4 DR. HINKLE: Which we're getting

5 ready to do right now in our health plan.

6 We've started the process and we don't have to

7 do it until 2013. We're seeing it as a

8 significant issue both from the standpoint of

9 payment, and as well as tracking quality

10 because the whole -- everyone has to do this

11 and no one is going to do it together and

12 whether Congress is going to be forced to move

13 the date from 2013. There's a lot of

14 unknowns.

15 I was just asking the question. I

16 think I got the answer which is STS, you have

17 your own identifier sort of coding in there,

18 so that can be mapped to whatever.

19 DR. JENKINS: It's actually an

20 international code.

21 DR. HINKLE: Yes. Right. So, that

22 helped clarify the question I have. Great.

1 Thanks.

2 DR. MAVROUDIS: Do you need a  
3 motion then?

4 DR. LOPEZ: Second.

5 CO-CHAIR JEFFRIES: Any other  
6 comments?

7 DR. MAYER: Is there anything I  
8 should write down here?

9 CO-CHAIR JEFFRIES: I think that  
10 our main discussion was around the indications  
11 that pacemakers and some variability in that,  
12 but the feeling of the measure developer was  
13 that this really is looking at postoperative  
14 arrhythmias and the indications are more --  
15 are not as varied.

16 DR. J. JACOBS: I would agree with  
17 that. Gus is like a world leader on this.  
18 It's his thing.

19 CO-CHAIR JEFFRIES: So, we're going  
20 to go back a measure since we skipped 15,  
21 post-op renal failure.

22 DR. LOPEZ: Post-op renal failure

1 is 15. The measure of percentage of pediatric  
2 and congenital heart surgery patients that  
3 require dialysis at hospital discharge due to  
4 new onset of post-op renal failure.

5 Numerator, the number of pediatric  
6 and congenital patients with new onset renal  
7 failure requiring dialysis after heart  
8 surgery.

9 And then these are new post-op,  
10 post-procedural requirements for dialysis  
11 including peritoneal dialysis and/or  
12 hemodialysis. Patient requires dialysis at  
13 the time of hospital discharge or death in the  
14 hospital.

15 Renal failure is defined as new  
16 onset oliguria with sustained urine less than  
17 .5 cc's per kilo per hour for 24 hours and/or  
18 a rise in creatinine greater than 1.5 times  
19 upper limit of normal for age or twice the  
20 most recent pre-op, pre-procedural value that  
21 this is, with eventual need for dialysis  
22 including peritoneal dialysis and/or



1 hemodialysis or hemofiltration.

2 Acute renal failure will be  
3 counted as an operative or procedural  
4 complication that must occur prior to hospital  
5 discharge or after hospital discharge, but  
6 within 30 days of the procedure.

7 Time window begins on admission to  
8 the operating room. It ends 30 days post-op  
9 or until time of discharge, whichever is  
10 longer.

11 Denominator is the number of  
12 pediatric and congenital heart surgery  
13 operations. There are some exclusions, and  
14 that is those requiring dialysis prior to the  
15 procedure or surgery.

16 Seems to be an important measure.

17 DR. MAVROUDIS: Just for the  
18 record, these definitions come right out of a  
19 certain book, right?

20 DR. J. JACOBS: Yes. So, just like  
21 the other ones there's a chapter here on Page  
22 222 to 225 that describes the rationale for

1 this definition, where it came from and the  
2 references that support it. And it's a  
3 harmonized definition that's been harmonized  
4 across multiple databases.

5 DR. MAVROUDIS: We were writing --  
6 we still are writing a paper on trying to do  
7 the metrics for morbidity like we did for  
8 mortality. And we approached this very  
9 difficult problem with these kinds of  
10 definitions which are extremely important. It  
11 seems like it's done extremely well here.  
12 It's pretty clear what is renal failure and  
13 what isn't. Nothing nebulous about it.

14 DR. LOPEZ: The importance to  
15 measure seems to be met.

16 CO-CHAIR JEFFRIES: Jeff, do you  
17 have a sense of what the incidence is?

18 DR. J. JACOBS: Very low.

19 DR. HINKLE: Under one percent?

20 DR. J. JACOBS: Very low. And it's  
21 extremely low in survivors because most  
22 patients -- most little babies with renal

1 failure, it's pretty unlikely they're getting  
2 out of the hospital on dialysis.

3 But it's an important metric to  
4 track because we're not just talking about  
5 neonates or infants here. And if you're a  
6 teenager that develops postoperative renal  
7 failure, you still have hemodialysis.

8 So, the incidence is less than one  
9 percent, but it's an important indicator to  
10 track.

11 CO-CHAIR JEFFRIES: I'm sorry.  
12 Maybe I missed it. So, if they die on  
13 dialysis --

14 DR. MAYER: It counts.

15 CO-CHAIR JEFFRIES: -- it counts.

16 DR. MAYER: What about if they are  
17 still on dialysis at 30 days, but recover  
18 while they're still in the hospital?

19 Which is the operative --

20 DR. J. JACOBS: Yes. You'd have to  
21 -- the period of data collection in the STS  
22 database, ends when two criteria have been

1 met. 30 days past, and you're out of the  
2 hospital.

3 So, if you're on dialysis on Day  
4 31, but you go home off dialysis on Day 55 --

5 DR. MAYER: You went home off  
6 dialysis.

7 DR. J. JACOBS: You went home off  
8 dialysis and you do not meet renal failure.

9 DR. MAYER: Okay. All right. Got  
10 it.

11 So, I mean what this will not  
12 capture is the patients who have renal failure  
13 severe enough to require dialysis, but who had  
14 recovered --

15 DR. J. JACOBS: Correct.

16 DR. MAYER: -- before they go  
17 home?

18 DR. J. JACOBS: Correct. Because  
19 that's not going to be counted as  
20 postoperative renal failure in the STS  
21 database.

22 DR. MAYER: Right. I understand.

1 CO-CHAIR JEFFRIES: So, this is  
2 going to be -- your sense is, is this around  
3 .1 percent, .01 percent?

4 DR. MAYER: I think it's pretty  
5 low. I mean it's really low.

6 DR. J. JACOBS: My sense is it's  
7 less than one percent. I don't want to begin  
8 to guess after that.

9 DR. HINKLE: Is there any exclusion  
10 for any other -- I mean I suppose at 30 days  
11 you could have renal failure from some other  
12 cause, you know, reaction to a drug or  
13 something.

14 DR. LOPEZ: Sepsis.

15 DR. HINKLE: Yes. So, is that an  
16 exclusion?

17 DR. J. JACOBS: No.

18 DR. HINKLE: No exclusion, right.  
19 Not at this point.

20 DR. J. JACOBS: I don't think there  
21 should be. Because if you're in the hospital  
22 for a VSD repair tetralogy and then you

1 develop a postoperative infection and you  
2 require aminoglycosides and you develop renal  
3 failure --

4 DR. HINKLE: Chances are the drug  
5 or whatever happens to you is a byproduct of  
6 having to have the VSD repair.

7 DR. MAYER: It's thinking about the  
8 whole hospitalization for the cardiothoracic  
9 surgery with whatever came after it.

10 DR. HINKLE: Yes. Right.

11 DR. MAYER: Rather than just  
12 thinking about the procedure.

13 DR. HINKLE: Yes.

14 DR. MAYER: Which I think is  
15 probably --

16 DR. HINKLE: I think it's the right  
17 thing.

18 DR. MAYER: -- the right thing to  
19 do, I would think.

20 DR. HINKLE: The right place to  
21 begin, yes.

22 CO-CHAIR JEFFRIES: Jeff, how do we

1 think about someone who's on hemofiltration on  
2 ECMO?

3 DR. J. JACOBS: Right.

4 CO-CHAIR JEFFRIES: And dies on  
5 ECMO.

6 DR. J. JACOBS: So, it depends on  
7 the indication. If you're put on peritoneal  
8 drainage or hemofiltration to remove volume,  
9 but you don't have the element of the  
10 oliguria, that doesn't meet this definition.

11 So, you have to have two things.  
12 You have to have the therapy, peritoneal or  
13 hemodialysis, but you also have to have  
14 oliguria and azotemia.

15 So, if you're put on that just to  
16 take volume off whether it's with the routine  
17 use of a peritoneal drain after a Norwood like  
18 Roger Mee used to do, or whether it's like  
19 hemodialysis because you've got a kids that's  
20 all swollen on ECMO and you hemofiltrate them,  
21 that would inquire as renal failure. That's  
22 something that requires renal -- that's

1 something that meets the requirements of renal  
2 failure requiring dialysis. That's simply bio  
3 overload using a mechanical device to remove  
4 the volume.

5 But if that's associated with a  
6 creatinine of three, that's different.

7 CO-CHAIR JEFFRIES: I mean the  
8 creatinine level here is 1.5 times. So I mean  
9 that's .6 for a baby. That's most, I would  
10 say, postoperative babies are .8. I'm looking  
11 at the Norwood. I mean, they don't usually  
12 come out.

13 DR. J. JACOBS: Hold on, 1.5 times  
14 --

15 CO-CHAIR JEFFRIES: Times the  
16 normal. The normal range is .3, .4 for a  
17 neonate. So, you're really getting to .6.

18 DR. J. JACOBS: But that has to be  
19 associated with a sustained urine output of  
20 less than 0.5 cc's per kilogram per hour over  
21 a 24-hour period.

22 CO-CHAIR JEFFRIES: It says or.



1 DR. J. JACOBS: Or. Okay. Yes.  
2 Right.

3 CO-CHAIR JEFFRIES: So, I'm just  
4 thinking that you're going to get to that --  
5 I would say -- I don't know what the  
6 percentage are, but I would say probably all,  
7 or close to all, I would think on the babies  
8 who --

9 DR. MAYER: But they don't go home  
10 with that. That's why the issue is the  
11 discharge, is the status of discharge which I  
12 think is really -- I was hanging up on the  
13 same kind of problem. That's why I asked that  
14 question before.

15 CO-CHAIR JEFFRIES: I guess I was  
16 just relating that to the hemofiltration. If  
17 you're going to filter someone, are they going  
18 to meet the criteria? Because most of the  
19 creatinines are going to be above .6.

20 DR. J. JACOBS: Yes, I agree.

21 CO-CHAIR JEFFRIES: I'm not saying  
22 it's not unheard of. I'm just saying it's --

1 DR. J. JACOBS: Well, actually, the  
2 task I have is that these are definitions that  
3 have been developed over a three-year period  
4 by a large committee that are implemented in  
5 about seven different databases.

6 CO-CHAIR JEFFRIES: Sure.

7 DR. J. JACOBS: So, we can decide  
8 that we're not going to use them here, but I  
9 can't really make any statement whatsoever  
10 about that we're going to change the  
11 definition.

12 CO-CHAIR JEFFRIES: Yes.

13 DR. J. JACOBS: There was  
14 nephrologists and representatives of the  
15 Nephrology Society that got involved in this  
16 stuff. A lot of experts were called in to  
17 create these definitions.

18 And I'm certainly not the guy that  
19 can solely defend them all because I wasn't  
20 the one who developed them all.

21 CO-CHAIR JEFFRIES: And I guess I'm  
22 not asking for a change. I'm just thinking

1 about what are some of the --

2 DR. J. JACOBS: It seems to me that  
3 if you're on hemofiltration and you've got a  
4 creatinine that's .6 and you're not making  
5 urine, that kind of meets the definition of  
6 renal failure to me.

7 Not the most common kind of renal  
8 failure, but I mean that's different from the  
9 kid who's just having volume taken off, but  
10 he's still making urine, but you want to take  
11 off more volume.

12 Now, one way to fix it is to  
13 exclude patients who are on mechanical  
14 circulatory devices.

15 CO-CHAIR JEFFRIES: I would say  
16 just as part of the review, just take a look  
17 at that. As this review is over those two  
18 years, take a look at how many patients are on  
19 --

20 DR. J. JACOBS: Versus not on  
21 mechanical support.

22 CO-CHAIR JEFFRIES: -- support who

1 are labeled as having renal failure when they  
2 die.

3 DR. J. JACOBS: I think that's good  
4 because that's analogous to the way we dealt  
5 with the gastrostomy for mediastinitis.

6 So, a research question is does  
7 the utilization of mechanical circulatory  
8 support or corrupt this indicator? That's a  
9 good question.

10 CO-CHAIR JEFFRIES: I'm not sure it  
11 does, but I --

12 DR. J. JACOBS: It might. No, it  
13 might. You're absolutely right. It might.

14 DR. MAYER: Okay. This should be  
15 pretty easy to figure out. There shouldn't be  
16 a usability issue here. And it certainly is  
17 feasible because it's not very common and --

18 CO-CHAIR JEFFRIES: I mean the only  
19 thing in my mind that just comes is just the  
20 small numbers and comparability of the small  
21 numbers and what that -- because, again, I  
22 can't imagine it happens very frequently.

1 CO-CHAIR JEFFRIES: You think it's  
2 more or less common than -- I guess it's  
3 probably less common than mediastinitis.

4 DR. MAYER: Yes, by a lot.

5 CO-CHAIR JEFFRIES: And it's  
6 probably less common than pacemakers.

7 DR. MAYER: Yes.

8 DR. J. JACOBS: But it's a big  
9 deal.

10 DR. MAYER: I mean if you count --  
11 if you count in there, and that's again why I  
12 was trying to ask you that, you know, the  
13 patients who die who were still getting  
14 dialyzed or something like that, now you've  
15 got a little, you know, that cranks the end up  
16 because I think the only question will be how  
17 much added information there is from just  
18 looking at the patients who died, you know.

19 I mean, to get out of the  
20 hospital, I mean I'm struggling in my head to  
21 remember a patient that we sent out of the  
22 hospital on dialysis.

1 DR. J. JACOBS: You've got to think  
2 outside the neonatal period, though.

3 DR. MAYER: No, but even in older  
4 patients.

5 DR. J. JACOBS: You don't have any  
6 heart transplant kids that are 16 years old  
7 that their kidneys shut down and they left the  
8 hospital on a peritoneal dialysis?

9 DR. MAYER: I don't think so.

10 DR. JENKINS: Even then, it is a  
11 question of qualification.

12 DR. MAYER: Well, but if it's a  
13 system issue writ large, I mean, whether it's  
14 antibiotics, preexisting -- I don't know. I  
15 don't know.

16 DR. JENKINS: It'd be difficult,  
17 going into the operation on the borderline.

18 DR. MAYER Right.

19 DR. JENKINS: There more likely to  
20 come out the other side.

21 DR. MAYER: I'm just trying to  
22 think back to the transplant population which,

1 you're right, is one where you might see it,  
2 but I don't know that we sent any of our  
3 transplants out on dialysis.

4 DR. J. JACOBS: I just know of one  
5 who --

6 DR. MAYER: That's indelibly burned  
7 into your memory.

8 CO-CHAIR JEFFRIES: Jeff, is that  
9 implantation? Is that a CPT code here?

10 DR. J. JACOBS: No.

11 CO-CHAIR JEFFRIES: Okay. And what  
12 about patients who leave with no kidney  
13 transplant?

14 DR. J. JACOBS: Do you know of  
15 anybody that had their heart surgery and got  
16 a kidney transplant in the same  
17 hospitalization?

