

THE NATIONAL QUALITY FORUM

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PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR  
PEDIATRIC CARDIAC SURGERY

OPEN SESSION

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WEDNESDAY  
OCTOBER 21, 2009

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The Pediatric Cardiac Surgery Steering Committee met in Congressional A in the Hyatt Regency Washington Hotel, 400 New Jersey Avenue, N.W., Washington, D.C., at 9:30 a.m., Howard Jeffries and Lisa Kohr, Co-Chairs, presiding.

STEERING COMMITTEE MEMBERS PRESENT:

HOWARD JEFFRIES, MD, MPH, MBA, Co-Chair  
LISA M. KOHR, MS, MPH, RN, CPNP, Co-Chair  
SCHONAY BARNETT-JONES, MBA  
PATRICIA A. GALVIN, RN, BSN, CNOR  
NANCY GHANAYEM, MD

DARRYL GRAY, MD, ScD  
ALLEN J. HINKLE, MD  
MARK HOYER, MD  
SYLVIA LOPEZ, MD  
CONSTANTINE MAVROUDIS, MD  
JOHN E. MAYER, MD  
LISA NUGENT, MFA

NQF STAFF PRESENT:

HELEN BURSTIN

SARAH FANTA

TINA GRANNIS

LISA HINES

CHRISTINA TSIATIS

ASHLIE WILBON

ALSO PRESENT:

DR. KATHY JENKINS

DR. KIMBERLEE GAUVREAU

DR. MARSHALL JACOBS

DR. JEFFREY JACOBS

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Adjourn

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

2 10:04 a.m.

3 CO-CHAIR KOHR: At this time since  
4 we're all face to face, we'll go around the  
5 room and introduce ourselves and also disclose  
6 any conflicts of interest that you have. And  
7 then we'll have the measure developers  
8 introduce themselves.

9 I'm Lisa Kohr, and I'm a nurse  
10 practitioner currently working at Children's  
11 Hospital of Philadelphia. And I don't have  
12 anything to disclose.

13 CO-CHAIR JEFFRIES: My name is  
14 Howard Jeffries. I'm a pediatric cardiac  
15 intensivist at Seattle Children's Hospital.  
16 And I don't have anything to disclose.

17 DR. MAYER: I'm John Mayer. I'm a  
18 pediatric cardiac surgeon at the Children's  
19 Hospital in Boston. I suppose I have a few  
20 things to disclose.

21 One of which is that I'm a past  
22 president of the Society of Thoracic Surgeons.

1 I was actually part of the original group that  
2 came down to Washington to meet with Ken  
3 Kaiser in those days. And we were one of the  
4 first professional organizations to put a set  
5 of measures through the NQF process for adult  
6 cardiac surgery.

7 I also was part of the group that  
8 you'll hear about later that was involved in  
9 developing the first risk adjustment for  
10 congenital heart surgeries called RACHS  
11 Scores. I was on the expert panel for that  
12 undertaking, now, at least ten or more years  
13 ago.

14 I think that's all I should need  
15 to disclose.

16 DR. BURSTIN: John, it would also  
17 just be helpful if you could emphasize that  
18 you were not involved, though, in the  
19 development of these measures beyond -

20 DR. MAYER: Right. That's correct.  
21 I was not involved in the development of this  
22 set -

1 DR. BURSTIN: Thank you. That's  
2 why you're here.

3 DR. MAYER: - of measures that's  
4 being put forward. Thank you for reminding me  
5 of that.

6 DR. GRAY: Darryl Gray. I'm a  
7 medical officer with the Center for Quality  
8 Improvement and Patient Safety at the Agency  
9 for Healthcare Research and Quality.

10 My background actually involves a  
11 doctorate in epidemiology with a project on  
12 patent ductus closure which John actually  
13 helped me with, now, almost 20 years ago.

14 And I've maintained an interest in  
15 this area of - I'm also involved at AHRQ with  
16 the Performance Management Advisory Group of  
17 the American Medical Association.

18 Which I think it's important to  
19 disclose that because PMA actually reviews  
20 measures after they've been approved by NQF or  
21 other bodies and helps, actually, formally get  
22 them into a form where they can actually be

1 implemented.

2           And that's, I think, not a  
3 conflict, but something that's important to  
4 disclose.

5           Also, I was not involved in the  
6 development of any of AHRQ's pediatric quality  
7 improvement measures. However, I was asked to  
8 review them.

9           The other thing which I should  
10 also disclose is that I started working with  
11 Jeff Jacobs and Marshall Jacobs and others  
12 developing a crosswalk between ICD-9 procedure  
13 codes and diagnosis codes and STS diagnosis  
14 and procedure codes with the goal of doing a  
15 project to actually assess the concordance  
16 between STS data and administrative data that  
17 are actually based on the ICD-9 codes.

18           DR. LOPEZ: I'm Sylvia Lopez. I'm  
19 a pediatrician. I work with the Oklahoma  
20 Healthcare Authority, which is a State  
21 Medicaid agency. I have nothing to disclose.

22           DR. HINKLE: My name is Dr. Allen

1 Hinkle. I'm a pediatrician and  
2 anesthesiologist and chief medical officer at  
3 Tufts Health Plan in Massachusetts.

4 MS. GALVIN: My name is Patty  
5 Galvin. I'm a nurse, a clinical coordinator  
6 in the cardiac operating room at Children's  
7 Hospital of Boston.

8 The only disclosure I have is that  
9 there - well, it's not a disclosure, but even  
10 though I work at Children's, the measure that  
11 was submitted by Children's I had no part of  
12 and have nothing else to disclose.

13 DR. HOYER: I am Mark Hoyer. I'm a  
14 pediatric cardiologist. I direct the cath lab  
15 at Riley Hospital for Children in  
16 Indianapolis.

17 I don't think I have any specific  
18 disclosures. I was nominated for this  
19 committee by the president of the Society for  
20 Cardiac Angiography and Intervention.

21 And obviously I work very closely  
22 with the surgeons and have an interest in the



1 way things kind of unfold because we're so  
2 closely allied with the patients that we take  
3 care of, but I don't think I have any other  
4 specific disclosures.

5 MS. BARNETT-JONES: I guess I  
6 better scoot closer here.

7 Good morning. My name is Schonay  
8 Barnett-Jones. I chair the Patient and Family  
9 Advisory Council here at Children's National  
10 Medical Center in Washington, D.C.

11 I have a five-year-old who had a  
12 heart transplant when she was 17 months. She  
13 is a thriving kindergartner today, and I'm  
14 very happy to be here.

15 I am a managing director for Visa,  
16 managing US and Canadian client testing for  
17 all end points here. Thank you.

18 DR. MAVROUDIS: Good morning. I'm  
19 Gus Mavroudis. I'm a congenital heart surgeon  
20 at the Cleveland Clinic.

21 I was involved in the inauguration  
22 of the Society of Thoracic Surgeon's

1 congenital database 21 years ago. I chaired  
2 that committee for a long time, after which it  
3 was transferred to Jeff.

4 I'm still on that committee, been  
5 involved in some of the risk stratification  
6 projects. However, I was not involved in any  
7 of these scores or these indicators that are  
8 being presented today. Thank you.

9 DR. GHANAYEM: Good morning. I am  
10 Nancy Ghanayem. I am a cardiac intensivist at  
11 the Children's Hospital of Wisconsin, Medical  
12 College of Wisconsin in Milwaukee.

13 I was nominated to this committee  
14 by NACHRI. I have participated in the multi-  
15 societal organization that has been overseen  
16 by Jeff. And I have not participated - I have  
17 not been involved with the development of  
18 these measures, however I do work with a  
19 surgeon who is on the task force.

20 MS. NUGENT: My name is Lisa Nugent  
21 and I work for Johnson & Johnson. I'm a  
22 creative director in the Global Strategic

1 Design Office and I work with the medical  
2 devices and diagnostic operating companies and  
3 franchises in that sector.

4 My focus has been on designing  
5 experiences and tools to empower patients to  
6 better manage their own care, and I have  
7 nothing to disclose. Thank you.

8 MS. TSIATIS My name is Christina  
9 Tsiatis. I'm NQF staff and I have nothing to  
10 disclose.

11 MS. FANTA: Hi, I'm Sarah Fanta,  
12 research analyst at the National Quality  
13 Forum, and I have nothing to disclose.

14 MS. GRANNIS: I'm Tina Grannis, and  
15 I'm project manager at National Quality Forum  
16 with nothing to disclose.

17 MS. WILBON: Hi. Good morning.  
18 Ashlie Wilbon, also a project manager at the  
19 National Quality Forum, and no disclosures.

20 DR. BURSTIN: Good morning. Hi.  
21 Helen Burstin, senior vice president, NQF for  
22 performance measures and nothing to disclose.

1 MS. GRANNIS: Can we just have the  
2 audience members stand up by the microphone  
3 and just introduce yourselves, please?

4 DR. GAUVREAU: I am Kim Gauvreau.  
5 I am a biostatistician at Children's Hospital  
6 in Boston, and also at the Harvard School of  
7 Public Health.

8 DR. M. JACOBS: Good morning. I'm  
9 Marshall Jacobs. I'm a congenital heart  
10 surgeon and the director of clinical research  
11 for congenital heart surgery at the Cleveland  
12 Clinic.

13 I'm a member of the Society of  
14 Thoracic Surgeon's Task Force for the national  
15 database.

16 I have been involved with  
17 evaluation of the Aristotle Complexity Score  
18 as a measure, and I have been a member of the  
19 expert panel not that created the first  
20 iteration of RACHS-1, but has worked on  
21 further development.

22 DR. J. JACOBS: Good morning. I'm

1 Jeff Jacobs. I chair the STS Congenital Heart  
2 Surgery Database Task Force, and I have all  
3 the same disclosures that Marshall just had,  
4 including the same last name.

5 (Laughter.)