18 MS. GALVIN: Yes, we had one.

19 DR. J. JACOBS: I'm not counting  
20 that. I'm talking about, do you know of a  
21 patient who came in with normal renal  
22 function, had heart surgery, developed

1 postoperative renal failure and stuck around  
2 to get a kidney transplant?

3 That, I don't think, is going to  
4 happen.

5 DR. MAYER: Not unless you have a  
6 double transplant.

7 DR. J. JACOBS: I mean, if it's  
8 somebody who had a double transplant that --

9 DR. MAYER: No, I understand. That  
10 wasn't a serious comment. Sorry.

11 CO-CHAIR JEFFRIES: But the reason  
12 I ask about that is because we had someone  
13 like that who had heart failure, got a VAD,  
14 developed renal failure, had a heart/kidney  
15 transplant.

16 DR. J. JACOBS: Right. So, we're  
17 not discussing -- if they approve what I'm  
18 counting Marshall on to make them approve, one  
19 of the things is the structure indicators that  
20 talk about denominators.

21 And the denominator for -- the  
22 denominator that they track is pediatric



1 congenital heart operations. There's a whole,  
2 big definition of what's included and excluded  
3 which the STS has published in peer review  
4 literature in the Annals of Thoracic Surgery.

5           And that includes open heart  
6 surgery on bypass, it includes cardiac  
7 operations on off bypass, and other operations  
8 based off bypass like coarc.

9           It excludes ECMO and VAD. And the  
10 only way ECMO and VAD plays a role in is if  
11 it's done in a patient who's already had an  
12 operation, can't come off bypass and who's put  
13 on ECMO or VAD.

14           But primary ECMO or primary VAD  
15 are not included in this denominator according  
16 to the definitions that they'll discuss over  
17 there and the structure indicators.

18           Now, what the STS does, and you  
19 know this, it approves operations, CPT/no CPT  
20 in cardiovascular, ECMO, VAD, thoracic minor  
21 procedure and others. And all it included  
22 here is CPT/no CPT in cardiovascular. And

1 that's where those codes came from.

2 CO-CHAIR JEFFRIES: So, any  
3 recommendation?

4 DR. MAYER: Approved.

5 DR. LOPEZ: Second.

6 CO-CHAIR JEFFRIES: So, we went  
7 through 16. And so the next one is 17.

8 DR. MAYER: That's me, I think.

9 CO-CHAIR JEFFRIES: Yes. Surgical  
10 re-exploration.

11 DR. MAYER: Let me just -- okay.

12 We voted yes on the pacemaker,  
13 right?

14 DR. MAVROUDIS: Yes, we did.

15 DR. MAYER: The arrhythmia measure?

16 DR. MAVROUDIS: Yes, we did. Yes.

17 Yes, we did.

18 DR. MAYER: Okay. Seventeen,  
19 that's me, right?

20 CO-CHAIR JEFFRIES: Yes.

21 DR. MAYER: Okay. So, this measure  
22 is to determine the percentage of patients

1 undergoing pediatric and congenital heart  
2 surgery who require postoperative unplanned  
3 surgical re-operation excluding re-exploration  
4 rate for bleeding and delayed sternal closure.

5           The numerator is simply that. The  
6 denominator is the denominator of all the  
7 patients having the described operations.

8           The exclusion is for -- probably  
9 the most common of the things that would  
10 require patients going back to the operating  
11 room without a so-called structural defect is  
12 bleeding after the operation requiring re-  
13 exploration. And that's been proposed to be  
14 excluded from this measure, so that this  
15 measure is directed at trying to measure the  
16 number of patients who have to go back to the  
17 operating room for a residual defect for a  
18 previously unidentified defect prior to their  
19 operation that requires surgical re-  
20 intervention.

21           I think this is, again, an  
22 important variable. It sort of assesses, if

1 you will, technical performance of the  
2 operation. Although, it also assesses whether  
3 a complete preoperative diagnosis has been  
4 made as well, since that can certainly be an  
5 indication for re-operation.

6 I think you could have an argument  
7 about whether going back for bleeding fits in  
8 this category or not. It is tracked certainly  
9 within the database, so -- but I think the  
10 implications might be a little bit different  
11 particularly since -- particularly in small  
12 children, you know, we induce coagulopathy  
13 just by going on bypass. And particularly as  
14 the time on bypass gets longer, the bleeding  
15 in general tends to be worse.

16 So, I think I understand the  
17 rationale and would be in agreement that  
18 that's okay to exclude the re-ops for bleeding  
19 and one could consider, I suppose, proposing  
20 that as an additional measure although I'm not  
21 sure that that's necessarily that valuable.

22 This is certainly, I think, easy

1 to track, would be easy to report. I don't  
2 think it's hard to acquire the data. It's  
3 pretty obvious when you have an event that  
4 takes you back to the operating room.

5           And the only other issue that came  
6 to my mind was whether -- and I don't -- and  
7 this is -- I don't quite know how to deal with  
8 this, to be honest with you: the patients who  
9 after their initial operation might have  
10 something else done in the catheterization  
11 laboratory to deal with a problem that was not  
12 adequately dealt with at the time of surgery  
13 or not understood prior to surgery. That  
14 certainly has happened.

15           So, I'm not trying to rewrite the  
16 thing, but there probably would be someplace,  
17 maybe in the future, for trying to get at this  
18 issue about sort of broadening this to make  
19 re-intervention during the same  
20 hospitalization because then it would include  
21 both the things that were done in the cath lab  
22 as well as in the operating room.

1 DR. MAVROUDIS: You raise a very  
2 good point, and that is closing a residual VSD  
3 through the catheter or through an operation.

4 Let me think about that.

5 DR. MAYER: I think I'm going to  
6 look something up before I speak.

7 CO-CHAIR JEFFRIES: I agree. I  
8 think it's important. I think if you have  
9 this sort of measurement and in some ways that  
10 encourages people to use interventional  
11 techniques to deal with problems which may or  
12 may not be the right way to --

13 DR. MAVROUDIS: Correct.

14 DR. MAYER: Although, to be honest  
15 with you, I'm not sure that that would  
16 actually -- I have a hard time imaging that  
17 that would influence my decision making, but,  
18 you know, I've tilted at windmills many times  
19 in my life here.

20 So, I may not be the right reality  
21 check on this.

22 DR. JENKINS: Guys, what about the

1 opposite, the paper that you and I wrote where  
2 you actually explain the terms rescue  
3 procedures for going back to the operating  
4 room just to try to salvage something minor  
5 that we found out in our death series was not  
6 that uncommon in the lab, but also in the OR.

7 DR. MAVROUDIS: Yes.

8 DR. JENKINS: Are you giving  
9 credit, bad credit --

10 DR. MAVROUDIS: Yes.

11 PARTICIPANT: You know, you could  
12 argue that hey, this kid has got a residual  
13 two-and-a-half-long shot, go back and fix it.  
14 No, let's give him a cath probe.

15 DR. MAYER: Right. Well, that's  
16 the other possibility is, what do you do with  
17 residual problems?

18 I mean some of the work that Emile  
19 has done is sort of looking at these technical  
20 outcomes. Scores, if you will.

21 Might be something to consider in  
22 the future. I think, given what we have now

1 here though, I don't know how to -- I'm not  
2 sure I know how to clean this up.

3 DR. MAVROUDIS: Given what we have  
4 now and what we can track at least in the  
5 database, because we don't have catheter  
6 dimension, I'm not sure that I would include  
7 this as an indicator.

8 DR. J. JACOBS: So, now I've got  
9 enough information in front of me that I can  
10 respond.

11 DR. MAVROUDIS: Okay.

12 DR. J. JACOBS: First of all, the  
13 STS database does track both unplanned cardiac  
14 re-operation during a postoperative or post-  
15 procedural time period and unplanned  
16 interventional cardiac catheterization  
17 procedure during the postoperative and post-  
18 procedural time period.

19 So, both of those are in the STS  
20 database. Okay. And we can use our database  
21 to track both operations and interventions.

22 This metric, as it stands now, was



1 written just to track unplanned re-operations.

2 That may or may not be the best thing.

3 For some reason, we made that  
4 decision to just track the unplanned re-  
5 operations and not unplanned interventions,  
6 but the database does track them both.

7 The other interesting point that  
8 I'd raise here is that clearly an unplanned  
9 cardiac re-operation or an unplanned re-  
10 intervention adds morbidity.

11 And if one was trying to come up  
12 with how much morbidity postoperatively did  
13 the patient suffer from, these would be things  
14 that would contribute that.

15 But that doesn't necessarily mean  
16 it's going to be the best-quality indicator  
17 because if we put the --

18 DR. MAYER: No, I think it more  
19 reflects on the initial operation and the pre-  
20 operative understanding of what's --

21 DR. J. JACOBS: That's all agreed.  
22 And, therefore, tracking it to keep track of

1 how much postoperative morbidity a patient has  
2 after an operation makes sense, because it  
3 depends on exactly what you just said.

4 Making it a quality indicator,  
5 though, may be associated with a problem that  
6 it disincentivizes people to intervene on  
7 things that need to be intervened upon.

8 DR. MAYER: Well, but you can make  
9 that argument really about all of the outcomes  
10 measures, right?

11 DR. J. JACOBS: You can, yes.

12 DR. MAYER: I'm not taking this  
13 case on because the risk is too high and it's  
14 going to make me look bad.

15 DR. J. JACOBS: Right.

16 DR. MAYER: I mean it's the same  
17 thing.

18 DR. J. JACOBS: So if we can  
19 swallow that, I don't see any problem with it  
20 with the exception of the fact that -- do we  
21 want to make it say unplanned re-operation in  
22 interventional cardiac catheterization

1 procedure, or do we just want to make it  
2 unplanned re-operation.

3 The database can handle both of  
4 those without modifying the database at all.  
5 And I don't feel strongly either way, but  
6 whatever the group would go with, we would be  
7 able to support from the database.

8 DR. MAYER: And I think they're  
9 both important.

10 DR. J. JACOBS: And that's the  
11 reason why we --

12 DR. JENKINS: Calling one  
13 collateral.

14 DR. J. JACOBS: Right.

15 DR. MAYER: No, no. But the  
16 question would be why they got to the cath  
17 lab.

18 DR. JENKINS: You're saying the  
19 fact they went is not good news.

20 DR. MAYER: Right. I mean there  
21 was usually --

22 DR. JENKINS: You were the one who

1 taught me about rescue procedures. Re-ops for  
2 technical difficulty. I mean we spent a year  
3 working that out because we found a lot of  
4 them.

5 DR. MAVROUDIS: You can't possibly  
6 leave this the way it is for just surgery and  
7 expect that to be a good indicator. Can't  
8 possibly. It has to include surgery and cath  
9 intervention. It has to.

10 DR. J. JACOBS: And that's doable  
11 with the database.

12 DR. MAVROUDIS: Has to.

13 CO-CHAIR JEFFRIES: Do you mean it  
14 needs to be in the same measure or two  
15 measures?

16 DR. MAVROUDIS: Well, two measures  
17 would be better because then you can weed it  
18 out. You can tease it out.

19 But you can't have just one.

20 CO-CHAIR JEFFRIES: Because I think  
21 the morbidity is associated with a different  
22 one

1 DR. MAVROUDIS: Well, maybe.

2 CO-CHAIR JEFFRIES: Or we don't  
3 know if they're different.

4 DR. MAVROUDIS: I mean just for the  
5 uninitiated here, I would give my little  
6 sermonette, right, that the best predictor of  
7 a smooth, postoperative course is the anatomic  
8 integrity in the repair.

9 And so I mean it's as simple and  
10 as complicated as that.

11 DR. MAVROUDIS: And he went to  
12 Yale.

13 (Laughter.)

14 DR. MAYER: So, I do think that  
15 these going-backs whether it's to the cath lab  
16 or to the -- I mean, that's really what we're  
17 testing here is both how good were the pre-  
18 operative processes to identify everything  
19 that needed to be dealt with, and the  
20 intraoperative processes of dealing what it is  
21 that we -- did we deal with what we're  
22 supposed to deal with in the operation.

1           So, I mean I don't know. I think  
2 either way is fine. And whether it's one  
3 measure or two, I'm not sure the -

4           DR. MAVROUDIS: We need them both.

5           DR. MAYBE: Yes. But I think we  
6 should capture them both, to be honest with  
7 you.

8           CO-CHAIR JEFFRIES: I think I'd  
9 like to capture them together.

10          DR. MAYER: Okay. I don't --

11          DR. MAVROUDIS: No, wait. Why did  
12 you change your mind?

13          CO-CHAIR JEFFRIES: Because taking  
14 what's stated here, I think my natural  
15 inclination, my experience, has been to say  
16 that going to the cath lab is better, but I  
17 don't think that's -- I don't think that's  
18 true.

19                 And I think if you put a measure  
20 which says cath and surgery re-operation, then  
21 the people who feel like cath is better, they  
22 say oh, well, look, we don't do any re-op

1 surgical, we do all interventional.

2 But I don't think we know enough  
3 to know which is better. So, I think at this  
4 point until we know which is better, we  
5 shouldn't have it alone.

6 DR. HINKLE: Cast a broader net. I  
7 would agree at this point.

8 DR. MAVROUDIS: If you put them  
9 both -- if you capture them both, you'll know  
10 which one is which anyway.

11 CO-CHAIR JEFFRIES: I mean you can  
12 talk. This discussion --

13 MS. GALVIN: I just have one  
14 question. So, what about the patient who goes  
15 back to the cath lab or the OR multiple times?  
16 Is it one even or is it multiple?

17 CO-CHAIR JEFFRIES: That's a good  
18 question.

19 DR. J. JACOBS: So, just like in  
20 Indicator 12, we said it was an all or none  
21 phenomenon, here we said percentage of  
22 patients, not --

1 DR. MAYER: Yes, I agree.

2 DR. J. JACOBS: Either you have a  
3 smooth postoperative course, or you got some  
4 badness and you go back and you get credit for  
5 it. And then after that, go back as many  
6 times as you want. Just get it right.

7 (Laughter.)

8 CO-CHAIR JEFFRIES: And so, what  
9 are we going to do? Are we all --

10 DR. J. JACOBS: Add re-intervention  
11 and keep it as one metric.

12 DR. MAYER: So, we'll put in here  
13 under the scientific acceptability part,  
14 right, this would be the --

15 DR. J. JACOBS: The committee felt  
16 that it would be important to make this re-  
17 operation and re-intervention and the metric  
18 developer agreed.

19 DR. MAVROUDIS: Does that end this  
20 discussion? Should I make a motion? I'm the  
21 motion maker here.

22 DR. HINKLE: Second.



1 DR. MAVROUDIS: I didn't make it  
2 yet.

3 DR. HINKLE: You said you were the  
4 motion maker.

5 DR. MAVROUDIS: Well, okay. I make  
6 a motion.

7 DR. HINKLE: We're in Washington,  
8 you know.

9 DR. MAYER: Those were my thoughts.

10 CO-CHAIR JEFFRIES: And usability?

11 DR. MAYER: I think these are  
12 easily countable and interpretable events, it  
13 seems to me. So, I think it's fine. It's  
14 certainly feasible to capture the data.  
15 There's no question about that.

16 All right. So, let me just see if  
17 I can translate this into something that makes  
18 sense.

19 CO-CHAIR JEFFRIES: So, there was  
20 going to be a suggestion that intervention is  
21 added? Is that --

22 DR. MAYER: Yes.

1 DR. MAVROUDIS: And he has  
2 acknowledged that.

3 DR. MAYER: Yes. I think that  
4 that's a good idea.

5 DR. J. JACOBS: I'm honestly not  
6 sure why it wasn't there.

7 DR. JENKINS: You're the chair.

8 DR. MAVROUDIS: I'm not.

9 DR. JENKINS: No, I know.

10 DR. J. JACOBS: That's why I love  
11 this guy.

12 DR. MAVROUDIS: I make the motion.

13 DR. HINKLE: Second.

14 CO-CHAIR JEFFRIES: Eighteen.

15 DR. MAVROUDIS: Now, this is the  
16 STS -- this is the --

17 DR. J. JACOBS: This is the STS'  
18 metric of stratification.

19 DR. MAVROUDIS: Yes. So, this  
20 metric of stratification is basically allows  
21 for the stratification method to be picked out  
22 by -- or to be selected by the program to be

1 one of three.

2           And that is RACHS, Aristotle or  
3 the STS-EACTS morality levels. So, it doesn't  
4 say that the test has to be one of them, it  
5 just says it has to be one of the three, and  
6 then you comply with that part of it. It  
7 doesn't say that it had to be one --  
8 specifically one in exclusion of any other.

9           The numerator is the number of  
10 patients who undergo pediatric and congenital  
11 heart surgery. And the --

12           DR. J. JACOBS: And died.

13           DR. MAVROUDIS: And died, yes. And  
14 it's prior to hospital discharge or within 30  
15 days of the date of surgery, whichever is  
16 longer.

17           The denominator is the number of  
18 cardiac index operations at each level of  
19 complexity stratification.

20           Of some note here is that the STS  
21 database gives in a report the stratification  
22 model for both RACHS and Aristotle in its

1 system with the corollary that it does not  
2 include the RACHS expanded function, shall we  
3 say -- if I'm saying this wrong, please let me  
4 know. Okay.

5 The STS database does not include  
6 the expanded RACHS, which I call the mini-  
7 comprehensive score by adding prematurity, age  
8 and multiple operations.

9 Is that correct? Did I get that  
10 right?

11 DR. JENKINS: What's in the STS  
12 database now with the high categories of  
13 RACHS.

14 DR. MAVROUDIS: Right. And it's  
15 not the one that --

16 DR. JENKINS: It's not a risk  
17 model.

18 DR. MAVROUDIS: Yes, it's not a  
19 risk model. Right.

20 Now, what this does, what this  
21 indicator does is that it allows for a broad  
22 scope of what people want to use.

1                   And the reality of the world is  
2   that different programs use different risk  
3   stratification models or complexity  
4   stratification models.

5                   And it's no secret or it shouldn't  
6   be any secret to anyone. This debate has been  
7   a hot and heavy debate in the literature,  
8   multiple papers have been written on it.

9                   It's not my intention to say which  
10   is better, which isn't. That's not the  
11   purpose of this discussion.

12                  The purpose of this discussion is  
13   to determine whether it's okay to have one of  
14   three models that would satisfy the compliance  
15   with this indicator.

16                  DR. JENKINS: Three types of  
17   categories. They're just different  
18   categories.

19                  DR. MAVROUDIS: Different  
20   categories, yes.

21                  DR. JENKINS: None of them are  
22   really models.

1 DR. MAVROUDIS: Okay. They're not

2 --

3 DR. JENKINS: In a mathematical  
4 sense.

5 DR. MAVROUDIS: In other words,  
6 you're talking about Aristotle, RACHS and STS-  
7 EACTS.

8 DR. JENKINS: They're just  
9 categories.

10 DR. J. JACOBS: Three methods of  
11 risk adjustment, none of which are formal risk  
12 models.

13 DR. JENKINS: They're all fine  
14 category.

15 DR. MAVROUDIS: Okay.

16 DR. JENKINS: By the Aristotle  
17 category, by the new STS categories or by  
18 RACHS.

19 DR. MAVROUDIS: I think that this  
20 discussion we're having is an important one  
21 because it's not my intention to skew one  
22 thing to another.

1 DR. JENKINS: It was just the term  
2 model. Where to me, that means a mathematical  
3 --

4 DR. J. JACOBS: It's a  
5 stratification.

6 DR. JENKINS: Stratification.

7 DR. J. JACOBS: Three tools of  
8 complexity stratification.

9 DR. MAVROUDIS: Right.

10 DR. JENKINS: Yes. That was the  
11 only point I was making.

12 DR. MAVROUDIS: And going further,  
13 I guess we can take it a step at a time that  
14 the first one is to say whether this is an  
15 important issue or not, correct? Importance.

16 CO-CHAIR JEFFRIES: Correct.

17 DR. MAVROUDIS: And so what they --  
18 from my point of view, the important part of  
19 this is that it takes advantage of the status  
20 quo. The reality of the world is that some  
21 centers report one way, other centers report  
22 in another way.

1                   Against that is the idea that  
2   there are people out there, users out there,  
3   industry, et cetera, et cetera, who would  
4   rather have one model. That is to say one -  
5   not model. Excuse me. One way of risk  
6   stratification.

7                   I think that's probably premature  
8   because already we have Aristotle developing  
9   Aristotle complexity score, RACHS going from  
10   RACHS-1 to RACHS-2, and now we have the EACTS-  
11   STS - or the STS-EACTS risk stratification  
12   scheme which is based on actual empiric data,  
13   where the other two are still, in some  
14   respects, based on the Delphian principles of  
15   expert opinion.

16                   So, I think that -

17                   DR. JENKINS: Actually, RACHS was  
18   based on both; adjustment and empirical data.

19                   DR. MAVROUDIS: Okay. And that  
20   empirical data comes from what?

21                   DR. JENKINS: The two large data  
22   sets that were used to derive RACHS. One



1 administrative and one prospective --

2 DR. MAVROUDIS: Which ones are the  
3 administrative? Tell us about that.

4 DR. JENKINS: In the derivative of  
5 RACHS, the empirical data to inform the  
6 process came from two large administrative  
7 data sets in two states and from the Pediatric  
8 Cardiac Care Consortium prospectively  
9 collected data over a several-year period.

10 DR. MAVROUDIS: Okay.

11 DR. JENKINS: So it was derived  
12 both by judgment and empirical data.

13 DR. MAVROUDIS: Thank you.

14 And so the point here is, is that  
15 do we as a committee say okay, we're going to  
16 pick one of these, or do we say let the  
17 development continue and that we would use as  
18 an indicator that it's okay to use one of  
19 these three systems as long as you are  
20 tracking some kind of risk adjustment?

21 DR. HINKLE: All right, so let me  
22 ask, I was the secondary on this. Let me ask

1 a question. I think it might be on the  
2 usability standard here. It sounds like what  
3 you're describing, these three different risk  
4 adjusters, you've got vanilla, to some extent,  
5 chocolate, and strawberry.

6 DR. MAVROUDIS: Except the  
7 strawberry, which is the last one, the STS-  
8 EACTS, is based on 80,000 cases and it -

9 DR. HINKLE: That's important now.

10 DR. MAVROUDIS: Yes.

11 DR. HINKLE: So I don't know if we  
12 can debate the value of each of those three  
13 risk adjusters, but you know where I'm going  
14 with this is that I would say operative  
15 mortality is probably of all the standards  
16 we've talked to today, probably the most  
17 important to the outside world.

18 And so now we've got - so we take  
19 that and now we have confused it with three  
20 different - unless they cross talk to each  
21 other, you can kind of be almost silent on it  
22 and just say well, believe us. These

1 complexities are all the same at all the  
2 different children's hospitals.

3 I would argue that the usability  
4 is one of the weaknesses of this standard is  
5 that that nuance - but I have to say that  
6 across the world of medicine as long as  
7 there's risk adjustment, then people get into  
8 what tool did you use to risk adjust it?

9 We say DxCG, somebody else says  
10 something else, and people are happy that it's  
11 at least risk adjusted. But this is such a  
12 complex area that you're into, you're not into  
13 general medicine or general surgery, that it  
14 seems like it might be important to have one,  
15 but I don't know what the gold standard is.

16 And then you'd have to - somebody  
17 -- the experts would have to go down to it -  
18 if you say there's 80,000 in one and 10,000 in  
19 the other, I'd pick the 80 -

20 DR. MAYER: I think, you know,  
21 there are several problems. Number one, even  
22 though there's a lot of cases, there - and

1 what I'm going to do is draw the contrast with  
2 the adult cardiac database.

3 The adult cardiac database, you've  
4 got three and a half million -

5 DR. HINKLE: That's your  
6 denominator.

7 DR. MAYER: - you've got maybe ten  
8 procedures, more or less, that are in there;  
9 coronary bypass, coronary plus valve, you  
10 know.

11 We got 80 or 90, so you take that  
12 -

13 DR. JENKINS: 200, actually. We  
14 have 200.

15 DR. MAYER: Well, anyway. It's a  
16 lot, right?

17 It's a bigger - the smaller number  
18 of cases is spread over a much larger thing.  
19 So just that all by itself makes it much more  
20 difficult to come to a strictly data-driven  
21 risk model.

22 And that's why in at least two of

1 the iterations of trying to get some handle on  
2 how to risk adjust this, this element of  
3 expert opinion, general consensus stuff, that  
4 sort of crept into - not crept. I mean it was  
5 intentionally added because it had to be  
6 added. There was no other way to get at this.

7           So I think - I don't know. I mean  
8 Kathy and others know more about this than I  
9 do, but I'm not quite sure we're all the way  
10 there that we know what the gold standard is.

11           DR. HINKLE: Right.

12           DR. MAYER: And so in the absence  
13 of - so then the question becomes do we pick  
14 the best of the lot knowing that it's probably  
15 going to change anyway, or do we allow a  
16 couple of, two or three different ways, each  
17 of which has been tested?

18           There have been a few comparisons.  
19 There's a comparison between the Aristotle and  
20 the RACHS system. The area -

21           DR. MAVROUDIS: So each time we're  
22 getting better and better.

1 DR. HINKLE: There's a sense - if  
2 one is picked, is there a sense that - right  
3 now I think what I read somewhere, that only  
4 out of 122 programs, 80 something reported to  
5 the STS.

6 And I assume that's - my  
7 assumption is that may be 90 percent of the  
8 patients. So we've got most of the patients.  
9 So the ones that aren't reporting, aren't  
10 reporting for some reason.

11 What you've alluded to here is the  
12 reason we have these three risk adjusters is  
13 the local environment probably just grew up  
14 with a particular -

15 DR. MAVROUDIS: Not exactly.

16 DR. HINKLE: Okay.

17 DR. MAVROUDIS: This is virtuous in  
18 every way. All three -

19 DR. HINKLE: No, I'm not saying it  
20 wasn't. I'm just saying for whatever reason.  
21 That's what you answered my question to is if  
22 you picked one, would you lose compliance with

1 - or would everyone just follow one? What is  
2 your thought on, you know, picking one would  
3 seem to make the most sense to me, but I don't  
4 know enough about the details of -

5 DR. MAVROUDIS: Well, first of all,  
6 let's just leave the idea of how you would  
7 pick it. Let's just leave that alone.

8 The STS allows now for the risk  
9 stratification, if you will, of both RACHS and  
10 of Aristotle. If you get that report back  
11 from STS, you have it. It's right there. So  
12 you use either one or use them both.

13 DR. HINKLE: Okay.

14 DR. MAVROUDIS: Now, soon we're  
15 going to have the new risk stratification  
16 scheme which is the STS-EACTS, which is based  
17 on empiric data. And when there's not enough  
18 empiric data in those small N groups, then  
19 Bayesian methods are used to give a reasonable  
20 statistic. And the C-statistic is the best  
21 from that in any of the - than both the other  
22 two.

1                   So how are you going to pick it?  
2    Secondly, if you have it all together, why not  
3    keep it all and have it all?  There's no  
4    reason to make the choice at the moment  
5    because what you really want is each center,  
6    you want them to be able to risk adjust their  
7    data with volumetrics as well.  And the STS  
8    database does that for you.

9                   Now, I don't know, for instance,  
10   and this goes back, this will go to 21 now,  
11   how much extra - what you have proposed, will  
12   the STS database the way it is right now be  
13   able to arrive at that without any further  
14   update -

15                  DR. JENKINS:  Are you talking about  
16   the SMR measure?

17                  DR. MAVROUDIS:  Yes, yes.  The SMR,  
18   yes.  Whatever you want.

19                  DR. JENKINS:  Maybe I could just  
20   give my perspective because this is -

21                  DR. MAVROUDIS:  Because it's all  
22   the same anyway.



1 DR. JENKINS: - a very important  
2 topic. I think that as already stated and I  
3 showed up here today, that I do believe that  
4 the SMR with the full models is actually --  
5 has advantages over the bicategorical  
6 adjustment in various ways to give an overall  
7 measure to improve the risk adjustment.

8 Having said that, in terms of  
9 these categories, they all work nearly about  
10 the same as the five categorical core  
11 procedure adjustments. And they have various  
12 strengths and weaknesses. The biggest  
13 strength of the Aristotle system is it's the  
14 standard in Europe that all the European  
15 systems have really gone to. When you're  
16 looking at comparability between Europe to the  
17 US, that's the clear one that is really to be  
18 used to make those empirical.

19 RACHS has the advantage of being  
20 by far the most flexible. It has that  
21 advantage.

22 The STS empirical categories are

1 the best empirical evidence coming from one  
2 data source, the STS, which is not a  
3 population-based data source. It's a  
4 voluntary data reporting system.

5 And those are the strengths and  
6 weaknesses, and that's why the world isn't  
7 picking one or another or another. There's a  
8 variety of reasons why, depending on your  
9 study, you choose one or the other.

10 So I actually think that the STS  
11 developers in their wisdom are trying to get  
12 into this game and get people into this game  
13 saying use one, okay, and not trying to put a  
14 line in the sand now that really forces a  
15 winner for the bicategorical. So that's my  
16 personal opinion.

17 DR. MAVROUDIS: Well, that was very  
18 good up until the STS wanting to choose one.

19 CO-CHAIR JEFFRIES: That's not what  
20 she said.

21 DR. JENKINS: I didn't -

22 DR. MAVROUDIS: Well -

1 DR. JENKINS: I'm saying that the  
2 advantage --

3 DR. MAVROUDIS: Oh, oh. I see.

4 DR. JENKINS: What did I say? An  
5 individual center may have a reason for  
6 choosing RACHS or choosing Aristotle or  
7 choosing the empirical evidence from STS if  
8 that's their core base for -

9 DR. MAVROUDIS: This is what I  
10 wanted to come to conclusion to that in fact  
11 that each center may want to choose one or the  
12 other and that this indicator, this one over  
13 here, this 18, allows for that. Allows for  
14 each one.

15 But if we choose 18, then by  
16 conclusion or by necessity you would have to  
17 reject 21 because 21 says that we will now use  
18 the RACHS SMR system exclusively.

19 DR. MAYER: That's not what -

20 DR. JENKINS: Any more than I might  
21 not choose renal failure in Boston because I  
22 think -

1 DR. MAVROUDIS: But maybe you could  
2 explain that then because -

3 CO-CHAIR JEFFRIES: This one is  
4 really looking at unadjusted mortality, but  
5 then stratified by particular levels of  
6 complexity. 21 is risk adjusted mortality.