6 MS. GRANNIS: Great. Thank you,  
7 everyone, and I'm going to be turning this  
8 meeting over to Ashlie Wilbon.

9 MS. WILBON: Good morning. We're  
10 just going to go over - I'm going to switch  
11 seats here to get to the computer.

12 We're just going to go over a few  
13 slides just to get everyone back in the mind-  
14 set and review the projects, our goals today,  
15 and talk a little bit about the breakout  
16 groups a little bit more and get everyone  
17 ready to start the discussion.

18 So, bear with me briefly while I  
19 relocate.

20 So, some of these slides you guys  
21 have already seen. We reviewed many of them  
22 during orientation.

1                   We just wanted to go back over the  
2 project scope and the list of measures. And  
3 we're going to have Helen go over the  
4 evaluation criteria again just in case you  
5 guys have any additional questions.

6                   Most of you have probably since  
7 reviewed the measures since orientation, so  
8 there may be some questions about the  
9 evaluation criteria that came up as you were  
10 reviewing the measures. So, we will have an  
11 opportunity to talk a little bit about that if  
12 you have any questions and before we go into  
13 the breakout groups.

14                  So, again, project staff, I think  
15 we've all introduced ourselves at this point,  
16 and Helen has given a pretty good overview  
17 already during the executive session. But in  
18 the interest of our audience members that are  
19 in attendance, I'll go ahead and kind of skim  
20 through these slides just about NQF in  
21 general.

22                  We're a 400-plus-member

1 organization organized into eight stakeholder  
2 councils including supplier industry,  
3 purchasers, consumers, health plan providers,  
4 quality measurement and research. And I'm  
5 sure I'm missing at least one, but we've been  
6 through that already.

7           The NQF structure includes a board  
8 of directors, the CSAC. Which once you  
9 recommend your measures, your recommendations  
10 then get forwarded to the CSAC and they review  
11 the measures that you've recommended and make  
12 their recommendations based on your  
13 recommendations for endorsement. And then  
14 they go on to the board of directors for a  
15 final endorsement.

16           Strategic goals, again, that  
17 standards endorsed here become the primary  
18 standards used for measuring the quality of  
19 healthcare in the United States, that we are  
20 the principal body that endorses national  
21 healthcare performance measures and quality  
22 indicators, that NQF will increase the demand

1 for high-quality healthcare and be recognized  
2 as a major driving force for facilitator of  
3 continuous quality improvement in American  
4 healthcare quality.

5           So, we went through a little bit  
6 with the diagram, I believe, that was in your  
7 packet about the consensus development process  
8 which is a process that we go through to  
9 ensure that it's transparent and open to the  
10 public, but allows experts to weigh in on  
11 standards that are submitted to the NQF for  
12 review.

13           We want to make sure that we have  
14 attention to overall strategy for measuring  
15 and reporting healthcare quality, including  
16 the establishment of national goals, that we  
17 represent on the committee that we have  
18 represented multi-stakeholder membership  
19 including, again, here at the eight councils,  
20 and that public and private sector  
21 representation are on the governing board.

22           So, here is a condensed version of



1 the CDP schema. You have a much more detailed  
2 one in your packet, I believe. And again, we  
3 are at the yellow area where the Steering  
4 Committee is reviewing. And again, once you  
5 review, they'll go to the CSAC, we'll draft  
6 your recommendations and they'll go for public  
7 comments and then on to the board.

8           So again project information, you  
9 guys are all again familiar with this. This  
10 is project focused. Our first project focus  
11 on pediatric cardiac surgery, there are the  
12 two AHRQ measures already endorsed for  
13 pediatric cardiac heart surgery, which are  
14 PDI-17 and PDI - I'm sorry - PDI-7 and PDI-6  
15 that were endorsed in May of last year. And  
16 there are also some similar adult cardiac  
17 surgery measures that are endorsed.

18           And I believe also in your  
19 materials that we had distributed to you,  
20 there's a table that lists similar measures  
21 together so you can kind of get an idea of how  
22 they're grouped. And as you're reviewing

1 those measures, you can compare in contrast  
2 based on what was submitted and what is  
3 already endorsed.

4           This project, again, was funded by  
5 the Pediatric Cardiac Surgery Coalition which  
6 is comprised of several hospitals and  
7 organizations. And we had 21 measures  
8 submitted from both STS and the Children's  
9 Hospital of Boston.

10           And again, because of the lack of  
11 field testing for these measures, you'll only  
12 be eligible to recommend them for time-limited  
13 endorsement.

14           Project goals, to review the  
15 submitted measures, recommend qualified  
16 measures for endorsement to the CSAC, and to  
17 hopefully eventually provide pediatric cardiac  
18 surgery community patients/consumers with  
19 measures for reporting.

20           Your role today is to discuss the  
21 measures and have a healthy discussion on the  
22 evaluation criteria to ultimately make

1 recommendations to NQF on how the measures  
2 should move forward.

3           Once the measures are recommended  
4 here, we put them out for public comment. And  
5 then we'll have - there will be an opportunity  
6 for the committee to respond to any comments  
7 that the public may have maybe based on the  
8 way you voted, what was not recommended, what  
9 was recommended, and based on your discussion  
10 here. So, that will be in a subsequent  
11 conference call following this meeting.

12           Also, once your recommendations  
13 are submitted to CSAC, which either Lisa  
14 and/or Lisa and Dr. Jeffries will attend to  
15 represent the discussions on behalf of the  
16 Steering Committee here, CSAC may have  
17 questions for you that they want you to  
18 respond to and so forth, which they would do  
19 on your behalf.

20           Here is the general timeline for  
21 the remainder of the project. The comment  
22 period is expected to begin November 6th.

1 Comments should end around November 30th for  
2 the public, and December 7th for the members.

3           The voting begins for members  
4 around December 18th, and it would end around  
5 January 16th. We're hoping that we'll have  
6 the measures along with the public comments  
7 and recommendations to go for the CSAC meeting  
8 that will happen in February of next year, and  
9 then on to the board of directors for their  
10 final endorsement by February/March of next  
11 year as well.

12           This is just a screen shot of the  
13 NQF website. For those of you that have not  
14 had an opportunity to look at the website, we  
15 just did a whole revamp of the website and  
16 have added some features that allow you to  
17 follow a project along the course of the  
18 consensus development process.

19           On the Project page, you'll notice  
20 we're on the Details tab of the Pediatric  
21 Cardiac Surgery Project, and each step of the  
22 process has a plus sign next to it. And you

1 can click on the plus sign and it will list  
2 any materials or documents that you can  
3 download for that step of the process and kind  
4 of give you a little bit of text around what  
5 was going on during that step of the process.

6 So, we encourage you just even  
7 beyond this meeting if you want to know the  
8 status of what's going on, we keep this site  
9 very up to date.

10 And if you feel like you've missed  
11 something from us, because everything is  
12 public, it will pretty much be on the website  
13 as well. So, we encourage you to use that as  
14 a resource.

15 So at this point, I'm going to  
16 hand it over to Helen. I'm not sure if you  
17 want to just go from there or - okay.

18 DR. BURSTIN: I believe you guys  
19 have all had the orientation session. It's  
20 just a very brief, high-level overview very  
21 quickly of our criteria. So, this is really  
22 what your evaluation is grounded and your

1 evaluation forms are grounded on the criteria  
2 and the sub-criteria.

3           So, just briefly to highlight some  
4 of the key features here, we updated  
5 evaluation criteria just about a year ago and  
6 specifically did that for several reasons.

7           One of which, we wanted to clarify  
8 what some of those terms actually meant and  
9 get more specificity.

10           And secondly, we really felt there  
11 was an opportunity to kind of raise the bar a  
12 bit, make sure we're bringing in measures that  
13 are actually achieving the goals or hoping to  
14 achieve in terms of better healthcare quality.

15           So, we specifically put a link in  
16 to the national priorities that NQF has been  
17 working with, a coalition called the National  
18 Priorities Partnership, to put forward, as  
19 well as specifically saying we wanted to get  
20 at measures in high-impact areas.

21           There was also a strong emphasis  
22 on measure harmonization. If you just look at

1 the cardiac measures alone within NQF, it is  
2 frightening how many beta blockade measures  
3 there are around cardiac surgery and  
4 cardiology.

5           There's really a need, I think, to  
6 begin thinking about how we bring those  
7 measures together especially as we start  
8 thinking about care across the full continuum  
9 from outpatient to inpatient and beyond.

10           I didn't know if we have a pre-op  
11 beta blocker or a post-op beta blocker or a  
12 beta blocker persistence measure, so really  
13 that's the idea of what we're trying to push  
14 out around harmonization.

15           A greater emphasis on outcome  
16 measures as much as possible. And process  
17 measures are great, they're very appropriate,  
18 as long as they're fairly proximate to the  
19 outcome. We don't want measures that are very  
20 distal.

21           So, for example, we had measures  
22 submitted to us that said did you consider

1 whether the patient needed a flu shot? Did  
2 the patient get a flu shot, is really  
3 ultimately what you want to know. Did you  
4 consider whether the patient needed one  
5 probably isn't proximate enough to the outcome  
6 that it's adding much to what we really want  
7 to get at.

8           So, we have specific conditions  
9 for consideration in these measures. The  
10 measure either has to be in the public domain  
11 or an intellectual property agreement or  
12 measure steward agreement if signed. This is  
13 still in process with at least on the STS  
14 side, but we have no issues, I think,  
15 proceeding.

16           We need to make sure there's a  
17 responsible entity, a measure steward, and  
18 this is really important. Because as I  
19 mentioned earlier, all of our measures require  
20 measure maintenance at least every three  
21 years.

22           We have to have a steward who



1 agrees to do the maintenance on it, keep up  
2 the evidence base, update the measure as  
3 needed.

4           We also not very often, but  
5 occasionally will do what's called ad hoc  
6 reviews. If we hear from the field that  
7 there's untoward consequences related to the  
8 use of a measure, we will feed that back to  
9 the measure developer and ask for their  
10 response in real time as well.