7 DR. JENKINS: It's giving an SMR  
8 for a center.

9 CO-CHAIR JEFFRIES: Right. So,  
10 it's risk adjusted mortality.

11 DR. JENKINS: You could do an SMR  
12 with Aristotle or with the empirical  
13 categories. You just haven't yet, so that's  
14 why RACHS has been used as an SMR. That's  
15 what we're proposing.

16 DR. J. JACOBS: So the last version  
17 of the STS database report produced an SMR  
18 with observed and expected mortality and a  
19 risk adjusted mortality with a model that was  
20 created fusing information from both RACHS and  
21 Aristotle, and also adding in the patient's  
22 weight and age and length of pre-operative

1 hospital stay. And that proved that, A, we  
2 could do it, and, B, that we could do it using  
3 RACHS and Aristotle.

4 I would think having looked at all  
5 this, somehow we have to come up with well,  
6 what are we going to do and how are we going  
7 to operationalize this? It seems to me that  
8 first of all, 18 is a good indicator in that  
9 it gives people the choice of using any of the  
10 three metrics and reporting it stratified in  
11 the categories. So that's a form of risk  
12 adjustment through complexity stratification,  
13 but it doesn't create for report any risk  
14 adjusted mortality.

15 My solution to this dilemma that  
16 we're faced here is that we would implement  
17 Number 18, and then we would also implement  
18 Number 21, but we would make this slight  
19 revision that the adjusted ratio of observed  
20 to expected in-hospital mortality can be done  
21 with any of the three systems because the STS  
22 can do that with any of the three systems

1 within the database, so you can make 21 apply  
2 to all three systems just like you apply 18 to  
3 all three systems.

4           What that would then allow is that  
5 Number 18 would mean you report your results  
6 using complexity stratification through any of  
7 the three ways, and Number 21 would mean that  
8 in addition to that you would report using any  
9 of the three complexity stratification tools  
10 or risk adjusted mortality from that.

11           When we do that, it would be very  
12 easy then to go back to the program which is  
13 DCRI and say okay, we want you to spit out  
14 adjusted ratio of observed to expected  
15 mortality by not only RACHS, but RACHS by  
16 Aristotle and by the new tool they created,  
17 and to do it utilizing the full model of RACHS  
18 when they do it for RACHS, and utilizing the  
19 other variables when they do it for Aristotle.

20           DR. MAVROUDIS: Can that be done?

21           DR. J. JACOBS: That can be done  
22 easy. Easy.

1 DR. JENKINS: Yes. The only  
2 counterpoint that I would make to that, Jeff,  
3 and this is being a little bit of a  
4 measurement nudge, whatever the word is, being  
5 tight on measurement, is that the first model,  
6 the RACHS model has been used and validated to  
7 be done that way, and there are seven years of  
8 experience doing it that way, and the other  
9 ones are new. So you just have less  
10 information about their validity and  
11 reliability, but methodologically they're just  
12 multi-variant models incorporating additional  
13 variables, and that's what they are.

14 DR. J. JACOBS: So I think my  
15 biggest principle is that when it's all said  
16 and done, we leave here treating these three  
17 systems the same way within the STS database  
18 and within the quality indicators. I don't  
19 think that our group should be the group that  
20 tries to legislate which one is better or  
21 worse. There's piles of publications that  
22 argue on either way, and I don't think that

1 there's any solid evidence one way or another.

2 We could talk about the timeline  
3 of how things have been around and Kathy is  
4 correct that RACHS has been around longer than  
5 Aristotle. But it's also correct that  
6 Aristotle has been in the STS database for six  
7 years more than RACHS.

8 DR. JENKINS: No, I'm just talking  
9 about the application --

10 DR. J. JACOBS: Understood.  
11 Understood.

12 DR. JENKINS: If the question is  
13 does STS want to propose an SMR model for  
14 Aristotle and empirical data, I certainly  
15 don't have any problem with that. That's not  
16 something I'm going to propose, but it's  
17 certainly something one could --

18 DR. J. JACOBS: Right. So my  
19 proposal would be that Metric 18 allows the  
20 utilization of all three stratification tools.  
21 Metric 21 should just say that you need to  
22 report an adjusted ratio observed to expected



1 mortality using any of the three  
2 stratification tools.

3 DR. HINKLE: So I'd like to ask a  
4 simple question again. So it sounds like what  
5 I've heard from all of you is that the three  
6 tools will in no way mislead the public.  
7 They're equal across the mortality rates that  
8 you're looking at by complexity.

9 DR. MAVROUDIS: No, they're not  
10 equal because - they're not equal because some  
11 of them are better than this than others, and  
12 others are better than this than others. So  
13 they're not equal.

14 Where we are - give us credit.  
15 We're being nice to one another. We don't  
16 want any bad feelings about this or anything  
17 like that, and that's why we are trying to  
18 find the common ground. So they're not equal.

19 DR. HINKLE: I mean if they're  
20 publically available, is it going to do any  
21 harm, you know?

22 DR. MAVROUDIS: No, no.

1 DR. HINKLE: I mean the variation  
2 in those is probably minuscule -

3 (Simultaneous speakers.)

4 DR. HINKLE: Okay.

5 DR. JENKINS: For the categories,  
6 for sure, no, because everybody's seen that  
7 and they've seen the areas under the ROC  
8 curves based on that, and they're all in the  
9 same range -- for adding the additional  
10 variables, they're in various stages.

11 DR. HINKLE: Yes.

12 CO-CHAIR JEFFRIES: No one is going  
13 to be able to game the system by picking one  
14 versus -

15 DR. HINKLE: Right. That's what I  
16 was trying - I'm trying to be polite to get  
17 there, but -

18 DR. JENKINS: You won't be able to  
19 compare an SMR with one compared to the other.

20 DR. J. JACOBS: I don't think that  
21 that would be the goal of - that's just like  
22 we can't compare the mortality of RACHS-1

1 versus Aristotle 1 -

2 DR. JENKINS: That's correct.

3 DR. J. JACOBS: - within that  
4 level. That's not the purpose of it.

5 I think Kathy could make a strong  
6 argument that use of adjusted ratios of  
7 observed to expected mortalities has been  
8 around longer with the RACHS system than it  
9 has with the Aristotle system, which is true.

10 The other argument could be made  
11 that the number of operations classified with  
12 the RACHS system is 86 percent in the STS  
13 database where there's - I'm sorry, 84 percent  
14 compared to 96 percent with Aristotle.

15 So, like I said, you can argue  
16 strengths and weaknesses of each system, and  
17 we can sit here and do that for hours. But  
18 the truth is, I think, as long as we create a  
19 set of indicators that allows for the  
20 utilization of all of these, I think we're  
21 supporting - what my ultimate goal is that  
22 eventually they're all going to end up as the

1 same tool not by a group of people around the  
2 table saying that's the way it has to be, but  
3 by eventually that's where the science will  
4 lead us.

5 CO-CHAIR JEFFRIES: So if someone  
6 wants to -

7 MS. HINES: I just want to get a  
8 clarification because these are being  
9 considered for public reporting. I've heard,  
10 and maybe I misunderstood, that RACHS and  
11 Aristotle and STS cannot be compared.

12 DR. JENKINS: To each other.

13 MS. HINES: Right. But I mean -

14 DR. JENKINS: -- compared if there  
15 were ten centers that all reported and either  
16 of those --

17 MS. HINES: That's not what would  
18 happen. When we're talking public reporting,  
19 we're talking -

20 DR. HINKLE: Public reporting.

21 MS. HINES: - public reporting.

22 DR. HINKLE: I think what they're

1 saying if I can maybe elaborate -

2 MS. HINES: Okay.

3 DR. HINKLE: - I think where I'm  
4 at, what they're saying is if it's Seattle -  
5 let's say Seattle Children's is using a risk  
6 adjustment. And the public goes in and says  
7 wow, look at that one. And then they go look  
8 at the Boston Children's Hospital maybe using  
9 a different method. And I think what I'm  
10 hearing is there's probably not much  
11 difference across - I mean it's not going to  
12 be -- the mortality rate -- because of the  
13 tool that's being used.

14 DR. J. JACOBS: But you have to do  
15 it within the tool that you're talking about.  
16 So what the STS does -- participation in the  
17 STS database means that your outcomes are  
18 analyzed with all three tools because -

19 MS. HINES: But only one should be  
20 used for reporting.

21 DR. J. JACOBS: But how do you -

22 DR. HINKLE: Why is that?

1 DR. J. JACOBS: Why is that?

2 MS. HINES: Well, I'm just saying  
3 if you -

4 DR. JENKINS: You're saying any of  
5 the three could be used.

6 CO-CHAIR JEFFRIES: But then they  
7 have to be able to be compared against each  
8 other.

9 MS. HINES: Right, right. If it's  
10 apples, oranges and grapes, they're not -

11 DR. JENKINS: - the whole group  
12 doing apples, and then you --

13 MS. HINES: Public reporting is not  
14 going to be apples to apples. Then in my  
15 mind, that makes this a quality improvement  
16 measure that can be used within a facility but  
17 couldn't be looked at at CMS or -

18 DR. JENKINS: If CMS came in and  
19 they just said pick one, and they randomly  
20 picked one of the three -

21 MS. HINES: Then that's what the  
22 measure would -

1 DR. JENKINS: Then that would be  
2 the measure.

3 MS. HINES: That's right. But that  
4 measure would not have three choices, they  
5 would just come in and say Aristotle, RACHS.  
6 And I understand what you're trying to do with  
7 giving someone three choices just to get them  
8 -

9 DR. MAVROUDIS: You're not giving  
10 them three choices, you know. We're not doing  
11 that. They've already made their choices.

12 MS. HINES: Well, to get -

13 DR. MAVROUDIS: We're not giving -

14 DR. JENKINS: You're saying any of  
15 the three are fine.

16 DR. MAVROUDIS: They're using them.  
17 It's different.

18 MS. HINES: But not for public  
19 reporting.

20 DR. MAVROUDIS: It's different.  
21 It's different. We are complying to them  
22 rather than them complying to us.

1 MS. HINES: But if it's public  
2 reporting -

3 DR. J. JACOBS: There's no  
4 scientific way to choose which one is better  
5 to use right now.

6 MS. HINES: Then in my mind it's  
7 not a public reported measure because -

8 DR. MAYER: But yet this is the  
9 measure that the parents are going to want to  
10 know more than anything else.

11 MS. HINES: But again -

12 DR. JENKINS: And this is the one  
13 the centers are using. This is the number one  
14 thing coming out of -

15 MS. HINES: But again, not apples  
16 to - I mean you've got -

17 DR. JENKINS: I'm not sure I agree  
18 with that.

19 MS. HINES: But that's what I'm  
20 hearing from you all. You're telling me that  
21 -

22 DR. JENKINS: No. We're talking



1 about two different things.

2 DR. J. JACOBS: So the STS I have  
3 been fairly involved with are public reporting  
4 efforts up until this point in time. Which as  
5 you probably know, were initially adult  
6 cardiac based on the coronary artery bypass  
7 grafting part.

8 And the task force that's doing  
9 that I happen to chair, so we've had a lot of  
10 talk about once that gets done, and our goal  
11 is to have that public reporting piece on the  
12 internet by May 15th, and I think we will.

13 Then we're going to try to look at  
14 well, what are we going to publicly report for  
15 adult thoracic and for congenital. And the  
16 discussions we've had for adult thoracic and  
17 congenital are preliminary but pretty good.

18 And what we're thinking about for  
19 the congenital database is that the outcomes  
20 from any given program can be reported in a  
21 very easily understood graph on the internet  
22 where you could go and say okay, here's

1 hospital A, and here's how they do with the  
2 RACHS system. Then you click it. And here's  
3 how they do with the Aristotle system, and you  
4 click it. And here's how they do with the STS  
5 system.

6           So our public reporting system  
7 would have a scenario in place where the  
8 parent or the referring doctor would be able  
9 to actually go to the internet and look and  
10 see how that hospital or how that surgeon,  
11 right now hospital, performs using any of  
12 those three systems. And then that guy could  
13 decide which one he wants to use to make his  
14 decision, but the public reporting metric will  
15 actually get any of the three.

16           And you just click one, two,  
17 three, and you see them all. That's why I  
18 think you need to treat them all as equals,  
19 and then the public actually gets more  
20 information.

21           MS. HINES: Well, and that's fine,  
22 and I'm playing devil's advocate because I'm

1 looking for holes in what you're saying  
2 because they will come up. And that's going  
3 to be something that you're going to have to  
4 be very clear about when you're writing  
5 because it's not - if this was a typical, say,  
6 CMS reporting, you can't do that. It has to  
7 be one thing. But if that's what your - if  
8 that's going to be a capability, then the -

9 DR. J. JACOBS: Well, that's our  
10 intent.

11 DR. JENKINS: It may change over  
12 time.

13 DR. MAYER: If I may say, we may  
14 not have found the holy grail in any one of  
15 these three.

16 DR. HINKLE: What you just  
17 described is a complex, I think, expectation  
18 to ask of a parent sitting in the  
19 pediatrician's office, you know, just looking  
20 and saying look at these three risk adjusters,  
21 these are the different performance around  
22 them and you need to be aware of how this

1 hospital -

2 DR. MAVROUDIS: They're so close.

3 DR. HINKLE: Well, maybe. So I'm  
4 just asking.

5 DR. JENKINS: So you're just saying  
6 that all of this is just one variable, the  
7 type of procedure, but we're talking about -  
8 that's why I was objecting to Gus talking  
9 about models because you guys were mentioning  
10 multi-variant models or something complicated.

11 It's one variable. What kind of  
12 procedure do you have? And it's a way of  
13 grouping together those procedures, grouping  
14 them together in one system. There's four  
15 categories in one, there's five in another,  
16 there's six which is functionally almost  
17 always used as five because there's very few  
18 in one category.

19 Okay. And so that's all it is.  
20 It's not adjusting for age or any other  
21 factors or complicated model. It's just that.  
22 So if you had a mother and you had a baby with

1 tetralogy of fallot, you would look up  
2 whatever category that's in in Aristotle and  
3 probably be focused in on that.

4           If you were looking at RACHS, it  
5 would be in Category 2. If you were looking  
6 at STS, I assume it would also be in Category  
7 2, right?

8           DR. J. JACOBS: Correct.

9           DR. JENKINS: And in the fine print  
10 of the smaller volume procedures based on how  
11 and when they were derived, there may be some  
12 variation about where your more unusual  
13 procedures fell.

14           Okay. But a general distribution  
15 of cases, how many are in each category, is it  
16 across the bar, so the categories would be  
17 relatively standard.

18           DR. HINKLE: So one other question.  
19 You said Europe went with Aristotle. Is that  
20 all through Europe?

21           DR. MAVROUDIS: One of the things  
22 about - Aristotle was developed by - not by a

1 Greek, but by a Frenchman. And he was very  
2 influential and he's moved here to - he moved  
3 here to Denver, now he's in New York.

4           Anyway, he was the sort of vision  
5 behind this kind of Delphian system, you know,  
6 based on experts' opinion.

7           DR. JENKINS: And that was purely  
8 by judgment.

9           DR. MAVROUDIS: Yes.

10           DR. HINKLE: So was there a process  
11 in the European Union they went through -

12           DR. J. JACOBS: What happened was -

13           DR. HINKLE: I'm just trying to  
14 figure was science -

15           DR. J. JACOBS: So there was a  
16 panel of experts of North Americans that  
17 developed RACHS with 11 people. And then  
18 there was a panel of experts that was set up  
19 to develop Aristotle.

20           DR. JENKINS: In two large data  
21 sets.

22           DR. J. JACOBS: Right. And then

1 the panel of experts that developed Aristotle  
2 had 50 people which were from Asia, Europe,  
3 North and South America. So that's why I  
4 think that got a little more buy-in in Europe  
5 because they were involved in the development  
6 of it, as were the Americans. But they're  
7 both valuable tools, and I don't think that  
8 there's any realistic way that we could choose  
9 one over the other.

10 DR. MAYER: I think the other thing  
11 that Jeff said that sort of might have gone by  
12 here a little bit is that since ICD - since  
13 RACHS is based on ICD-9 diagnosis and  
14 procedure codes, you know, it's hard --  
15 because the ICD system hasn't kept up, to be  
16 honest with you. There's a population that  
17 doesn't fit very well in -

18 DR. JENKINS: That's not true  
19 though, John. Actually, RACHS includes all of  
20 the coding frameworks, it just can be used in  
21 an ICD-9 framework. It wasn't only for an  
22 ICD-9 framework.

1 DR. MAYER: Well, then help me  
2 understand what -

3 DR. JENKINS: So that's where  
4 there's -

5 DR. MAYER: Is what Jeff said -

6 DR. JENKINS: - been a real  
7 misunderstanding here. The idea that RACHS  
8 can only be applied and was derived from ICD-9  
9 codes is not true and was never true.

10 MS. HINES: You know, I think one  
11 thing - we don't have to choose one or the  
12 other.

13 DR. MAVROUDIS: That's what we're  
14 trying to say.

15 MS. HINES: Okay. Well, it sounds  
16 like -

17 DR. MAVROUDIS: Actually, to be  
18 fair, this came up because of you.

19 DR. HINKLE: I mean you made a  
20 statement which is a goal in the United States  
21 to have a national standard. Otherwise -

22 DR. JENKINS: And quite frankly --



1 is because AHRQ came forward with a RACHS-like  
2 model and it's exclusively an ICD-9  
3 application and did not use the original RACHS  
4 methodology. And that's what in your PDI --  
5 whatever it is.

6 MS. HINES: Well, it sounded like -

7 DR. JENKINS: And we actually like  
8 the real RACHS. I personally like the real  
9 RACHS better than what AHRQ came up with in  
10 their application.

11 MS. HINES: It sounded like you  
12 were trying to -

13 MR. HARDER: I think what Lisa is  
14 saying, Lisa is saying that there's councils.  
15 There's a consumer council, there's these  
16 other councils that are going to have to grasp  
17 this discussion.

18 DR. J. JACOBS: Right.

19 MR. HARDER: So just be prepared.

20 DR. MAYER: No, no. But I think  
21 the -

22 MR. HARDER: But this is the -

1 DR. MAYER: Although I recognize  
2 that that's the issue, right, the question is,  
3 is how much does that drive this versus how  
4 much does the people who actually know a lot  
5 about this drive what happens. And I think  
6 that's the tension that's in effect here right  
7 now.

8 DR. J. JACOBS: And I think the  
9 people who have published the most about this  
10 and researched the most about this would agree  
11 that we should not try to choose one over the  
12 other and just include them all in these  
13 metrics and treat them as equals. But the  
14 problem is selling that to everybody else, I  
15 think.

16 DR. HINKLE: Yes, so help me with  
17 the process here. So we wouldn't want  
18 operative mortality removed.

19 DR. J. JACOBS: Right.

20 DR. MAVROUDIS: Well, we're not  
21 going to remove operative mortality. What  
22 we're debating here is stratification.

1 DR. HINKLE: Well, I know. But if  
2 this is going to move -

3 DR. MAVROUDIS: Yes.

4 DR. HINKLE: Let's say we approve  
5 this, it moves on to another process up the  
6 chain here at NQF where it's going to start  
7 bumping more against consumers, and, I mean,  
8 that's where it could be. We would not want  
9 to lose this.

10 DR. J. JACOBS: A consumer group  
11 that's not as literate in these topics as we  
12 are, just like we're not as literate in  
13 consumer topics as they are, comes back and  
14 says well, we have to choose one, we can't  
15 have three.

16 DR. HINKLE: No, I don't think  
17 they'll say that. My guess is -

18 DR. MAVROUDIS: Well, you'll have  
19 trouble with compliance then. You'll have  
20 trouble with compliance.

21 MS. HINES: No, I think what you're  
22 going to - the consumers -- are going to want

1 outcomes and they're going to want what's good  
2 for the kids. So that's in both favors.

3           Sitting back here and listening at  
4 you all go - you know what you're talking  
5 about. It very much sounded like it was going  
6 to be one or the other. So what I'm trying to  
7 do is message if you want to put or if you  
8 surely put both of these through, then what we  
9 need to do when we do the comments for it to  
10 move forward is to say why each is important  
11 in its own right.

12           CO-CHAIR JEFFRIES: Why each  
13 measure is?

14           MS. HINES: Yes.

15           CO-CHAIR JEFFRIES: So -

16           MS. HINES: So you could - both  
17 could go through, they're both going to be  
18 time limited.

19           DR. JENKINS: Are you talking now  
20 about the SMR and the categories or the three  
21 kinds of -

22           DR. HINKLE: 18 and 21.

1 MS. HINES: 18 and 21. The  
2 measures.

3 CO-CHAIR JEFFRIES: So I think  
4 that's what we should actually --

5 DR. HINKLE: Move for that.

6 MS. HINES: So I think that could  
7 be important to show why both should go  
8 forward in the testing -- we'll remove the  
9 time limited, if that's what you're truly  
10 saying.

11 CO-CHAIR JEFFRIES: I don't think  
12 we should - I guess I wouldn't - I don't think  
13 we should spend time comparing 18 and 21.  
14 Let's just talk about the merits of each one  
15 and then we'll report on the merits and move  
16 forward that way.

17 So I think -- so for 18, Gus, did  
18 you have anything else you wanted to -

19 DR. MAVROUDIS: No. I think that  
20 you can all remember what I said. I'm  
21 comfortable with making that motion. I think  
22 that it's inclusive. To use the word, I think

1 it's ecumenical.

2 So I think that that will work.

3 And further, it will allow all the people who  
4 are using them now to continue to use them and  
5 without any acrimony of any kind and so forth.

6 So the STS will give the reports out. And in  
7 the reports there will be the RACHS  
8 stratification and the Aristotle  
9 stratification. And sooner or later the STS-  
10 EACTS stratification as well.

11 And so I think that if we treat  
12 this as an ongoing development - as a motion,  
13 a plan in motion, then what Jeff said is going  
14 to happen. Sooner or later one of these will  
15 go forward and then there will be some kind of  
16 a meeting of the minds of one thing or  
17 another. And then in a year or two, three,  
18 they'll have one probably. And then that will  
19 be a good one, it will be a great one. It  
20 will be based on good data and the rest.

21 So I'd like to make that motion  
22 that we approve this, 18. Yes, and we can

1 have discussion

2 DR. HINKLE: Second.

3 DR. MAVROUDIS: You know what I'd  
4 like to do? I would actually love to hear you  
5 two. You may not be voting, but I certainly  
6 would like to hear your opinion.

7 DR. JENKINS: I already stated  
8 mine.

9 DR. MAVROUDIS: Yes. Okay. Motion  
10 made.

11 DR. HINKLE: I second. I think the  
12 conversation was good. It helped me at least  
13 move to a place I was stuck on.

14 And I think the measure, the  
15 operative mortality is so critical to the  
16 public going forward and the nuances within.  
17 And people are just all over the internet.  
18 Maybe these patients are going to be driven to  
19 find granular and more granular information.

20 They're going to be probably  
21 looking to figure out these three things, what  
22 do you think, and they're going to have to

1 search out the pediatric cardiac surgeon in  
2 their community to help them, maybe, with  
3 this, and that's healthy.

4 That's sort of where I've - so I  
5 think I'm in favor.

6 DR. MAVROUDIS: So motion made and  
7 seconded.

8 CO-CHAIR JEFFRIES: Okay. All  
9 right.

10 DR. MAVROUDIS: Sylvia, you don't  
11 have anything to say?

12 DR. LOPEZ: No, I agree.

13 CO-CHAIR JEFFRIES: Why don't we  
14 talk about 21 since we're well into that  
15 discussions?

16 DR. MAVROUDIS: Well, unfortunately  
17 I'm the lead on that as well.

18 CO-CHAIR JEFFRIES: Yes.

19 DR. MAVROUDIS: What I did was I  
20 tried to prepare all three with as much  
21 information as I had. All three meaning the  
22 SMR associated with RACHS or the RACHS SMR,



1 Aristotle and STS-EACTS system.

2 And there have been papers written  
3 about this. And I looked at the C score.

4 What is it called?

5 DR. MAYER: C statistic.

6 DR. MAVROUDIS: C statistic. And  
7 the C statistic you can - they're very close.  
8 All three of them are very close. It turns  
9 out that the EACTS-STIS seems to do better  
10 because it's based on 80,000 patients - not  
11 80,000, is that right?

12 DR. JENKINS: Gus, can I just ask  
13 for a clarification?

14 DR. MAVROUDIS: Well, you could  
15 even do more than that.

16 DR. JENKINS: When you say you're  
17 comparing all three, I don't know what that  
18 means.

19 DR. MAVROUDIS: Right, right.

20 DR. JENKINS: Because the measure  
21 we proposed was the SMR based on RACHS.

22 DR. MAVROUDIS: I'm not comparing

1 the SMR in this one. I made a chart, and it  
2 did not compare the RACHS SMR. And 21 is  
3 about the RACHS SMR.

4 DR. JENKINS: I thought you were  
5 discussing 21.

6 DR. MAVROUDIS: We are.

7 DR. JENKINS: That's why I -

8 DR. MAVROUDIS: I know, but what  
9 I'm trying to say is that to try to get some  
10 understanding -

11 DR. JENKINS: But when you said you  
12 compared all three, I just don't understand  
13 what you compared it with.

14 DR. MAVROUDIS: I compared the C  
15 statistic on all three for their risk  
16 stratification.

17 DR. JENKINS: For the categories  
18 only.

19 DR. MAVROUDIS: Yes.

20 DR. JENKINS: Okay.

21 DR. MAVROUDIS: Yes, that's what I  
22 did.

1 DR. JENKINS: I just want to point  
2 out that the SMR that we proposed -

3 DR. MAVROUDIS: Is different.

4 DR. JENKINS: - is different.

5 DR. MAVROUDIS: No question.

6 DR. JENKINS: Okay.

7 DR. MAVROUDIS: No question. And I  
8 tried to make that known, too.

9 DR. JENKINS: Okay.

10 DR. MAVROUDIS: But what we're  
11 talking about for the SMR is comparing  
12 observed mortality and expected mortality.

13 DR. JENKINS: Based on five  
14 factors.

15 DR. MAVROUDIS: Right.

16 DR. JENKINS: Category across the  
17 four other variables.

18 DR. MAVROUDIS: Exactly. And those  
19 four other variables are part of another  
20 program, right, that you've -

21 DR. JENKINS: They're part of 21.

22 DR. MAVROUDIS: Right.

1 DR. JENKINS: They're the measure  
2 that we're proposing.

3 DR. MAVROUDIS: Correct.

4 DR. JENKINS: Those four other  
5 variables in the SMR.

6 DR. MAVROUDIS: Correct. We've  
7 talked about the pros and cons of all three so  
8 far. And this - if we put this in with just -  
9 just for RACHS SMR, then it excludes others -  
10 the other system which can be done. And it  
11 strikes me as not moving in the same direction  
12 as 18 insofar that it allows - that 18 allows  
13 all programs - the program to do whatever -  
14 pick whatever they wanted or to emphasize  
15 whatever they want.

16 And this one you're going to get  
17 dinged if you're a program, you're going to  
18 get dinged if you don't use 21. That is it  
19 say RACHS SMR calculation. So I would like to  
20 see 21 move in the direction - I actually  
21 would love to see that 21 be melded into 18  
22 with the SMR being reported by all three

1 categories and not just RACHS.

2 In other words, make 18 not only  
3 risk stratification mortality, but also for  
4 SMR. And then each program would be allowed  
5 to use one of those three classifications or  
6 one of those three metrics.

7 DR. J. JACOBS: Or better yet the  
8 STS could calculate an SMR with each of the  
9 three metrics.

10 DR. MAVROUDIS: Yes. Right.

11 DR. J. JACOBS: Because it's been  
12 very hard for an individual program to  
13 calculate that unless they have their own  
14 biostatistician, and most of us aren't lucky  
15 enough to have that.

16 DR. MAVROUDIS: That was one of the  
17 things. That was one of the problems that I  
18 saw as a viewer, that -- let's just say, I  
19 don't know. Let's pick a place in California,  
20 a small place in California. They may not  
21 have the wherewithal to do it.

22 If Duke and the STS can get that

1 program and figure it out in that family of  
2 data, then it can be done there for all three  
3 categories and it will be there. And for the  
4 price of what you would pay for to have the  
5 STS database, you can have everything there at  
6 once.

7                   And I welcome any discussion. I  
8 would welcome that we take 21 and instead of  
9 having it there all by itself and having it  
10 sort of in a pregnant pause elsewhere, to move  
11 that into 18. And then have the STS calculate  
12 the SMR for all three categories.

13                   MS. HINES: That could be a  
14 research recommendation, but that leads us  
15 then to changing the measure.

16                   DR. MAVROUDIS: I see. That's a  
17 problem, isn't it?

18                   MS. HINES: And what we're doing is  
19 we're supposed to be looking at the submission  
20 form as it's submitted.

21                   DR. MAVROUDIS: Okay. So, what  
22 you're saying is, is that -

1 MS. HINES: So you could -

2 DR. MAVROUDIS: - you either  
3 accept or reject it; is that what you're  
4 saying?

5 MS. HINES: Right.

6 DR. MAVROUDIS: Didn't we amend the  
7 one about interventional cath?

8 DR. J. JACOBS: Yes, we did.

9 DR. MAVROUDIS: Adding  
10 interventional cath into the re-operation?

11 MS. HINES: That was because you've  
12 got one measure developer that agreed to do  
13 it. You're crossing two measure developers in  
14 the -

15 DR. MAVROUDIS: Well, I don't know  
16 if we can agree to do it then.

17 DR. J. JACOBS: I would agree to  
18 add adjusted ratio observed to expected  
19 mortalities to Metric 18, doing it for all  
20 three, doing it exactly as described within  
21 Measure 21 for RACHS, and then doing it the  
22 same way, basically, for Aristotle and STS

1 Score. So that would be easy for us to do and  
2 that would make all of this work together.

3 MS. HINES: I'm just afraid -

4 DR. J. JACOBS: So I would support  
5 that.

6 MS. HINES: Right.

7 DR. JENKINS: I guess the issue  
8 that I would have - my understanding, Jeff, is  
9 that we don't right now have the additional  
10 variables in STS although they will be coming  
11 in soon.