11           As I mentioned earlier, the intent  
12 is really ultimately that all these measures  
13 should really be used for both public  
14 reporting and quality improvement.

15           And lastly, just the fact that the  
16 measure's submission is complete. And that if  
17 it hasn't, if the measure developer can't  
18 provide evidence that the measure's been  
19 testing, it could only be put forward for what  
20 we call time-limited endorsement.

21           The measure is still endorsed  
22 fully, but there is an expectation that within

1 12 to 24 months the developer will return with  
2 our testing results.

3           Those testing results go to our  
4 CSAC for review that the measure has in fact  
5 fulfilled the testing requirements.

6           So, importance to measure and  
7 report is sort of foundational. We really  
8 consider all outcome measures essentially  
9 meeting this, so that's not a problem.

10           We want to make sure, essentially,  
11 are the resources expended to collect these  
12 data to do the measure worth it, we're getting  
13 something out of it in terms of impact.

14           And specifically here we're  
15 thinking about is it related to one of those  
16 National Priorities Partnership goals? And  
17 certainly many of these are; patient safety,  
18 care coordination. I don't think there's much  
19 of an issue for these measures today.

20           And specifically thinking about,  
21 as well, the evidence to support the measure  
22 focuses under importance.

1           This is a must-pass criteria.

2   This is a change from when we updated the  
3   criteria last year.

4           If a measure is not judged to be  
5   important, it doesn't matter if it's  
6   scientifically acceptable, usable and  
7   feasible. It's out. So, that has actually  
8   been a change in our process.

9           Scientifically acceptability of  
10   the measurement properties is obviously  
11   critical. We want to ensure that the  
12   specifications are precise, that they are  
13   reliable and valid and can discriminate  
14   between providers.

15           I mean if the ultimate goal here  
16   is public reporting and quality improvement,  
17   you want to be sure that as you aggregate  
18   these data for providers or clinicians that  
19   you're getting a reasonable estimate of their  
20   performance and can be compared to others.

21           And you want to make sure at least  
22   in the part of the work we've done, and this

1 has been an issue we've had discussing with  
2 STS over the years, our preference is not to  
3 control for issues that could be related to  
4 disparities like race, ethnicity, language,  
5 insurance status, and then set to stratify by  
6 those variables so we can actually see  
7 disparities as opposed to having them control  
8 for in a risk model.

9           And exclusions is the other big  
10 issues, next slide there. We are increasingly  
11 having trouble with measures just loaded down  
12 with exclusions.

13           This is especially important as we  
14 envision moving many of the measures to an  
15 electronic platform. The more exclusions, the  
16 more difficult it is to collect the data.

17           So, we are requiring that it's  
18 fine to have exclusions. Things that are  
19 medical contraindications or relative  
20 contraindications should absolutely be  
21 exclusions.

22           What we don't want is things that

1 are really excluded and the reality is they  
2 contribute very, very little to the overall  
3 distortion of the measure if you actually  
4 didn't have them in there. So, this is  
5 definitely a work in progress.

6           Usabilities, as I mentioned  
7 earlier, really important. We really are all  
8 about trying to make sure that people can use  
9 these data at the end of the day to make  
10 better decisions.

11           So from where a patient sits, for  
12 example, can they begin at some point to be  
13 able to go to some website and figure out  
14 who's performing well and make decisions about  
15 their care, or purchasers, for that matter, as  
16 well.

17           And obviously the use for internal  
18 quality improvement has been well demonstrated  
19 with the STS cardiac surgery data measures to  
20 date, so that's certainly not an issue.

21           Feasibility, again increasingly  
22 trying to move to measures that we can collect

1 without undue burden. Being able to go into  
2 charts to pick up these kind of measures is,  
3 I think, fallen away.

4           Increasingly we're seeing lots of  
5 measures come in, which we are delighted with,  
6 off clinically registries. I think it's the  
7 right way to go for many of our clinical  
8 specialties.

9           It just doesn't make sense that  
10 you're going to kind of do this on paper or  
11 that you're going to be able to get the  
12 clinical richness you need off administrative  
13 data. So, we fully expect a lot of these  
14 measures will come forward off of clinical  
15 registries.

16           As much as possible as time goes  
17 forward, we would also like to ensure that in  
18 our work we're doing in the health IT sphere,  
19 we work to make sure that whatever these  
20 registries are ultimately interoperable with  
21 the electronic health records where perhaps  
22 not the ones we have now, but the ones we

1 should have in the next few years where you've  
2 pulling in the key pieces of clinical data  
3 from the EHR and supplementing it with the  
4 required pieces of data through a clinical  
5 registry that you wouldn't otherwise have in  
6 your EHR, so very much we're hoping to go.

7           And we're also requiring all  
8 measure developers at this point on that path  
9 forward, to indicate which of the data  
10 elements within those measures could be  
11 captured electronically and which ones can't  
12 and what's the path going forward here.

13           A particularly exciting time. I  
14 mean there's actually a meeting next week that  
15 I'm presenting at for the Health IT Policy  
16 Committee completely focused on specialty  
17 measures and the use to clinical registries as  
18 we envision this health IT-enabled world.

19           So, quite optimistic. This is an  
20 exciting opportunity for us, but we still need  
21 to have the measures based on the registries  
22 as that starting point.

1           And I'll stop there and see if  
2 there are any questions.

3           MS. GRANNIS: We're going to ask  
4 the measure developers at this time, just if  
5 you have any general comments, if you would  
6 just step up to the microphone and you can  
7 present your comments to the Steering  
8 Committee.

9           And this would probably be an  
10 excellent opportunity maybe to explain the  
11 book, Dr. Jacobs, that you have brought along.

12           DR. BURSTIN: And also just to put  
13 this in context, it's also very helpful since  
14 we, as you heard from our introductions, we  
15 can't allow those who have been involved in  
16 the development of the measures to sit at the  
17 Steering Committee table.

18           But we've tried to build into our  
19 process the opportunity to both hear from the  
20 measure developers up front, and also as  
21 you'll see in the two workgroups, they'll be  
22 with us. I assume we'll have a Dr. Jacobs in



1 each room for the two workgroups. This is  
2 quite simple.

3 And so feel free to interact with  
4 the measure developers, get their input. We  
5 don't want to exclude them from the process,  
6 but at the same time need to be able to ensure  
7 we don't have conflicts at the table.

8 I'm sorry. Go ahead.

9 DR. JENKINS: All right. Well,  
10 it's nice to be here, and it's been exciting  
11 to see this field actually move forward so far  
12 in the last ten years.

13 I would just like to give a little  
14 bit of background to the measure that we're  
15 proposing from the Children's Hospital in  
16 Boston.

17 It's called or we refer to it as  
18 the RACHS-1 Methodology. And the measure that  
19 we're proposing is a standardized mortality  
20 ratio using the RACHS-1 Methodology in its  
21 full form.

22 As John mentioned, this work

1 actually started around ten years ago. And  
2 cardiac surgeons and cardiologists together  
3 provided the judgment to the derivative  
4 methodology.

5           It was also empirically tested  
6 originally in two large data sets and has been  
7 used - it was published in January of 2002 and  
8 has been used really widely both nationally  
9 and internationally since that time. We found  
10 over 39 publications that have relied in some  
11 manner on RACHS-1.

12           One of the points that I would  
13 like to emphasize to the Steering Committee,  
14 is that the measure we're proposing is for the  
15 full standardized mortality ratio using RACHS-  
16 1.

17           And I emphasize that because there  
18 have been applications that have used only the  
19 categories that are a fundamental part of the  
20 procedural adjustment for RACHS-1. But the  
21 additional clinical variables for the full  
22 model which is relatively parsimonious, just

1 includes age, prematurity and other major  
2 cardiac anomalies, also are important  
3 components to an overall assessment.

4           The primary reason that we  
5 developed the measure was to provide an  
6 overall assessment of risk for short-term  
7 mortality for the core pediatric component of  
8 a cardiac surgeon's caseload.

9           It doesn't include the adult  
10 congenital heart population. It's limited to  
11 patient's less than 18 years of age.

12           It actually can be used in a  
13 variety of data sources, both administrative  
14 data and prospectively collected data.

15           And I do provide information in  
16 the packet that I submitted, of really  
17 widespread variation in the United States  
18 using this measure. It's definitely one that  
19 does show center-specific differences.

20           The data that I showed, showed  
21 variation in standardized mortality ratios  
22 from .54 to 3.01 in a set of children's

1 hospitals that submit data to the Pediatric  
2 Health Information System's database.

3           And the table that I provided is  
4 actually the one that we use at the Children's  
5 Hospital in Boston to benchmark our own  
6 performance using a one-year outcome and a  
7 three-year rolling average.

8           So, I really just wanted to give  
9 you that introduction to our methodology.

10           And as Marshall mentioned, I know  
11 that you now have a three-year rule for  
12 revising these measures. RACHS-2 is in  
13 process.

14           It's been a little bit more  
15 complicated this time because there's a lot  
16 more data to use to revise the methodology,  
17 but both Jeff and Marshall and a number of  
18 other surgeons have participated in that  
19 process.

20           But your time frame came in before  
21 that process was done, so the measure we're  
22 proposing is based on the RACHS-1 original

1 methodology.

2 DR. J. JACOBS: Good morning, and  
3 thank you for giving me the opportunity to  
4 come and talk with you all this morning about  
5 the STS measures.

6 The Society of Thoracic Surgeons  
7 is the largest congenital hearty surgery  
8 database in the world. And a group of  
9 surgeons from the STS spent about the last  
10 year-and-a-half developing these 20 measures  
11 that we've proposed.

12 To understand those measures, I  
13 think the first step is to give a little  
14 background about the STS database.

15 So, the STS congenital heart  
16 surgery database, like I said, is the largest  
17 database in the world. Right now 85 of 122  
18 hospitals that do pediatric heart surgery in  
19 the United States participate in the STS  
20 database.

21 More importantly, 19 of the 20  
22 largest hospitals participate, and we think

1 that 28 of the 30 largest hospitals  
2 participate. The non-participants are some of  
3 the smaller hospitals.