12 DR. J. JACOBS: They'll be coming  
13 in in -

14 DR. JENKINS: So I don't think you  
15 can actually -

16 DR. J. JACOBS: They'll be coming  
17 in in five weeks.

18 DR. JENKINS: Right. And I think  
19 the reason the comparative papers did not  
20 compare the full RACHS model is because you  
21 didn't actually have the variables in the  
22 current version to do it that way, which is



1 why it was done differently with part of it,  
2 but not all of it.

3 DR. J. JACOBS: Right. So starting  
4 five weeks from now we're going to have all  
5 those variables and we're going to be able to  
6 do that. And the one thing I have to be  
7 fairly strong about is that it's very  
8 important to the STS that whatever we adopt,  
9 we adopt with the ability of the STS database  
10 to be able to do it.

11 And that's why all 20 of these  
12 variables were written so that participation  
13 in the STS database allows one to do these 20  
14 things.

15 DR. JENKINS: Right, but we're at  
16 the -

17 DR. J. JACOBS: And I think that we  
18 can make number -

19 DR. JENKINS: - NQF so centers that  
20 are not part of STS -

21 MS. HINES: We're not driving  
22 toward making everything STS.

1 DR. J. JACOBS: I understand.

2 MS. HINES: So, I mean, we need to  
3 be really careful because we have 20 STS  
4 measures and -

5 DR. J. JACOBS: Right. No, I'm not  
6 saying -

7 MS. HINES: - one additional  
8 measure.

9 DR. J. JACOBS: I'm not saying that  
10 we should make a metric come into existence,  
11 that the only way to do it is to participate  
12 in the STS database. That's absolutely not  
13 what I'm saying. But what I am saying is that  
14 I don't want to put a metric into play that  
15 the STS database can't do.

16 MS. HINES: Well, and you're a  
17 measure developer.

18 DR. J. JACOBS: Right.

19 MS. HINES: And you're speaking as  
20 that.

21 DR. JENKINS: And I'm just saying  
22 that we have been able to do our measures in

1 various ways with various tools.

2 DR. J. JACOBS: From administrative  
3 data sets.

4 MS. HINES: Well -

5 DR. JENKINS: And other data sets,  
6 too. So my perspective would be that it would  
7 be wonderful if STS could be incorporated to  
8 do the full RACHS model.

9 What I'm objecting to and the  
10 reason I'm here is that AHRQ did this as a  
11 partial implementation of RACHS. Okay. And  
12 then saying it's RACHS, but it's not. It's  
13 something a little bit like RACHS. It's not  
14 the full RACHS.

15 They use different age categories.  
16 They use only the admin data application, not  
17 the broader uses and other kind of data and  
18 some other quirky things that were harmonized  
19 with something AHRQ was doing, but it wasn't  
20 the real RACHS.

21 I'm agnostic as to whether the  
22 models using Aristotle or the new STS

1 categories with the additional variables that  
2 are part of RACHS will work better or worse  
3 because I haven't' seen that analysis.

4 But I'm assuming it will probably  
5 be reasonable in which case SMRs derived as a  
6 result of adjusting is probably very  
7 reasonable.

8 But having never seen it, it's  
9 hard to endorse it. That's all I'm saying.  
10 I've never seen the validity, whether the  
11 changes in categories do or don't require the  
12 additional variables.

13 I've just never seen it because  
14 it's not -- I'm agnostic about an opinion  
15 about it.

16 DR. J. JACOBS: Where would a given  
17 hospital get this from?

18 DR. JENKINS: Where would a given  
19 hospital --

20 DR. J. JACOBS: Where would a  
21 hospital that doesn't have their own  
22 biostatistician be able to come up with an

1 adjusted ratio observed to expected in-  
2 hospital mortality?

3 DR. JENKINS: Jeff, we get calls  
4 all the time from people who use RACHS with  
5 biostatisticians who can use the coefficients  
6 from the model because people do it on pencil  
7 and paper. The database can do it. People  
8 have cranked it out with their kid. The  
9 algorithms are in the public domain.

10 DR. J. JACOBS: Administrative  
11 datasets.

12 DR. JENKINS: So, believe it or  
13 not, other people really actually are doing it  
14 with something other than their STS report.

15 DR. MAYER: So, wasn't there as  
16 proposed in one of the -- I mean didn't we  
17 hear about this a month or so ago where there  
18 was actually an intent to compare the data  
19 that was collected through these two different  
20 mechanisms?

21 I mean one of the underlying  
22 issues here is that the data that gets into

1 the administrative claims data gets acquired  
2 and entered by an entirely different mechanism  
3 than what happens with the STS data.

4 DR. JENKINS: Yes.

5 DR. MAYER: And there is a paper in  
6 the adult world from Massachusetts that  
7 suggests that there are significant  
8 discrepancies in exactly the same time period,  
9 three-year time period, between the data that  
10 went in and from the administrative claim  
11 side, and the clinical data that went into the  
12 STS database.

13 MS. HINES: Happens all the time  
14 in the ambulatory measures and hospital  
15 measures according to whatever --

16 DR. MAYER: Right.

17 DR. JENKINS: So, the validity of  
18 the administrative approach is simply based on  
19 the fact that the administrative codes are  
20 sufficient to categorize the patients well  
21 enough for about 85 percent of the case mix to  
22 yield an area under the ROC curve of

1 approximately .8 or seven years.

2           So, it's not saying it's the same  
3 or making a claim and saying that that's a  
4 validity claim about the use of the model as  
5 developed.

6           DR. J. JACOBS: The problem with  
7 that though is that that assumes that the  
8 classification was correct from the beginning  
9 using the ICD-9 codes. And what John is  
10 talking about is a very big issue that the  
11 CDC, Center for Disease Control, did a study  
12 comparing clinical and administrative coding.  
13 And that's also in this book here.

14           And unfortunately, their  
15 conclusion is analysis based on ICD-9  
16 diagnostic codes of cardiac disease may have  
17 substantial mis-classification of congenital  
18 heart disease. Isolating the major defect is  
19 difficult and certain codes do not  
20 differentiate between variants that are  
21 clinically and developmentally different.

22           So, that's why the whole purpose

1 of pushing to use the clinical database like  
2 the STS database exists.

3 DR. JENKINS: Could be. Could be,  
4 Jeff. But it turns out there's sufficiently  
5 good to generate an area under the ROC curve  
6 that's actually quite reasonable.

7 DR. J. JACOBS: Right. If you  
8 assume that the actual diagnosis that that's  
9 been based on is correct.

10 DR. JENKINS: We're just using the  
11 big dataset. And that's what the mortality  
12 discrimination is coming out.

13 So, that's an admin database  
14 versus prospective database argument. But at  
15 the end of the day, those databases are more  
16 informative than one would imagine.

17 That although subject to repeated  
18 audits, actually at Children's Hospital of  
19 Boston there's ten to fifteen two source  
20 document audits of that database per month for  
21 the pairs.

22 So, your point is well taken. I



1 actually agree with you that prospective data  
2 is probably better. But at the end of the  
3 day, the codes are sufficiently robust to be  
4 discriminated.

5           And we're not proposing an SMR  
6 based on that. That's what AHRQ did last  
7 year. We're proposing it based on a variety  
8 of data sources.

9           CO-CHAIR JEFFRIES: Okay. Let's go  
10 through this measure by the points. So, go  
11 through the importance, which I think we sort  
12 of got through that. Mortality is clearly  
13 important here.

14           So, next is the scientific  
15 evidence.

16           DR. MAVROUDIS: Well, I'm supposed  
17 to be leading this. And if I'm supposed to  
18 lead on the scientific evidence of how good  
19 the measure is, I'm not so sure I -- I mean  
20 I've looked at this. I'm not so sure I can  
21 make a good statement on it because it  
22 requires a total understanding of

1 administrative data and how accurate it is.

2           It also requires a knowledge of  
3 the program that was used to include the four  
4 expanded metrics, which I don't think is going  
5 to be hard to understand, but there are papers  
6 that talk about mis-coding in administrative  
7 databases and how important this is.

8           Now, we probably use  
9 administrative databases all the time and that  
10 there are metrics to say that we might have  
11 one percent or three percent mis-coded, but  
12 the vast majority are appropriate and we can  
13 make inferences from that based on this  
14 statistic and that statistic.

15           And I, you know, quite frankly I'm  
16 not a statistician, so I can't really comment  
17 on that and I look, actually, for the rest of  
18 you to make comment on that.

19           I think administrative data, I've  
20 read some papers and actually had my own  
21 experience where I said let's take a look at  
22 all the truncus arterials, just connect them

1 up with transposition, let's take a look at  
2 all the tetralogies that come up with  
3 transposition after transposition, I come up  
4 with single ventricles a lot.

5           And so the people who are putting  
6 in data in the STS are trained data managers,  
7 et cetera, et cetera. The database is  
8 verified ten percent per year, which is a  
9 pretty good number.

10           I don't know how the  
11 administrative database will allow an  
12 important measure like this to be verified.  
13 You know, I just don't know.

14           And I think that, you know, I  
15 really -- I'm not sure it's for us to figure  
16 that out.

17           MS. HINES: I think it's really  
18 tough for this group because it does keep  
19 getting back to the STS database.

20           DR. MAVROUDIS: No, it doesn't. It  
21 doesn't for me.

22           MS. HINES: Well, that's what you -

1 -

2 DR. MAVROUDIS: No, it doesn't.

3 MS. HINES: But as far as  
4 administrative data just from an NQF  
5 perspective, we just did a huge administrative  
6 data project looking at tiers of clinically-  
7 enriched data, pure administrative,  
8 administrative plus pharmacy data or x-ray  
9 data, whatever, and then registry data.

10 So, I mean they've just gone  
11 through 270 measures and I think 74 or  
12 something like that are getting voted through.

13 There's a bunch of harmonization.

14 So, I just -- if it's -- if there's no --

15 DR. MAVROUDIS: Let me interrupt  
16 for a moment. I'm sorry. I'm being rude, but  
17 I doubt that radiology and other sub-  
18 specialties have double outlet right ventricle  
19 tetralogy type, transposition type, single  
20 ventricle type. I doubt that they're listed  
21 under that. I doubt it very much and, you  
22 know, it's the norm for us. It's the norm for

1 us.

2           Again, we're getting into the  
3 debate on how good administrative data are and  
4 so forth and so on, and I didn't want to do  
5 that.

6           I think that this is a premature  
7 thing that we're doing here. We're edging  
8 towards deciding that one metric is better  
9 than another. It's way premature for that.

10           I think these metrics have to be  
11 put into the system and they have to be -- go  
12 their normal and their natural way, and  
13 eventually we'll find one.

14           And I think to say like you want  
15 to do, like EMS wants to do, what everyone  
16 wants to do is to choose one now and --

17           MS. HINES: No, no, no.

18           DR. MAVROUDIS: -- that's wrong.

19           MS. HINES: My - I shouldn't say  
20 this: My preference is to put them both  
21 through and see what the comments are that  
22 come through.

1 DR. MAVROUDIS: But I was supposed  
2 to do this and now we're just basically saying  
3 that I didn't know. And that's what I just  
4 said. I don't know about this stuff, and so  
5 I can't make a comment about it if it's any  
6 good or not.

7 DR. JENKINS: I guess you could  
8 propose an SMR based on the other two systems.

9 DR. MAVROUDIS: So, in other words,  
10 would you like to see --

11 DR. JENKINS: Just separate it  
12 from 21 so that I'm not in a position of  
13 having to --

14 DR. MAVROUDIS: You're playing an  
15 important part here.

16 DR. JENKINS: Why don't you just  
17 make a 22 and propose an SMR using -

18 DR. MAVROUDIS: Oh, I see.

19 DR. JENKINS: -- just the two that  
20 you are involved with so that I can keep my  
21 paper trail for validity of the one that was  
22 derived differently than the others and have,

1 in my mind, more of a history. Just propose  
2 an SMR and I won't object to that.

3 DR. MAVROUDIS: But you see, the  
4 problem with that is, is that then if you have  
5 one Metric 21 and Metric 22, if you don't use  
6 Metric 21 and you use Metric 22, you get  
7 dinged.

8 DR. JENKINS: I don't know where  
9 we're getting dinged in the story.

10 My understanding is at the end of  
11 the day centers will choose I'm going to do 2,  
12 4 and 7. I'm not going to do 1, because I  
13 decided I don't --

14 DR. MAVROUDIS: Oh, is that how it  
15 is?

16 MS. HINES: It won't be a whole set  
17 necessarily.

18 DR. JENKINS: There's no dinging.

19 DR. MAVROUDIS: Oh.

20 DR. JENKINS: There's no dinging.

21 DR. J. JACOBS: Well, there is when  
22 Blue Cross and Blue Shield chooses one.

1 DR. JENKINS: That's different.

2 DR. J. JACOBS: There is a major  
3 difference.

4 DR. JENKINS: But they're going to  
5 choose for a reason and that's a long  
6 conversation with them. Actually, the Tufts  
7 health plan is a very long conversation with  
8 them.

9 DR. MAVROUDIS: Well, you know --

10 DR. JENKINS: This is what we do.  
11 We argue over --

12 DR. MAVROUDIS: If Blue Cross/Blue  
13 Shield comes in and picks 21 and other people  
14 are doing 22, that's going to be a big pain in  
15 the neck to try to get to all the stuff --

16 DR. JENKINS: If they're working  
17 in a system where their Blue Cross and Blue  
18 Shield for whatever reason chooses 21, they're  
19 probably going to end up choosing 21.

20 DR. J. JACOBS: Of course. So,  
21 then we're going to have the decision on which  
22 complexity stratification tool to be used made



1 by the insurance companies.

2 DR. JENKINS: But you'll have given  
3 them a laundry list of ones that are approved  
4 by NQF.

5 DR. J. JACOBS: But not the ones  
6 that should be making that decision.

7 DR. JENKINS: They do. So anyway,  
8 that's my suggestion, Gus. Make your proposal  
9 to --

10 DR. MAVROUDIS: Oh, I don't --

11 DR. JENKINS: -- for the other  
12 two.

13 DR. MAVROUDIS: I could make --

14 DR. J. JACOBS: So, modifying  
15 yours is a non-option?

16 DR. JENKINS: You're putting us in  
17 a hard situation.

18 DR. J. JACOBS: I'm just asking  
19 would you consider modifying yours to consider  
20 all three?

21 DR. JENKINS: No. I'm agnostic on  
22 that because I have never seen evidence of how

1 it works. That's all I'm saying.

2 MS. HINES: The other thing is you  
3 guys want to take this offline. I mean we're  
4 not held to a hard fast end point. And  
5 instead of somebody having to make a decision,  
6 you could table.

7 DR. HINKLE: Well, let me ask --  
8 tomorrow morning we're going to meet again.

9 MS. HINES: Right, but Kathy is  
10 only here today.

11 DR. JENKINS: That's all right.

12 DR. HINKLE: But my suggestion is  
13 whether we should sleep on this. And we all  
14 know, we've beat it up enough and what I'm  
15 struggling with, just to put it on the table,  
16 is 18 we decided that we would pick -- allow  
17 all three.

18 DR. MAVROUDIS: We would accept 18  
19 as is.

20 DR. HINKLE: Yes, accept it as is.

21 Now, when we get to 21 I'm looking  
22 at all of the statistical data. It looks

1 pretty darn good.

2           And the whole idea -- I think  
3 you'll always criticize the claims database,  
4 but the fact of the matter is it's getting  
5 better and better and better every year. We  
6 use it tremendously in healthcare already with  
7 the 42 HEDIS. We are using it quite  
8 extensively.