4 The STS database has worked over  
5 the last 15 years to create a platform for  
6 data entry that can work across the country  
7 and is harmonious with international centers  
8 in Europe and Asia and Australia as well.

9 So, there's really six principles  
10 within the STS database that establish the  
11 platform for the creation of these quality  
12 improvement/quality assessment metrics.

13 And just to quickly go through  
14 these six principles, first of all, we've  
15 since the 1980s worked to standardize the  
16 nomenclature and terminology used in our  
17 database so that the same words/names for  
18 diseases, names for operations that are used  
19 in the STS database are used in the American  
20 College of Cardiology Impact database, are  
21 used in the Pediatric Cardiac Intensive Care  
22 Society database, are used in the Congenital

1 Cardiac Anesthesia Society database, and are  
2 used in the equivalent databases of  
3 cardiology, cardiac surgery, anesthesia and  
4 critical care in Europe as well, and in some  
5 developing databases in Asia.

6           And this terminology is being  
7 harmonized now with SNOMED and ICD-11, and the  
8 committee that developed the STS nomenclature  
9 has representatives sitting on SNOMED and ICD-  
10 11 committees. So, I think that's very  
11 important when you think about electronic  
12 medical record, which you were talking about  
13 before.

14           These metrics will work in the  
15 electronic medical record because it's going  
16 to be based on the same terminology.

17           Beyond nomenclature, the second  
18 part is harmonizing database standards. So,  
19 over the last decade we published a series of  
20 rules to define "mortality" and "morbidity"  
21 within our database, rules that have been  
22 adopted in the surgical databases in six

1 continents, and that have also been  
2 implemented in cardiology, cardiac surgery,  
3 anesthesia and critical care databases across  
4 the United States.

5           The third piece that we used to  
6 develop these metrics is tools for  
7 stratification of complexity. And what I mean  
8 by that is that we have to have a way within  
9 the database to be able to separate out  
10 operations that have a very high risk of dying  
11 versus a low risk of dying, and operations  
12 that have a high risk of complications versus  
13 a low risk of complications.

14           And within the STS database, we  
15 use the RACHS Methodology as described by  
16 Kathy. We also use another methodology, the  
17 Aristotle Methodology. And we've just  
18 recently published a new score that's based on  
19 actual data within the STS database based on  
20 200,000 operations rather than being based on  
21 subjective probability and expert opinion.  
22 And that's kind of where we get to some of



1 these books.

2           So, the big book is a book that  
3 was published last December. And the first  
4 half of that big book is divided into the six  
5 points that I'm talking about now; the  
6 nomenclature, database standards,  
7 stratification of complexity, data  
8 verification, sub-specialty collaboration and  
9 longitudinal follow-up, and there's between  
10 one and several articles on each of those  
11 areas.

12           In the smaller book, there's four  
13 more recent publications. One on defining  
14 mortality, one on defining morbidity, one on  
15 the application of the basic forms of RACHS  
16 and Aristotle within the STS database, and  
17 then the last one is on the newer  
18 stratification methodology that we've  
19 developed on objective data.

20           And this can provide a source as  
21 we're discussing different methods to stratify  
22 complexity and how we're going to apply that

1 within our quality improvement metrics.

2           The fourth area of the STS  
3 database I wanted to mention briefly is data  
4 verification. We have an active system in  
5 place to verify the completeness and accuracy  
6 of the data so that there is really three  
7 levels of data verification.

8           There's an intrinsic data  
9 cleansing method that eliminates  
10 inconsistencies and illogical applications of  
11 the data.

12           Beyond that there's a site visit  
13 program where sites participating in the STS  
14 database are audited over a three-day period  
15 in collaboration with the Iowa Foundation for  
16 Medical Care and a senior level congenital  
17 heart surgeon.

18           And then finally, we're in the  
19 process now of linking the STS database to the  
20 Social Security Death Master File which  
21 provides a third method for verifying the  
22 accuracy of the mortality data.

1           The fifth topic is sub-specialty  
2 collaboration. And although we're talking  
3 about congenital heart surgery outcomes, the  
4 care of a patient with pediatric congenital  
5 heart disease is a team sport. It's not just  
6 the surgeons. It's surgeons, cardiologists,  
7 anesthesiologists and intensivists.

8           And when we look at the blue book  
9 that I've handed out, this blue book has been  
10 written by surgeons, cardiologists,  
11 anesthesiologists, intensivists,  
12 profusionists, nurses, respiratory therapists,  
13 the full spectrum of the team that cares for  
14 these patients.

15           And the standards for  
16 nomenclature, database, complexity  
17 stratification and data verification have been  
18 harmonized across all these sub-specialties so  
19 that what the STS database is doing is what  
20 the American College of Cardiology database is  
21 doing and what the Congenital Cardiac  
22 Anesthesia Society database is doing.

1                   Briefly, the last component of  
2 these six components is longitudinal follow-  
3 up.

4                   And the STS database is making  
5 major efforts to become a tool for  
6 longitudinal follow-up because what parents  
7 really want to know is not is my baby going to  
8 go home alive from the hospital, but how is  
9 the baby going to be doing in six months or a  
10 year or two years or ten years and can they go  
11 to college and have children?

12                   So, we're implementing methods  
13 within the STS database, to make the database  
14 function as a tool for longitudinal follow-up.  
15 So, that's the background on the STS database.

16                   When John Mayer was president of  
17 the STS, a committee was established within  
18 the STS to develop pediatric and congenital  
19 heart surgery quality indicators. And this  
20 committee was made up of a group of surgeons  
21 really representing small hospitals, large  
22 hospitals, academic hospitals and private

1 practice hospitals.

2           And over the course of a year  
3 through bi-weekly phone conferences, the 20  
4 metrics were developed. And as you go through  
5 them, you'll see some are structure metrics,  
6 some are process metrics, some are outcome  
7 metrics.

8           A hundred percent of them can be  
9 tracked within the STS database, a hundred  
10 percent of them can eventually be in an  
11 electronic medical record that could  
12 communicate with the STS database, and I think  
13 also as you go through them you'll see that  
14 they build on one another.

15           So, several of the structure  
16 metrics provide the foundation for the  
17 subsequent outcome metrics.

18           And as one goes through these  
19 metrics, the definitions used to define some  
20 of the structure metrics about volume are then  
21 applied in the outcome metrics.

22           The two books will provide a lot

1 of source material, charts, graphs and data  
2 that support how we came up with these metrics  
3 and also document some of the testing these  
4 metrics have had so far.

5 RACHS has been in the STS database  
6 since 2006. The Aristotle score since 2002.  
7 There is over a hundred thousand operations  
8 between the STS and the EACTS that have been  
9 scored with these complexity stratification  
10 tools.

11 They're using the STS database  
12 right now, as Kathy said, not in the full  
13 form, but in a form that is a group of  
14 categories to categorize operations.

15 But within the last year, the STS  
16 has started to develop ways to use complexity  
17 stratification tools in a more complete form  
18 that also takes into account patient variables  
19 like prematurity and associated anomalies.  
20 And that's being implemented now within the  
21 STS database.

22 So, I think I'll stop talking now.

1 That provides a little information about why  
2 everybody has this big book to carry home on  
3 the airplane and a little bit of background  
4 about how we got to where we are now.

5           And Jacobs and Jacobs will be here  
6 all day and we're happy to help in any way we  
7 can. Thank you.

8           (Off the record comments.)

9           DR. J. JACOBS: That's a good  
10 point, Marshall.

11           So the big blue book, the first  
12 half talks about those six areas I talked  
13 about; nomenclature, database, complexity  
14 stratification, data verification, sub-  
15 specialty collaboration and longitudinal  
16 follow-up.

17           The second half of this book is a  
18 group of definitions that are consensus-based  
19 definitions that were developed by a group  
20 called the Multi-Societal Database Committee  
21 for Pediatric and Congenital Heart Disease.

22           This multi-societal group had, on

1 the average, three three-day meetings a year  
2 over a four-year period. And a large portion  
3 of that was centered on developing these  
4 definitions.

5 And these are the definitions that  
6 are used in all of the sub-specialty  
7 databases; cardiology, cardiac surgery,  
8 anesthesia, critical care, both in Europe and  
9 North America.

10 And the consensus basis of these  
11 definitions, I think, is very, very important  
12 as we start discussing some of these metrics,  
13 because some of the metrics talk about things  
14 like stroke or renal failure. And there's a  
15 very clear, concise, consensus-driven  
16 definition that's been harmonized across  
17 multiple medical sub-specialties of these  
18 complications.

19 And the source of those is the  
20 multi-societal group that are published in  
21 this blue book. That's the other reason we  
22 brought the blue book.



1           The definitions were not just  
2 developed with experts in pediatric and  
3 congenital heart disease, though. Experts in  
4 the organ system involved with the  
5 complication were also consulted.

6           So when we worked on stroke,  
7 you'll see that the chapter on neurologic  
8 complications and stroke is authored by a  
9 group of cardiologists and cardiac surgeons,  
10 but also has a co-author that's a pediatric  
11 neurologist that specializes in the neurologic  
12 complications after heart surgery, from  
13 Children's Hospital of Philadelphia. And that  
14 applies to all of the organ system  
15 complications.

16           So, we consulted infectious  
17 disease experts for the infectious  
18 complications, we consulted pulmonary experts  
19 for the pulmonary complications.

20           That also allowed us then to  
21 harmonize the stroke definitions with the  
22 definition of "stroke" that's used by

1 neurology societies.

2           It allowed us to harmonize our  
3 infectious definitions with the infection  
4 definitions used by the Center for Disease  
5 Control.

6           So what we call mediastinitis in  
7 the Congenital Heart Surgery database is what  
8 mediastinitis is called in the Adult Heart  
9 Surgery database, and is what the CDC calls  
10 mediastinitis. And that's clearly pretty  
11 important for metric development.