9           And I know it has holes in it, but  
10 it's much better than most physicians give it  
11 credit for. And it's going to get -- it gets  
12 better and better over time and it's a way to  
13 move the country forward on some of these  
14 things.

15           So, I'm stuck because I see both  
16 sides of it here and I'm trying to wrestle  
17 with that and saying okay, you know. So, it's  
18 tough to come to a clean conclusion on this  
19 one, I think.

20           DR. MAYER: I don't disagree with  
21 most of what you said. I think the problem is  
22 we probably will have an answer to this

1 question in two years when this comes around  
2 again. And we will know whether or not -- I  
3 mean there as I mentioned before, I think  
4 there is a study that's actually either being  
5 contemplated or has already been proposed and  
6 funded to compare the two datasets. I mean  
7 that would help us understand that.

8           There will be the ability to do --  
9 take the same standardized mortality ratio  
10 approach that has been taken in RACHS with  
11 other complexity or risk stratification  
12 mechanisms.

13           The concern I guess that I have is  
14 that I'm a little worried that we're going to  
15 get into a rush to judgment here which I don't  
16 think is wise.

17           I think we ought to be basing this  
18 as much as we can going forward, on data.  
19 Right? I mean that's something we can all  
20 salute.

21           And I think the notion that we are  
22 going to be picking winners and losers here is

1 one that I think we've all agreed is probably  
2 not wise. Right?

3           So, now the question is how do we  
4 try as best we can to keep this process from  
5 preventing the real process which is important  
6 to all of us, which is the acquisition of data  
7 and the comparison of things when we have the  
8 ability to do it. And then picking the best  
9 or maybe the newest one that evolves as some  
10 merger of these things, then that becomes the  
11 sort of gold standard.

12           I'm not sure we want to be in the  
13 gold standard picking business right now. And  
14 so I'm -- I mean we've got a -- I think what  
15 we have to be careful of is we're not going to  
16 do Heisenberg Uncertainty Principle here.  
17 We're going to screw this up by trying to get  
18 too close.

19           So, I understand your -- I mean  
20 some of us have sort of been more or less  
21 tightly involved in this. Obviously we've got  
22 two people or three people around here who

1 thought a lot about it. I thought a little  
2 bit about it.

3           So, let's think about this maybe  
4 from a tactical rather than picking losers and  
5 winners. I mean how can we do this through  
6 the NQF process that accomplishes both of  
7 those goals? That it doesn't preclude us  
8 getting to the point where we can continue to  
9 evolve and determine with more data, what  
10 works well, what doesn't work well?

11           How can we do that within this  
12 context, but still allow us to get to that end  
13 goal. Which I suspect we probably haven't  
14 seen the ideal end goal yet, to be honest with  
15 you.

16           DR. MAVROUDIS: So in terms of  
17 process, what do we do with this proposal?

18           Do we approve it, disapprove it or  
19 table it?

20           CO-CHAIR JEFFRIES: So, can we  
21 propose a Measure 22?

22           MS. HINES: I'm sorry?

1 CO-CHAIR JEFFRIES: Can we propose  
2 Measure 22?

3 DR. MAVROUDIS: We can propose  
4 Measure 22 if there's someone to propose a  
5 Measure 22.

6 CO-CHAIR JEFFRIES: Can we ask Jeff  
7 to --

8 MS. HINES: Jeff is right there. I  
9 mean --

10 DR. J. JACOBS: I'm not going to  
11 propose it where there are two separate  
12 measures. I don't think that that's right.

13 DR. JENKINS: Why does it matter if  
14 it's like 21A or 21B?

15 So, the only way we can do this is  
16 if I propose it? Is that what you're saying?

17 DR. J. JACOBS: No. I think it  
18 would be easy if you would agree to modify  
19 yours so that it would work for all three  
20 systems.

21 I'm not going to create a system  
22 where we have two different metrics that --

1 DR. JENKINS: I don't know how to  
2 fill out the answers to these questions for  
3 that model.

4 MS. HINES: I think we need to --  
5 you kind of -- it's kind of, I'm going to say  
6 strawman it, but we're not really voting,  
7 voting here.

8 This needs to go back to the  
9 broader Steering Committee, I think for  
10 everybody's -- because it's just going to go -  
11 - and, really, all of the discussions, you're  
12 kind of making preliminary suggestions that  
13 are all going to be discussed at the broader  
14 steering committee, but there is diversity and  
15 there are some different votes and stuff like  
16 that.

17 I don't know that we're going to  
18 get any further than this right now with the  
19 workgroup. You've got two more measures to  
20 go.

21 CO-CHAIR JEFFRIES: Okay.

22 DR. MAVROUDIS: I want to make sure



1 that you get -- you have your say in this at  
2 least from my point of view.

3 What do you think about tabling it  
4 and then talking about it some more? What do  
5 you think about that?

6 DR. JENKINS: You mean for right  
7 now?

8 DR. MAVROUDIS: Yes.

9 DR. JENKINS: I'm not sure I  
10 understand the NQF process enough to know what  
11 that means. I mean I think I've been clear  
12 I'm more than happy to amend my proposal with  
13 the other measures. I just -- I'm agnostic.  
14 I'm agnostic on its properties or its value  
15 because I just haven't seen it.

16 And just modifying my measure, I  
17 think, reduces the validity of my measure,  
18 quite frankly.

19 MS. HINES: So, that kind of take  
20 tabling off because I just didn't want you to  
21 feel pressure that you had to do something,  
22 make a modification without looking at other

1 data.

2 But if you want yours to stand as  
3 is, then that --

4 DR. MAYER: Well, Kathy, can I  
5 understand why would that undercut or diminish  
6 the validity of what this measure is  
7 proposing?

8 DR. JENKINS: Because I think that  
9 when this goes to the science committee,  
10 they're going to ask questions about  
11 reliability and validity and tests, re-tests  
12 and use and variations, and that's going to be  
13 the basis of the final approval decision and  
14 I have a paper trail of using this one.

15 I mean I know I can show you this  
16 variation, I can show you how it's used, I can  
17 tell you the area under the ROC curve, I can  
18 show you -- use it in admin data and non-admin  
19 data. I can do all that so it's like a full  
20 proposal.

21 So, that's why I am proposing it.  
22 I can do that. And I realize that some of the

1 measures you guys are proposing are much less  
2 well-developed than that. Some of them you  
3 don't even know what the deal looks like and  
4 you're putting them through this process.

5           So, maybe we can do 21b, and 21b  
6 will require further evaluation over a 24-  
7 month period or something. Maybe that's true.

8           But you need to put the Aristotle  
9 categories and add the mixed variable and see  
10 what the area of the ROC curve is, then put  
11 the next variable and put the next one and  
12 make your decisions that make your final model  
13 and then it would probably look great. It's  
14 just that you haven't done it.

15           So, if you need me to agree to  
16 something, I'm willing to agree in spirit, but  
17 both models should be built and looked at and  
18 might be equally valid.

19           That would be more -- I'm more  
20 than happy to do that, if that helps.

21           DR. J. JACOBS: Well, I cannot  
22 propose a measure.

1 MS. HINES: I don't mean to be  
2 rude, but the workgroup -- I've got to  
3 distinguish who has a vote and you're here as  
4 a developer, so the discussion has to kind of  
5 stay at the table. I don't want it going  
6 back.

7 DR. MAVROUDIS: Yes, but we do want  
8 to hear what they have to say because they  
9 know more about it than we do. I mean they  
10 are the experts in this and we are responding  
11 to their understanding of what the two  
12 processes are.

13 DR. J. JACOBS: I wasn't critical  
14 of a lot of input we had from them on the  
15 other 19 metrics we discussed, and I welcomed  
16 it and --

17 MS. HINES: No, no, no, no, but I  
18 just --

19 DR. JENKINS: That's true.

20 MS. HINES: But I'm just making --

21 DR. J. JACOBS: I think it would be  
22 sub-optimal if we would have -- first of all,

1 I understand why Kathy doesn't want to  
2 incorporate this into her proposal because she  
3 has the data on the RACHS system and she can  
4 write a very strong proposal based on that  
5 system only. So, I understand why she would  
6 not want to incorporate the other systems into  
7 her proposal, and I think that's reasonable.

8 I would not want to put forth a  
9 proposal that is another metric so that  
10 anybody who then chooses to use these metrics  
11 could be in a position where they could choose  
12 using one or using the other for an insurance  
13 company or a governmental agency or anybody  
14 because I think that that's problematic.

15 We all acknowledge that each  
16 system has its strengths and weaknesses within  
17 the system. Kathy is right that she's going  
18 to have more years of data on this particular  
19 application of RACHS than we will have on  
20 Aristotle, because RACHS is older and been  
21 around longer.

22 That also means, though, that

1 because of those more years of data we would  
2 favor implementing a system that allows for  
3 coding of 84 percent of the operations instead  
4 of 96 percent of the operations. So, we would  
5 miss four times higher the number of  
6 operations and I find that problematic.

7 I also find it problematic that by  
8 putting two competing measures, that means  
9 that anybody, another group other than the  
10 group that's here, would be the one that would  
11 decide which measure should be used when they  
12 don't have the knowledge base about those  
13 measures that we do.

14 So, I certainly wouldn't propose a  
15 competing measure to Kathy.

16 MS. HINES: It happens all the time  
17 with NQF and AMA and, I mean that's not our --  
18 while we're concerned with harmonization, that  
19 -- we can't control for that.

20 And I hear what you're saying and  
21 I think it makes sense to try to make a  
22 judgment here and choose one, but if the

1 measure stands --

2 DR. MAYER: If you just look at  
3 this, the C statistic number that it seems  
4 like we're working around is .8, right?

5 I mean the data that Kathy has is  
6 .8, the data from the latest thing when STS  
7 and EACTS data were merged together and stuff,  
8 the C statistic is still the same. It's in  
9 exactly the same range.

10 I mean I'm just concerned about --  
11 but I can't think of a way out of this little  
12 box here that we're in. And I'm a little  
13 concerned fundamentally about this picking one  
14 business because I don't think we're there.

15 The science isn't there, the  
16 information isn't there.

17 DR. JENKINS: I'm not  
18 understanding why if you accepted this measure  
19 as a valid measure, it's picking one.

20 DR. MAYER: Well, I'm picking up  
21 on what you said when you used the word,  
22 "picking one." So, that's what I'm trying to

1 figure out is how we're --

2 DR. HINKLE: I mean I think that  
3 what he's --

4 DR. MAYER: I think Allen raised  
5 the same question.

6 DR. HINKLE: I think what he's  
7 raising is there's no question in the -- you  
8 mentioned you want to the insurance companies  
9 picking these things for us.

10 And so I think if I read into you,  
11 one of your fears is that if a singular  
12 measure gets out in methodology like this, it  
13 could be. Because NQF measures do find their  
14 way into pay for performance programs.

15 DR. MAYER: And then reimbursement  
16 is going to be tied to it.

17 DR. HINKLE: And the problem with  
18 that is now in that previous one in 18, we say  
19 you can pick all three methods. And there are  
20 hospitals which I don't understand which I'm  
21 still missing -- I mean I wish I knew which  
22 was the superior methodology because this



1 would make this much easier, but no one knows.

2           So, it seems like what you're  
3 saying is that the hospital might be using  
4 Aristotle, then using this methodology for  
5 this calculation would be problematic to that  
6 hospital, for instance.

7           Have I got that right?

8           DR. J. JACOBS: You got that  
9 right. And then if all of a sudden the  
10 insurance company says they have to do it,  
11 that means that there's -- now reimbursement  
12 is tied to which complexity stratification  
13 tool you use.

14           DR. JENKINS: Jeff, just explain  
15 to me why if it's 21 or 22 you call that  
16 different. That's all I --

17           DR. J. JACOBS: Because we've been  
18 very careful within all 20 methods that we  
19 proposed to treat all of these systems as  
20 complete equals so that anyone could choose  
21 which one they use for their own purposes.

22           And to propose two competing

1 measures where then you could choose to use  
2 RACHS or choose to use Aristotle as competing  
3 measures --

4 DR. JENKINS: But I don't  
5 understand how that's different than 18 where  
6 it was all in one. I really don't understand.

7 So if you could explain to me why  
8 just having to do that --

9 DR. MAVROUDIS: Because in 18, you  
10 have the choice of all three. And if you pick  
11 21, you don't, and if you pick 22, you don't.

12 DR. J. JACOBS: Right. If you  
13 comply with metric number 18 --

14 DR. JENKINS: I really don't get  
15 it. My center might choose RACHS, and yours  
16 might choose Aristotle --

17 DR. HINKLE: It leaves it up to --

18 DR. J. JACOBS: You're going to  
19 meet the requirements of Metric 18 by choosing  
20 any of them.

21 CO-CHAIR JEFFRIES: I think we  
22 need to move on because I don't think we're

1 going to get anymore closer than --

2 DR. JENKINS: If I could  
3 understand the interest of this I might be  
4 able to agree to what they're proposing.

5 CO-CHAIR JEFFRIES: So, can I ask  
6 --

7 DR. JENKINS: I just really don't  
8 understand.

9 CO-CHAIR JEFFRIES: Can I ask you  
10 and Jeff to talk? Why don't you guys get  
11 together and talk so that way we can finish up  
12 the last two measures.

13 DR. J. JACOBS: So, we're going to  
14 table it and do the last two measures and then  
15 --

16 CO-CHAIR JEFFRIES: Well, I think  
17 we're going to bring it up to the larger  
18 group. I think that's the next step with it.

19 So, Number 19.

20 DR. HINKLE: Okay. 19, that's me.  
21 I think we've covered in so many other  
22 measures, we've covered a lot of this one. I

1 think it will be straightforward.

2 DR. J. JACOBS: This one builds on  
3 everything.

4 DR. HINKLE: It builds on  
5 everything that we've had. So, let me remind  
6 everybody what it is. I'll find the right  
7 page here.

8 Okay. The title of this measure  
9 is Operative Mortality for Six Benchmark  
10 Operations.

11 DR. MAYER: Where are we now?

12 DR. HINKLE: Number 19.

13 DR. MAYER: Okay. Sorry. Just  
14 trying to catch up.

15 DR. HINKLE: Okay. So, the  
16 description of the measure is operative  
17 mortality for six benchmark pediatric and  
18 congenital heart surgery operations.

19 The denominator is the number of  
20 index cardiac operations to each of the six  
21 procedures. And they are as follows: Number  
22 1, VSD repair; 2, tetralogy of fallot repair

1 excluding TOF with pulmonary atresia, TOF with  
2 atrial ventricular septal defect and TOF with  
3 absent pulmonary valve syndrome, 3, AV septal  
4 defect repair excluding TOF with AVSD, 4,  
5 arterial switch operation excluding arterial  
6 switch with VSD closure and/or aortic arch  
7 repair, 5, primary or completion Fontan  
8 operation excluding Fontan revision or  
9 conversion, i.e., redo Fontan; and 6, Norwood  
10 Stage 1 uni-ventricular operation.

11           And the numerator, obviously, is  
12 deaths from those procedures. Let's see.  
13 Comments along -- so, I think first of all  
14 there's no question of the importance of this  
15 measure. It has high impact.

16           These are, you know, obviously  
17 it's a high resource intensify need in  
18 hospitals to conduct these surgical  
19 procedures.