12           DR. BURSTIN: Can I just ask one  
13 general question?

14           Some of these measures look  
15 incredibly interesting, while some of them  
16 look very similar. We've seen these obviously  
17 on the adult side.

18           I mean ultimately is there a  
19 thought that there could be a cardiac surgery  
20 measure that could be stratified depending on  
21 the age group of the patient?

22           DR. J. JACOBS: It's really a

1 totally different science operating on  
2 children versus operating on adults. And I  
3 think that if we want to do this right, we  
4 have to develop metrics specifically looking  
5 at - what we focused on was children, and then  
6 adults with congenital heart disease.

7           And that's a very different world  
8 from the world of coronary bypass and aortic  
9 and mitral valve replacement.

10           DR. BURSTIN: Yes.

11           DR. J. JACOBS: And the same  
12 reasons that we have separate databases for  
13 adult cardiac surgery and pediatric and adult  
14 congenital heart surgery is I think, at least,  
15 the same reason why we should have a separate  
16 set of metrics.

17           The definitions of certain terms  
18 should be harmonized whenever possible, and  
19 we've tried to do that, but I think that it's  
20 not realistic to say that we would just have  
21 one set of metrics.

22           DR. BURSTIN: I was actually

1 thinking more of - I should be more specific -  
2 some of the structural measures, for example.  
3 So, the participation in our database, for  
4 example, seems to me well, we've now got one  
5 for thoracic, one for cardiac surgery, now one  
6 pending for cardiac surgery.

7           It seems like one of those ones  
8 ultimately you want to know is your provider  
9 part of a systematic risk-adjusted database  
10 that provides feedback to them.

11           DR. J. JACOBS: Absolutely.

12           DR. BURSTIN: I'm just saying it's  
13 just something to think about whether it needs  
14 to be that.

15           And I was especially excited to  
16 see the one about the time out, you know, the  
17 actual - and that, to me, seems like one,  
18 again, doesn't seem unique to cardiac surgery.  
19 Would love to see that one potentially  
20 expanded to other kinds of surgery.

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

1 DR. BURSTIN: Yes.

2 DR. J. JACOBS: I think the one  
3 that we wrote about time out could be applied  
4 to all forms of intervention. It's just that  
5 it was the right time for us to do it whereas  
6 maybe someone else two years ago or three  
7 years ago it might not have been the right  
8 time.

9 (Off-the-record comment.)

10 DR. J. JACOBS: Thanks.

11 MS. WILBON: Thank you. So, we're  
12 at about 10:45, running a little bit ahead of  
13 schedule. And Tina is just telling me that it  
14 takes them a little bit of time to set up for  
15 the breakout groups, which is going to be our  
16 next phase of the meeting.

17 So, I'll talk a little bit more  
18 about the breakout groups, and then we'll kind  
19 of break for a few minutes and let them set  
20 up, and then we'll kind of have you guys  
21 migrate to your groups.

22 So everyone is aware, I'm sure, at

1 this point, which group they've been assigned  
2 to. We divided you up by process and  
3 structure measures for one group, which Lisa  
4 Kohr will be facilitating, and then an  
5 outcomes group which Dr. Jeffries will be  
6 facilitating.

7           Within your group, we'll be giving  
8 each group one thumb drive. And on that thumb  
9 drive will be the blank document that Sarah  
10 showed earlier where you can take notes within  
11 that.

12           So, however that group decides to  
13 take notes, if you want one person to be the  
14 note taker for your group and just take notes  
15 into that document and then save it on the  
16 thumb drive. And then when your group is  
17 complete, you will hand it to us and we will  
18 be able to download it to our computer.

19           And then potentially that same  
20 person may want to continue to take notes  
21 during the full Steering Committee meeting to  
22 add any additional notes for that measure, or

1 you may want to have the secondary reviewer  
2 for that measure just use the thumb drive for  
3 that measure and then pass it on when the next  
4 measure is discussed, and then have that  
5 secondary reviewer take notes.

6           So, however your group decides to  
7 do it, we just need to make sure that  
8 everything is typed and saved onto the thumb  
9 drive at the end and that notes - that blank  
10 document for the notes.

11           I'm trying to think is there  
12 anything else? I believe the breakouts are  
13 going to be in this room.

14           So, we'll kind of direct Group A  
15 and Group B once we have the room set up a  
16 little bit more.

17           Does anyone have any questions  
18 about the groups or - I think we have some  
19 notes in one of the documents we sent, about  
20 things you might want to think about when  
21 you're presenting your measure.

22           So, if everyone is comfortable

1 with that and the process for the breakout  
2 groups, then - you look like you have a  
3 question, Dr. Hinkle.

4 DR. HINKLE: Yes, just real quick.

5 MS. WILBON: Okay.

6 DR. HINKLE: I think I understand.

7 For the developers, we will have one of each,  
8 I guess, in each of our rooms. That's why  
9 there's four people here.

10 That's all. Just for  
11 clarification purposes.

12 MS. WILBON: Yes. And they may  
13 want to rotate or what have you, but it is a  
14 public meeting.

15 And Lisa and I will also be  
16 rotating the room. If you guys have any  
17 logistical questions or questions about the  
18 process, we'll be here to answer those for you  
19 as well.

20 Okay. We'll go ahead and break  
21 then to get set up. Thank you.

22 (This portion of the meeting



1 adjourned at 10:51 a.m. for Workgroup  
2 Discussions.)

3 (Meeting reconvened at 3:47 p.m.)

4 OPEN SESSION RECONVENED

5 3:47 p.m.

6 MS. WILBON: So, just a brief  
7 overview of what we're going to do for the  
8 rest of the afternoon.

9 We were a little bit off schedule.  
10 I think both groups actually ran over a little  
11 bit with their discussions, which is good  
12 because everyone wanted to be very thorough in  
13 their discussion of the criteria and making  
14 sure that they had all their bases covered.  
15 So, sounds like everyone had a really good  
16 discussion.

17 So, the way we're going to move  
18 forward with this is both groups were given  
19 the USBs labeled "Group A" and "Group B" where  
20 you were tasked with recording the notes  
21 during the discussion for each measure in  
22 there so that there would be some record of

1 the group's discussion for each measure for  
2 each of the criteria, and the group's vote on  
3 whether they would recommend it, and their  
4 ratings for high, medium, low.

5           So, once we get the USBs from both  
6 groups, we will put that up on the screen so  
7 that everyone can kind of read a little bit  
8 visually as the primary reviewer presents that  
9 measure.

10           So, we'll only have the primary  
11 reviewer present that measure. If you could  
12 give a recap of the measure itself and a  
13 little bit of the discussion that went on  
14 within your individual group so that the other  
15 group has an idea of what went on and what the  
16 group's recommendations were, and then we will  
17 open it up to the entire group for discussion.

18           Sarah Fanta from NQF, will be  
19 taking notes on a separate version not  
20 directly into the one that you guys did, but  
21 a separate version of the discussion of the  
22 entire group.

1                   And what we'll do is send that  
2 back out to the group after the meeting  
3 tomorrow so that anything we missed, you guys  
4 will have the opportunity to add any  
5 additional notes if she missed something or we  
6 missed something.

7                   So, we'll have a really  
8 comprehensive record of the discussion that  
9 happened both in the individual group, as well  
10 as the entire group sitting down together.

11                   So that being said, does anyone  
12 have any questions about how that's going  
13 flow?

14                   So primary reviewer presents,  
15 discuss the measure and what happened in your  
16 smaller group, and then open it up to the  
17 larger group for discussion, and then the vote  
18 and so forth.

19                   So, I'll hand it over to Lisa and  
20 Howard to take over from there. I believe we  
21 plan to start with 18 and 21, which was the  
22 Children's Hospital of Boston measure, along

1 with one of the, I believe, STS outcome  
2 measure as well.

3 So, I'll go ahead and hand it over  
4 and we will go from there.

5 CO-CHAIR JEFFRIES: Okay. So,  
6 we'll start with Measure 18. And the primary  
7 reviewer was Dr. Mavroudis.

8 MS. WILBON: Just a quick reminder  
9 to turn your mics on. That's what records -  
10 thank you.

11 DR. MAVROUDIS: The measure deals  
12 with the three different metrics for measuring  
13 risk stratification/risk complexity - or  
14 complexity analysis for mortality.

15 The group had a good discussion on  
16 this issue. Basically the metric-- it was  
17 noted that all three metrics are noted in the  
18 STS database and are given to every program  
19 that's a participating program as part of  
20 their report and it can be easily gleaned from  
21 the database process.

22 I think like I said before, the

1 discussion was a good discussion and it was,  
2 I believe, unanimously approved, and it  
3 obviously is a very important metric.

4           And I don't want to go any longer  
5 than I have to, but I think that, Mr.  
6 Chairman, I think, or, Ms. Chairman, I think  
7 that does it.

8           Part of this is that some programs  
9 use RACHS-1 metric, some use Aristotle. Some  
10 undoubtedly will be using the new STS-EACTS  
11 metric which has just been published this  
12 month.

13           They all measure classifications  
14 within close proximity. They are based on  
15 different units of -- metric units, more or  
16 less, data, some all opinion, expert opinion.

17           But the classifications that have  
18 been presented in the literature are  
19 relatively close, and we feel that if they all  
20 are used, sooner or later the new upscaled  
21 versions of each of them will eventually come  
22 to pass. And we hope, we expect that within

1 a few years or so these metrics will meld into  
2 one and that we'll eventually have one metric.

3 CO-CHAIR JEFFRIES: That was the  
4 essence of the discussion. We had talked a  
5 bit about the need for - well, was there - is  
6 there a need to pick one? And the feeling of  
7 the workgroup was that we did want to pick  
8 one, and that three would be looked at and  
9 would there be some ability at least within  
10 the STS data set, if not within other data  
11 sets, to look at all three measures for a  
12 center.

13 Any comments from other members of  
14 the Steering Committee? Anybody.

15 DR. GRAY: Something came up in our  
16 group when I was actually looking at the codes  
17 here, was the issue that there -- this one  
18 sort of come up with a lot of them, but that  
19 it's listed with CPT codes. And we're not  
20 sure exactly why that is given the fact that  
21 the hospitals are going to be reporting using  
22 ICD-9 codes, and obviously the STS has its own

1 separate set of codes.

2           And while physicians report with  
3 CPT codes, that's not going - we're not sure  
4 exactly how that is that that would actually  
5 work.

6           And in addition when I was just  
7 looking at some of the codes, I noticed that  
8 you might want to include diagnosis codes for  
9 adults with congenital heart disease because  
10 you can't otherwise determine on the basis of  
11 a procedure that's done in adults, whether  
12 it's done for acquired or congenital heart  
13 disease.

14           And so, you'd need to be able to  
15 make sure that the centers are if they're  
16 including adults, that they're including only  
17 the ones that are basically with congenital  
18 heart disease.

19           And then also some of the codes  
20 that are in there, like there's sternal  
21 debridement, which I don't know that you'd  
22 necessarily want to include as a cardiac

1 procedure, there are a couple of  
2 interventional cardiology codes as well, and  
3 I'm not sure if you necessarily wanted to  
4 include those as well.

5 CO-CHAIR JEFFRIES: So, Jeff, do  
6 you have a comment about that? Marshall?

7 DR. M. JACOBS: I will just share  
8 with you what I shared with our sub-group.

9 When we initially prepared these  
10 measures, inclusionary or exclusionary  
11 criteria when applicable were derived from STS  
12 database terminology and codes.

13 My understanding is that a dialog  
14 took place between STS staff and NQF staff,  
15 and the NQF had specifically requested that we  
16 include the CPT codes.

17 And I imagine that was in  
18 allowance for the possibility that in the  
19 future a center could comply by participating  
20 in a registry database that was not the STS  
21 database and would want to define those fields  
22 by other widely applicable codes.



1                   I think we're not in any way wed  
2 to leaving those CPT codes in the measure  
3 descriptions if it's confusing, which I think  
4 it is.

5                   Do you agree with that, Jeff?

6                   DR. J. JACOBS: 100 percent.

7                   DR. GRAY: So again, I guess you  
8 just might want to include some list of ICD-9  
9 diagnosis codes for capturing the adult cases  
10 because just even the STS procedure codes are  
11 not necessarily going to capture that, I  
12 guess.

13                   CO-CHAIR JEFFRIES: Is there  
14 rationale from NQF for the inclusion of the  
15 CPT?

16                   MS. HINES: That probably was your  
17 discussion with Helen way back at the -  
18 probably because we ended up, as you well  
19 know, with what began as facility level adult  
20 measures, also using them as individual  
21 levels.

22                   So my guess, and I wasn't part of

1 the conversation, was just to allow for that  
2 to happen.

3 (Off the record comments.)

4 DR. J. JACOBS: We can submit these  
5 measures with ICD-9 codes, we can submit them  
6 with CPT codes or we can submit them just with  
7 the appropriate list of diagnostic or  
8 procedural terminology, however you guys want.

9 We submitted them with CPT codes  
10 this time because that's the instructions that  
11 we received.

12 And as far as Darryl's question  
13 regarding adding additional ICD-9 codes to  
14 cover adults -

15 DR. GRAY: The diagnosis codes.

16 DR. J. JACOBS: Diagnosis codes.

17 Again, the codes that would apply  
18 to adults can also be submitted as ICD-9  
19 codes, as CPT codes or from the STS  
20 nomenclature list, because the STS  
21 nomenclature list also applies to adults.

22 So, codes for adults with

1 congenital heart disease and codes for  
2 children can be submitted in any way that the  
3 NQF desires and we'd be happy to send it that  
4 way.

5 We have it at the STS office in  
6 all those ways anyway, so just let us know.

7 CO-CHAIR JEFFRIES: Other comments?

8 DR. MAVROUDIS: Does the process  
9 require that we vote again on this?

10 CO-CHAIR JEFFRIES: Yes.

11 DR. MAVROUDIS: And does the  
12 process allow me as the lead discussant to  
13 make a motion?

14 MS. GRANNIS: No, I'm sorry.  
15 Actually, it's the co-chairs who make the  
16 motion.

17 CO-CHAIR JEFFRIES: So, I'll ask  
18 for a motion for a recommendation vote on  
19 this.

20 DR. MAYER: So moved.

21 CO-CHAIR JEFFRIES: Okay. So,  
22 there are three ways that we can vote on any

1 measure. And that is recommend for time-  
2 limited endorsement, recommend for time-  
3 limited endorsement with conditions, and the  
4 final one was do not recommend for time-  
5 limited endorsement.

6 So, can I get a show of hands who  
7 recommends for a time-limited endorsement?

8 Okay. So, we have a vote of 12  
9 for that measure.

10 So, if we can move now to Measure  
11 21?

12 MS. HINES: Just for the record,  
13 there were no no's. We have 12 members here.

14 CO-CHAIR JEFFRIES: There were no  
15 no's.

16 Measure 21, standardized mortality  
17 ratio for congenital heart surgery, risk  
18 adjustment for congenital heart surgery. And  
19 the primary reviewer is Dr. Mavroudis.

20 DR. MAVROUDIS: Thank you. This is  
21 an indicator to introduce the RACHS-1 model  
22 that has been expanded to include four other

1 categories which include weight, number of  
2 operations - number of procedures that are  
3 done on one patient and age, so that the  
4 metric can measure observed and expected  
5 mortality.

6           And, please, if I'm getting any of  
7 this wrong, don't wait until the end. Raise  
8 your hand. It's a rather complex issue and I  
9 don't want to understate it or even overstate  
10 it.

11           The reason I believe why this was  
12 brought into - why it was introduced is  
13 because there was no other metric, including  
14 no other metric extant in the STS database,  
15 and that the idea being that this was  
16 something new and that the data has been  
17 verified by the Boston group.

18           The discussion during this time  
19 period centered around the idea that in 18,  
20 Category 18, there was more of an inclusive  
21 approach to the three different metrics for  
22 the measurement of death. Not observed death

1 and expected death, but the calculations of  
2 risk stratification, and that it was  
3 recognized that different groups around the  
4 country used different metrics.

5           And that both the Aristotle and  
6 the RACHS-1 not associated with SMR, but the  
7 RACHS-1 are part of the reporting structure of  
8 the STS.

9           Included also in 18, was the new  
10 metric which was based on empiric data of  
11 80,000 congenital cases that had a better C  
12 statistic than the other two. That is to say  
13 the STS-EACTS had a better C statistic of  
14 correlation than STS and RACHS.

15           In any case, since that was, that  
16 18, Indicator 18, allowed for choice of any of  
17 those three, the discussion centered around  
18 perhaps there could be a choice for this SMR  
19 metric.

20           To that end, Jeff stated that this  
21 is being looked at now in the STS database and  
22 will be available in the next couple of

1 months, whereas the SMR equivalent or the SMR  
2 - not equivalent, but the SMR calculation is  
3 ready to go now.

4           So, the conclusion that was never  
5 met, we never had a conclusion on this  
6 discussion, mainly because we were interested  
7 in a fair approach, perhaps, or an inclusive  
8 approach like we chose in Category 18.

9           And there were some suggestions,  
10 one by Jeff, that Number 21 be melded into 18  
11 so that the SMR can be calculated not only by  
12 the RACHS method, but also by the Aristotle  
13 method and also by the EACTS-STC method.

14           The objection to that on the other  
15 side, was that this hasn't been done yet by  
16 the STS or the EACTS-STC method. And since  
17 there are no data, there are no calculations,  
18 then how could the Boston group understand  
19 what they are being put into and how that is  
20 going to compare.

21           The tenor of the discussion was, I  
22 believe, free from contention. And the import

1 was also free from contention.

2           The idea was that we were looking  
3 for a way to do this in an ecumenical way, if  
4 you will. We never arrived there.

5           And we didn't only because we  
6 stopped the discussion and I think that the  
7 idea was to bring it back here.

8           Now, I'm sure that in my  
9 description of all this that I didn't consider  
10 all the sides equally, although I tried to and  
11 it was my intention.

12           My personal thought was that the  
13 SMR ought to be moved from 21 into 18 so that  
14 it would be part of the overall system of  
15 mortality expression, for instance. 18 had  
16 risk stratification and that this is a subset  
17 of risk stratification. After all, we're  
18 talking about observed mortality and expected  
19 mortality.

20           And it could be and that the RACHS  
21 could be one way of dealing with it, and then  
22 STS would come up with another way, and the



1 EACTS-STIS would come up with another way and  
2 that would be in that - however, since this  
3 was already proposed as 21, it would be maybe  
4 a little difficult to do that.

5           And then the other alternative  
6 would be to as the presenters of 21, to accept  
7 the fact that not only could RACHS be used to  
8 calculate the SMR, but also measurements from  
9 the STS and also the EACTS-STIS metrics.

10           The response to that was that they  
11 didn't know what this entailed. And how could  
12 they agree to something that they didn't know  
13 about, they didn't see, they didn't have their  
14 arms around, they didn't understand it?

15           The word was "agnostic to it,"  
16 which I think was a nice succinct way of  
17 putting it.

18           So, right now we are at a little  
19 bit of a standstill here or standoff what to  
20 do about this.

21           We considered tabling it, we  
22 considered having the two parties perhaps talk

1 about it.

2           And we also considered the  
3 ramifications of allowing a 21 to exist, and  
4 also another one, a 22 to exist. That means  
5 21 would have an SMR based on the RACHS  
6 classification, and 22 would have an SMR based  
7 on the STS and EACTS-STC calculation.

8           The problem with that is, is that  
9 it would allow the insurers, the government,  
10 whoever else is interested in this, to pick  
11 out one of those and that it would be sort of  
12 a - they would be doing the picking out of  
13 what is the right metric and not us.

14           Furthermore in complicating that  
15 is that we really all agreed that we didn't  
16 know, and we still don't know, what is the  
17 best metric.