20           Parents who go through this  
21 operation have a high need to know going into  
22 it, what the expected mortality may be.

1                   And the opportunity for  
2   improvement my read on what the literature  
3   that we had is that even though the overall  
4   mortality for congenital heart disease is  
5   going down, it's something like four percent  
6   or something -- going down, that that's not a  
7   good enough measure now and there's a need for  
8   more granularity with regards to both  
9   morbidity, but then mortality by procedure  
10  types and trying to get at that is the way --  
11  one of the attempts here.

12                   So, let me see if I've got some  
13  notes here. I'm going to walk through this  
14  pretty quickly, but I'm going to try to  
15  hesitate on the places that I had questions.

16                   One of my questions was around --  
17  let me just put this one on the table first.  
18  I've struggled with these because of the size  
19  issue.

20                   So, I'm thinking of it from the  
21  standpoint of going back to the public looking  
22  at mortality rates when there's ten cases.

1           So, I went through the math and  
2 John helped correct me with it. Okay. One in  
3 125 live births have congenital heart disease,  
4 right? That's the statistic. About 4 million  
5 births in the United States a year. 32,000  
6 cases a year in the United States.

7           And then John tells me only half  
8 of those go to surgery, roughly, because I  
9 guess the PDAs or ASDs that close or whatever  
10 --

11           DR. MAYER: Yes. I mean it's  
12 probably the most common thing they close is  
13 these --

14           DR. J. JACOBS: All those numbers  
15 are pretty reasonable so far.

16           DR. HINKLE: So, then you go down  
17 to -- so, you got 122 centers. So, I divided  
18 that and they said okay, I'm still using the  
19 32,000 figure. 262 per year at each center  
20 with under 22 centers.

21           And then I divided that by six  
22 figuring we got these six procedures and we

1 come up with 43 at each hospital at each year.  
2 And then I have to cut that somewhere in half,  
3 I guess, because only half the kids -- so,  
4 we're talking about potentially small volumes,  
5 but I know that the network is skewed towards  
6 high-volume centers, right?

7 So, what I was struggling with is  
8 the denominator for mortality around a  
9 Norwood, for instance.

10 DR. J. JACOBS: That's a good  
11 question.

12 DR. HINKLE: So, you're going to  
13 have one death out of 10 or even one out of  
14 20. You got the overall mortality of four  
15 percent, and now you've got that hospital --  
16 my only question was the usability I guess of  
17 this because the public kind of --

18 DR. J. JACOBS: We said this  
19 should be recorded in one and four-year  
20 intervals. And if it's reported in a four-  
21 year rolling time window --

22 DR. MAVROUDIS: Okay. You know



1 Marc De Laval wrote a paper out about this.

2 DR. J. JACOBS: Yes.

3 DR. HINKLE: So, you thought  
4 through those.

5 DR. J. JACOBS: And you're  
6 absolutely right. It won't work if you do  
7 this just for one year.

8 DR. MAVROUDIS: No.

9 DR. J. JACOBS: But if you do it  
10 in a four-year rolling window, it will work.  
11 And we chose lesions that were not of  
12 sufficient volumes and most program are a  
13 four-year window to do a reasonable analysis.

14 DR. HINKLE: Okay.

15 DR. MAVROUDIS: I just want to --  
16 may I interrupt you for a moment?

17 DR. HINKLE: I think you're my  
18 secondary, aren't you?

19 DR. MAVROUDIS: Well, I think the  
20 issue here is, Jeff, do you want to include in  
21 the exclusionary TOFs you have to  
22 appropriately, I think, put down pulmonary

1 atresia, AV canal and absent pulmonary valve.

2 Do you want to put anomalous  
3 coronary thrust through right ventricle  
4 output?

5 DR. J. JACOBS: That's just part  
6 of the deal. If you get in there, you have  
7 got to fix it.

8 DR. MAVROUDIS: So, you tell me if  
9 you take a hundred cases, if you take a  
10 hundred cases with an anomalous coronary  
11 artery and cross the right ventricle output,  
12 and a hundred cases without both tests, you  
13 think the results are going to be the same?

14 DR. MAYER: Short term.

15 DR. MAVROUDIS: They won't be the  
16 same. But if you guys vote that way, that's  
17 fine with me.

18 DR. J. JACOBS: I think you should  
19 be able to --

20 DR. MAVROUDIS: They're not going  
21 to be the same. You're going to have a  
22 complication like coronary arteries, if you do

1 a hundred of them, you're going to have a  
2 complication. But anyway --

3 DR. J. JACOBS: Well, isn't there  
4 all these strategies that you can implement to  
5 avoid that like RV to PA conduit and all that  
6 stuff.

7 DR. MAVROUDIS: Sure. But what's  
8 going to happen is that you're going to be in  
9 the middle of it. You already have injured  
10 the right coronary artery.

11 DR. J. JACOBS: Well, that's what  
12 we want to find out.

13 DR. MAVROUDIS: That's fine.  
14 Okay.

15 DR. HINKLE: So, you're okay with  
16 --

17 DR. MAVROUDIS: I'm okay with this  
18 especially when I have these overwhelming --

19 DR. HINKLE: So, my other question  
20 was around the unit of measurement. I know  
21 that most of these were measuring -- were  
22 looking at the group level. So, I assume that

1 the group is pediatric cardiac surgeons at  
2 practice.

3 I mean there's no question if  
4 you're -- I mean I think the numbers -- I  
5 think I've answered my own question. You  
6 can't do it at the individual clinician level.

7 DR. J. JACOBS: None of these are  
8 proposed to be done at the individual  
9 clinician level at this point. These are team  
10 measures.

11 DR. HINKLE: So, I was wondering  
12 about this comment. I think this is something  
13 you submitted, you guys submitted here,  
14 summary of evidence around does the measure  
15 have a high impact aspect on healthcare.

16 And there was something in here  
17 that said the six benchmark operations  
18 identified in this measure are among the most  
19 common procedures performed by pediatric and  
20 congenital heart surgeons spanning a spectrum  
21 from simple to complex outcomes. The easiest  
22 operations have often been used as benchmarks

1 for surgeon and programmatic performance.

2 I think to make sure I understand,  
3 what you're saying is you use it to improve  
4 the individual surgeon.

5 DR. J. JACOBS: No.

6 DR. HINKLE: What is meant by  
7 that?

8 DR. J. JACOBS: What that has  
9 meant was that there's previous publications  
10 that have used these lesions to benchmark both  
11 surgeon and programmatic performance.

12 Our proposal here is just on uses  
13 to benchmark programmatic performance because  
14 we believe that this is a team sport and that  
15 you don't tie it down to an individual  
16 clinician, but to the whole team.

17 CO-CHAIR JEFFRIES: Some of these  
18 were part of the US News and World report when  
19 they were looking across centers and they  
20 wanted to know mortality from TETs.

21 DR. HINKLE: Yes.

22 DR. J. JACOBS: And beyond that

1 there's peer review papers by some pretty good  
2 surgeons like Stark and De Laval that did  
3 that.

4 So, the did this on individual  
5 surgeons, and we were just referencing that,  
6 but we're not advocating doing that ourselves.

7 DR. HINKLE: Okay. That was just  
8 for clarification.

9 DR. J. JACOBS: It's a good point  
10 though.

11 CO-CHAIR JEFFRIES: I had a  
12 question.

13 The CPT codes that you have listed  
14 in this, do those have the exclusions built  
15 within them, or does somebody have to then go  
16 and figure out that separately?

17 DR. J. JACOBS: CPT codes are not  
18 granular enough to do that.

19 CO-CHAIR JEFFRIES: So, they're  
20 just going to say tetralogy repair?

21 DR. MAYER: No. There are three  
22 different -- sorry. I happen to know this.

1 DR. J. JACOBS: Right. From a  
2 tetralogy standpoint, John is absolutely  
3 right. But for the other examples, that's  
4 where --

5 DR. MAYER: But for instance,  
6 tetralogy with AV canal you can't report with  
7 a single CPT code. You have to report two.  
8 Tetralogy with absent pulmonary valve you  
9 would essentially never report as a single  
10 code because you'd miss all the pulmonary  
11 artery reconstruction work.

12 So, I think that the, you know, I  
13 mean the point is we can distinguish these  
14 things in the database.

15 DR. J. JACOBS: Right. But we  
16 can't with CPT codes always.

17 DR. MAYER: Right.

18 DR. J. JACOBS: Some of them we  
19 can with CPT codes, but certainly not all of  
20 them.

21 DR. MAYER: You can distinguish  
22 between a -- I mean the way the CPT goes is

1 there's non-transannular patch, transannular  
2 patch and RV to PA conduit. Those are the  
3 three CPT codes -- individual codes.

4 And then if you had tetralogy with  
5 AV canal, then you'd have to add a secondary  
6 code with a 51 modifier. That's --

7 CO-CHAIR JEFFRIES: Do, if you're  
8 not doing STS, you have to do is measure this  
9 from the data.

10 DR. MAYER: You're right about  
11 that.

12 DR. J. JACOBS: I mean you can  
13 track what type of tetralogy repair you did  
14 with any database in the world. And with any  
15 database in the world, the CPT codes will not  
16 be granule enough to tell you that all.

17 So, it's absolutely not STS  
18 database dependant. Any clinical database can  
19 do it. It's just that most administrative  
20 databases won't allow this level of  
21 differentiation.

22 CO-CHAIR JEFFRIES: Okay.



1 DR. HINKLE: I think this one is  
2 straightforward, the rest of it. I mean I  
3 have no other questions or comments about the  
4 rest. It seems fairly --

5 CO-CHAIR JEFFRIES: What's your  
6 sense of relative importance of this measure  
7 versus the --

8 DR. J. JACOBS: The RACHS and  
9 Aristotle?

10 CO-CHAIR JEFFRIES: Versus 18.

11 DR. J. JACOBS: So, when we had  
12 our phone conference of the group of people  
13 that developed these, there was a feeling that  
14 a substantially important denominator,  
15 increased information could be gained by  
16 looking at the benchmark operations and not  
17 just using complexity stratification.

18 And to support that, they  
19 referenced papers by De Laval and Stark who  
20 have used that approach and presented that at  
21 the STS and the AATS as a good approach for  
22 benchmarking programs.

1                   It's used by the United Kingdom  
2 Central Cardiac Audit Database and it's been  
3 published in other papers.

4                   So, our group felt that it added  
5 additional information above and beyond the  
6 information we would get from complexity  
7 stratification alone because these are common  
8 operations, they're benchmark operations.

9                   CO-CHAIR JEFFRIES: I mean I think  
10 from a family point of view --

11                  DR. J. JACOBS: Yes, my kid's got  
12 a TET.

13                  CO-CHAIR JEFFRIES: -- this is  
14 what they're going to want to see.

15                  DR. J. JACOBS: Yes. They're  
16 going to know my kid's got a tet, not my kid's  
17 got a RACHS-1.

18                  CO-CHAIR JEFFRIES: Exactly.  
19 These are the most common things.

20                  DR. J. JACOBS: So, I think it  
21 adds -- it just adds more information and it  
22 adds information in a more digestible format

1 toward families who happen to have a kid with  
2 one of these six problems.

3 DR. HINKLE: I only have one other  
4 question. It's a crazy question, probably  
5 going to be. Maybe I've thought too much  
6 about this.

7 But when you get into the 30-day  
8 death, it says prior to hospital discharge or  
9 within 30 days of the date of surgery.

10 DR. J. JACOBS: Yes.

11 DR. HINKLE: Do any of these  
12 procedures, will they get out before 30 days?  
13 Is it possible?

14 DR. J. JACOBS: Yes, a lot of  
15 them. Most of them.

16 DR. HINKLE: Right. That's what I  
17 thought. So, they get out and they get hit by  
18 a car.

19 DR. J. JACOBS: Great question.

20 DR. HINKLE: Or they go back into  
21 the hospital because they have appendicitis,  
22 and they die during surgery.

1 DR. MAVROUDIS: So, it's an  
2 operative mortality.

3 DR. HINKLE: Yes. Okay.

4 DR. MAYER: This has been dealt  
5 with.

6 DR. MAVROUDIS: It's operative  
7 mortality.

8 DR. HINKLE: Okay. That's enough  
9 said.

10 DR. J. JACOBS: That's what this  
11 paper talks about.

12 DR. MAVROUDIS: You get shot by  
13 the Taliban. Operative mortality.

14 DR. HINKLE: Thought it was a  
15 crazy thought, but --

16 DR. J. JACOBS: Well, there's less  
17 likelihood of having that happen than there is  
18 having gaming the system that gets it or not  
19 related to the heart or excluded.

20 DR. HINKLE: That's what I figured.  
21 Okay.

22 So, my recommendation is for this

1 to be accepted and proceed.

2 DR. MAVROUDIS: I make a motion  
3 that we accept the measure is that what you're  
4 asking?

5 DR. HINKLE: Yes. I can't make  
6 the motion. I put it on the table.

7 DR. MAVROUDIS: I move that we  
8 accept it.

9 DR. LOPEZ: I'll second.

10 CO-CHAIR JEFFRIES: We're going to  
11 skip 20 in this group.

12 DR. MAVROUDIS: Let's go back to  
13 21.

14 (Laughter.)

15 CO-CHAIR JEFFRIES: John, we'll  
16 have you do 20.

17 DR. MAYER: In the big group?

18 CO-CHAIR JEFFRIES: In the  
19 meeting.

20 DR. MAYER: All right.

21 CO-CHAIR JEFFRIES: Okay.

22 DR. MAYER: Yes, that's fine.

1 CO-CHAIR JEFFRIES: I mean I think  
2 it's sort of a good mix. I think you know  
3 what's discussed.

4 DR. J. JACOBS: Yes, there's  
5 nothing new there. That's just taking pieces  
6 of all the previous ones and gluing them  
7 together as something new.

8 DR. MAYER: Do I understand  
9 correctly that mortality is not in 20?

10 CO-CHAIR JEFFRIES: That's a good  
11 question.

12 DR. J. JACOBS: Right.

13 DR. MAYER: It's everything but.

14 DR. J. JACOBS: Correct.

15 DR. MAYER: Or not everything but,  
16 but it's the defined complications? Is it?  
17 I mean I wasn't clear when I read it, and I  
18 may have been a little foggy on it.

19 DR. J. JACOBS: The intent was  
20 that you take -- I think the denominator is  
21 probably written wrong. It's supposed to be  
22 a percentage of your survivors that are free

1 of these complications.

2 DR. MAYER: Okay.

3 DR. J. JACOBS: So, the title says  
4 that operative survival free of major  
5 complications, but I think that the  
6 denominator may actually say all pediatric and  
7 congenital heart surgery, but it should say  
8 all surviving pediatric and congenital heart  
9 surgery, and then it will work.

10 So, that's a technical flaw in the  
11 proposal as written that needs to be  
12 corrected.

13 DR. MAYER: All right. That was --

14 DR. J. JACOBS: Good pickup.

15 DR. MAYER: -- a source of a  
16 little confusion.

17 DR. J. JACOBS: So, you're not  
18 just typing, are you?

19 Sorry. I couldn't resist that.

20 DR. MAYER: Not just another  
21 pretty face, right?

22 DR. J. JACOBS: That's what I

1 started to say, and then I said I better not  
2 say that.

3 (The above-entitled matter went  
4 off the record at 3:29 p.m.)

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<b>A</b>				
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