18           This is a procedure in motion.  
19 This is something that in one or two or four  
20 years, or who knows what, the science alone  
21 will determine which system is better.

22           It could be that RACHS-2 when it

1 comes out, will be better. It could be that  
2 the EACTS-STS combination will be better. And  
3 to allow someone to pick something a priori  
4 and not have the benefit of a natural  
5 selection, is probably wrong. We didn't want  
6 that.

7                   We wanted a natural selection to  
8 take place. Not so much as the winner take  
9 all, but what would be the best for this  
10 metric, and what would be best for public  
11 reporting.

12                   So in a very long-winded way,  
13 which I was trying to be careful not to add  
14 any kind of gasoline to the fire - although we  
15 haven't had any fire yet, I just didn't want  
16 to even start it. And I don't think we need  
17 to because people who are disagreeing here are  
18 disagreeing from virtuous positions.

19                   People believe in what they are  
20 doing, and what else do we want except that?  
21 That's great.

22                   But we should continue this. We

1 should continue to have people believe in what  
2 they're doing which eventually will probably  
3 come into an understanding of what we should  
4 do moving forward.

5           So it's wrong, I think, to make a  
6 decision on this now to sort of embrace one  
7 over another even though that one is existing  
8 and the other one is four weeks away.

9           And so if I have to make a  
10 decision here, I would say that we should  
11 table this and not approve it as it is right  
12 now.

13           But if there is any other way, any  
14 other more diplomatic way of doing it, I'd  
15 love to see that as well.

16           We're faced with one of three  
17 choices. I don't like any of them. But if I  
18 had to vote, I would say that we should table  
19 this and try to see if we can move in a more  
20 Venus way than a Mars way.

21           I'm finished.

22           (Laughter.)

1 CO-CHAIR JEFFRIES: Okay. Is there  
2 anybody who was part of the workgroup want to  
3 add anything to what Dr. Mavroudis said,  
4 though I think he summarized the discussion  
5 very nicely?

6 DR. MAVROUDIS: Long winded.

7 CO-CHAIR JEFFRIES: Kathy.

8 DR. JENKINS: I would just like to  
9 weigh in and be sure that - Gus, I actually  
10 thought you described that very, very well.  
11 And I think you did take - it was a really  
12 nice summary of the discussion that we had.

13 The only thing, I guess, that  
14 wasn't clear to me, but hearing you explain it  
15 again, why it is that you want the SMR either  
16 part of 18 or you want all of the methodology  
17 incorporated in 21 a little bit as a strategy  
18 that won't allow picking of one measure over  
19 another by the insurance companies, I'm not  
20 sure that that's true.

21 But if there's a concern that  
22 that's true, it would be fine with me to have

1 the three SMRs proposed under 21 as long as  
2 it's the STS that's proposing the other two.

3           Because I'm just finding myself in  
4 this difficult position about being the  
5 sponsor of a measure who's responsible for its  
6 scientific content, who's approving it and  
7 making it better in three years, for a measure  
8 that I just don't have my hands around the  
9 science for.

10           So, my only objection is being the  
11 individual proposing the additional SMRs and  
12 taking responsibility for it.

13           However, the language was about  
14 putting it with 18 or keeping it separate or  
15 putting it together with 21, I really have no  
16 objection to.

17           I want to be sure that's clear.  
18 It's only having it be my responsibility as  
19 the proposer. That's my only objection.

20           CO-CHAIR JEFFRIES: Marshall.

21           DR. M. JACOBS: Well, I think that  
22 that was a very appropriate, informative,

1 terse response after Dr. Mavroudis' soliloquy.

2 I didn't have the advantage of  
3 sitting in on that group and I see there being  
4 three issues.

5 One is a measure of performance  
6 related to a calculated ratio of observed to  
7 expected mortality, which is a very useful  
8 tool and a very informative tool. It's used  
9 in the STS adult database.

10 And in fact since two reports ago  
11 in the fall of 2008, it's used for neonatal  
12 and infant mortality reporting in the STS  
13 congenital database.

14 So, at least to the extent that I  
15 can speak on behalf of the STS, we have no  
16 negative or contentious issues with regard to  
17 expression of observed to expected mortality  
18 or a derived ratio or index from that and I  
19 think it's an excellent idea. That's Issue  
20 Number 1.

21 Issue Number 2 is the issue of  
22 whether outcome reporting by complexity

1 stratification for the NQF should rely on one  
2 stratification tool, two or three.

3           And Howard addressed that. And I  
4 think the sentiment of the group was expressed  
5 in their vote on Measure 18. That is what it  
6 is and I think it was important.

7           I think it's entirely possible to  
8 work together and accomplish what Kathy  
9 mentioned in her last discussion. I don't see  
10 very much challenging about calculating a  
11 comparable ratio based on observed and  
12 expected mortality using the Aristotle Score  
13 and STS data or using the STS-EACTS Score and  
14 STS data.

15           I think the quandary or the  
16 conundrum to be resolved if I understand  
17 correctly, is the reference data set from  
18 which the expected mortality is derived.

19           Which for your preliminary work on  
20 the SMR, is one particular multi-institutional  
21 data set which is different from the STS data  
22 set.



1                   So, insofar as one can make  
2 preliminary proposals not speaking on behalf  
3 of an entire organization, I think if we can  
4 sort out the question of the reference data  
5 set from which the expected mortality is  
6 derived, then it ought to be very possible for  
7 the STS to work with Dr. Gauvreau and Dr.  
8 Jenkins to create something very much SMR-like  
9 using all three complexity stratification  
10 measures.

11                   DR. MAVROUDIS: If I may, the power  
12 of discussion is overwhelming. It sounds like  
13 we have a very nice resolution, I think, to  
14 this problem, to this conundrum.

15                   And that is that perhaps this  
16 could be a hybrid 21, that in fact the Boston  
17 group represents the SMR within 21. The STS  
18 can take control of their own metric and that  
19 it can be put together in the same kind of  
20 way, in the same spirit as 18. That's what it  
21 looks like to me.

22                   MS. HINES: Just to recap on that,

1    though, you have to have a measure steward  
2    responsible for each measure.  So, if Kathy  
3    wants to maintain Boston's measure as it  
4    stands and STS is going to make a  
5    complementary measure with the other  
6    databases, that's still two metrics because  
7    STS would own one, and one Kathy would own.

8                    So, we would still need to vote in  
9    that case on the measure in front of us, and  
10   then STS could submit a second measure.

11                   DR. MAVROUDIS: On the other hand,  
12   the Measure 21 could be temporarily tabled to  
13   give the particulars with the people in - who  
14   are approaching unity on this to develop a  
15   metric that would include all three.  That's  
16   the other way of looking at it as well, I  
17   think, although not knowing the process as  
18   well as you do.

19                   MS. HINES: Right.  And I think we  
20   have a measure on the table that we're going  
21   to have to deal with, and it sounds like the  
22   development of that measure could be a new

1 measure that has all three versus one.

2 I'm not seeing tabling because  
3 we're not combining the two and we're not  
4 going to have one owner, so it - I'm still -

5 DR. J. JACOBS: So, I think that  
6 Kathy's idea was a brilliant idea. And what -  
7 her original concern about combining these  
8 two metrics with hers, the measure steward,  
9 was how could she be responsible to write  
10 about the other two metrics.

11 I think what we could do is Kathy  
12 could continue to be the measure steward and  
13 she could have substantial help from me,  
14 Marshall and Sean O'Brien at DCRI to write the  
15 components relating to the other metrics. And  
16 a revision of this metric could be submitted  
17 with Kathy still as the primary steward, but  
18 with the support of us to fill in the  
19 remaining piece. And then it would be a  
20 metric that would be supported by all groups.

21 So, the process might be that it  
22 has to be tabled now and resubmitted with the

1 revised version. But we could help do our  
2 piece, and then we could come back with  
3 something altogether that would be harmonious.

4 CO-CHAIR JEFFRIES: Kathy, what's  
5 your opinion on that?

6 DR. JENKINS: Whatever works.  
7 Seriously, I think that quite frankly an SMR  
8 is a very, very useful measure for centers,  
9 provided it covers a reasonable component of  
10 the case mix and really does give centers a  
11 very good sense of how they're doing as long  
12 as the risk adjustment is at a reasonable  
13 level.

14 And I think it would be a shame to  
15 not have an SMR endorsed because of this issue  
16 about what's the best way to categorize the  
17 patients and incorporate the additional  
18 variables.

19 I'm a little confused about the  
20 NQF process about how's the best way to do it.  
21 It's not possible, you know, the STS database  
22 process doesn't allow a lot of other people to

1 see their data and evaluate their data, modify  
2 their data. They make changes through a very  
3 hierarchical surgeon-driven process.

4 So, it probably does make more  
5 sense to retain flexibility, for us to do it  
6 Jeff's way rather than in the other direction.  
7 But seriously, whatever works best for the  
8 process.

9 My goal is to have an SMR proposed  
10 with the validity that we developed in 2002,  
11 to be available for centers to benchmark their  
12 performance.

13 CO-CHAIR JEFFRIES: Thanks. So,  
14 would this fall under the endorsement with  
15 conditions?

16 MS. HINES: Kathy, I mean if you -  
17 we can table it if you two want to talk and  
18 come up with a solution or proposed solution  
19 to--I just want to - we have a measure on the  
20 table to consider as is to vote. We've had  
21 suggestions for modifications to add in the  
22 other two data sources. If -

1 DR. JENKINS: No, not data sources.

2 MS. HINES: Well, the different  
3 models.

4 DR. JENKINS: We've had the  
5 suggestion to propose three SMRs.

6 MS. HINES: Right.

7 DR. JENKINS: One, the SMR that we  
8 proposed. One, if I understand correctly,  
9 it's an SMR derived by four Aristotle  
10 categories and the variables, I assume, that  
11 are currently part of RACHS. And then the  
12 five STS categories and the variables that are  
13 currently a part of RACHS.

14 And I think that that's a very  
15 reasonable suggestion. I don't have any  
16 objections to proposing those SMRs.

17 (Off-mic comment.)

18 DR. JENKINS: For the RACHS  
19 Methodology as we outlined in our proposal,  
20 RACHS can be used within various types of data  
21 sets. So, it could certainly be generated  
22 within the STS database. It can also be

1 generated in other ways.

2 I'm not as certain about the other  
3 two just because I'm less familiar with the  
4 details. But that's the measure that we  
5 proposed, and that's the measure that we are  
6 still willing to put forward.

7 So, the reference for RACHS  
8 changes based on the user. It's not  
9 exclusively a reference set from the STS  
10 database.

11 But it certainly can be used  
12 within the reference set of the STS database  
13 once the database has the variables that are  
14 part of RACHS, which I understand will be true  
15 soon. And then data will accrue and that will  
16 be able to happen every quarter or every six  
17 months or -

18 MS. HINES: So conversely, the STS  
19 measure or the STS modification would be  
20 purely from the STS database, or you're going  
21 to add the additional data sources.

22 DR. JENKINS: Well, the other

1 categories can also - it's a methodology. So,  
2 presumably it will be used in the EACTS  
3 database and other databases, but -

4 DR. J. JACOBS: I would agree with  
5 what Kathy said. The methodologies that we're  
6 proposing to add to this metric can be applied  
7 to any data set that exists.

8 So, Kathy's RACHS tool and our  
9 Aristotle and STS-EACTS tools, all three have  
10 been used in the STS database and the full  
11 RACHS can be applied to the STS database. And  
12 conversely, all three tools could be applied  
13 to any other data set, including  
14 administrative data sets.

15 I think that this process has led  
16 to a very good ending conclusion of a way to  
17 solve this problem in that we could team up  
18 together and revise this metric in such a way  
19 that it deals with all three complexity  
20 stratification tools equivalently and that it  
21 would have the full support both of the team  
22 from Boston and of the STS.



1 DR. MAVROUDIS: If I may offer a  
2 suggestion -

3 DR. J. JACOBS: And excellent  
4 flexibility -

5 DR. MAVROUDIS: This may not fit  
6 into your categories of what we should do, but  
7 I don't know why we couldn't: We can table  
8 this for the moment and ask Jeff and Kathy and  
9 Marshall to look at this a little further and  
10 then come up with another proposal, which  
11 would be 21. And it would be a part different  
12 from 18. I think I was wrong in my having to  
13 associate this with 18.

14 The way Kathy said with 21 is, I  
15 think, a good idea. SMR is a different  
16 metric. Let them come up with something  
17 that's agreeable. I mean if they're agreeable  
18 to it, we would be agreeable to it.

19 We're sitting here in some  
20 solemnotic Buddhist kind of way in trying to  
21 find out what the best way to deal with this  
22 and because of your metrics, you're not

1 allowing us to.

2           And I think that we should bend  
3 here a little bit and say okay, we'll table  
4 this and we can discuss it at our next  
5 telephone conversation. And we should invite  
6 the particulars in that telephone conference  
7 and do it.

8           And I guess if your bosses don't  
9 like it or if you're the boss and you don't  
10 like it, I would say look at it again and make  
11 it so you do like it.

12           MS. HINES: What I'm making sure,  
13 and thank you for your thoughts, what I'm  
14 making sure is that I have both developers  
15 that are saying yes, that they're willing to  
16 talk and try to come to some - that's all I  
17 need to hear is that Kathy is willing to put  
18 her metric back on the table and try to work  
19 it out and bring it back to us.

20           I guess just to make it worth  
21 their while, do you want to do a straw vote to  
22 just say that this, in concept, is a good

1 metric and the group supports that?

2 DR. HINKLE: Just a point. Can I  
3 ask a question, a clarification? So, a  
4 process question.

5 It seems to me if they can work on  
6 it tonight or today, then we could reconvene  
7 the outcomes group to look at it again and  
8 vote it for the committee so that the, you  
9 know, because we've been batting this around  
10 for a while and -

11 CO-CHAIR JEFFRIES: We would just  
12 review it in committee.

13 DR. HINKLE: In the committee?

14 CO-CHAIR JEFFRIES: Yes.

15 DR. HINKLE: The whole committee?

16 CO-CHAIR JEFFRIES: Yes.

17 DR. HINKLE: Okay. So, I just  
18 wanted to ask that clarification, but -

19 DR. J. JACOBS: I think we need a  
20 little more time than one night to get -

21 DR. HINKLE: Okay. That - yes,  
22 that's what I didn't quite understand. I mean

1 otherwise -

2 DR. J. JACOBS: We can give you a  
3 one-sentence or two-sentence metric. But to  
4 fill up that whole packet -

5 DR. HINKLE: Yes. So, maybe the  
6 teleconference. You mentioned that someplace.

7 DR. MAVROUDIS: Do you need a whole  
8 packet, or can they give you additional -

9 MS. HINES: Yes, it would be  
10 changed enough that we would have to modify  
11 what we've got.

12 DR. MAVROUDIS: What kind of a  
13 motion do we need?

14 CO-CHAIR JEFFRIES: I think we  
15 should do a straw vote and see with the  
16 changes that could have been outlined here if  
17 that - when that comes back to this group,  
18 that the group would recommend it.

19 DR. MAYER: I'm sorry. I've been  
20 trying to stay quiet here, but it seems to me  
21 that what we're talking about, and maybe just  
22 hopefully to clarify this a little bit, is

1 we're talking about using the standardized  
2 mortality ratio approach as a measure, right?

3 DR. MAVROUDIS: Yes.

4 DR. MAYER: And, I mean, that's the  
5 only conceptual question here. And I think we  
6 are then looking for a way for the two  
7 respective sponsors, each of whom has access  
8 to differing data sets and may have  
9 incorporated slightly different variables in  
10 one way or another to see if they could agree  
11 on either a common data set or some way to  
12 rationalize this in such a way that a  
13 standardized mortality ratio approach could  
14 come forward as a measure for the - as an  
15 approved NQF measure.

16 Did I reflect the discussion  
17 correctly?

18 CO-CHAIR JEFFRIES: That's my  
19 understanding.

20 DR. MAVROUDIS: It may not be a  
21 unified approach after three or four days of  
22 discussion, but it would set the stage for

1 that over a period of time that what we would  
2 hope to happen is that we eventually have one  
3 metric for all of these things.

4 I believe that that's what we -

5 DR. MAYER: I'm not sure that, you  
6 know, I think the likelihood might be that  
7 from two different data sources you might  
8 actually get slightly different answers.

9 I think what we're talking about  
10 is the common approach of creating the SMRs at  
11 the institutional levels and recognize that  
12 the answers might actually - I mean one would  
13 hope not, but it is conceivable and possible  
14 that we might wind up with differing -

15 DR. MAVROUDIS: Agreed.

16 DR. MAYER: That's all.

17 CO-CHAIR JEFFRIES: Yes, Marshall.

18 DR. M. JACOBS: May I just

19 supplement what John said?

20 I mean my understanding of this  
21 discussion is that one of the positive aspects  
22 of Measure 18 was that it gave the participant

1 the option of reporting using one of three  
2 complexity stratification tools.

3 Is that correct?

4 DR. MAVROUDIS: That's correct.

5 DR. M. JACOBS: And so we're now  
6 proposing that the participant report an SMR  
7 using their choice of three complexity  
8 stratification tools with our two teams  
9 working together to develop those metrics.

10 Is that what seems to be on the  
11 table?

12 CO-CHAIR JEFFRIES: Yes.

13 DR. M. JACOBS: Okay.

14 CO-CHAIR JEFFRIES: And so with  
15 those clarifications, let's take a straw vote  
16 and see how people would agree based on that  
17 measure when we see it again.

18 DR. HOYER: Are you asking how we  
19 would vote if in fact everything was  
20 reconciled?

21 CO-CHAIR JEFFRIES: Correct.

22 DR. HOYER: Or are we voting right

1 now with -

2 CO-CHAIR JEFFRIES: No.

3 DR. HOYER: - the three choices?

4 CO-CHAIR JEFFRIES: We're voting as

5 if it was reconciled so they know that the

6 work they're doing is not going to be in vain.

7 Okay.

8 Straw. So, we have 11 straw

9 votes, and the one not in the room. Okay.

10 DR. MAVROUDIS: That was easy.

11 CO-CHAIR JEFFRIES: Yes. The

12 workgroup clearly dealt with all the issues.

13 So, we have time for a public

14 comment, for the public who hasn't commented.

15 (Laughter.)

16 MS. WILBON: Operator, are you

17 there on the conference line?

18 THE OPERATOR: Yes, I am.

19 MS. WILBON: Is there anyone on the

20 participant's line for the public?

21 THE OPERATOR: Yes, Boston is on.

22 MS. WILBON: I'm sorry?



1 THE OPERATOR: Boston is on.

2 MS. WILBON: Oh, Boston is on.

3 We're opening it up for public  
4 comment. So, if you'd like to make a comment  
5 at this time, you're on.

6 THE OPERATOR: Please press Star 1.

7 PARTICIPANT: The only thing that I  
8 would like to say is that I think just from a  
9 perspective of having a metric that's been in  
10 the public domain versus one that would  
11 require participation in a database that  
12 requires funding, I just think that that does  
13 have an option.

14 And that's just a comment that I  
15 have about this as stewards of this measure.

16 DR. J. JACOBS: That's an excellent  
17 comment from the phone.

18 The metrics that have been  
19 proposed, best as I can tell, all 20 of them -  
20 all 21 of them, none of them require  
21 participation in any specific database  
22 whatsoever.

1                   And when we developed the 20 that  
2 we developed, and the same is true for  
3 Kathy's, we were all very careful to put  
4 wording in place that did not require use of  
5 any specific database whatsoever.

6                   MS. WILBON: Is there anyone else  
7 on the line that would like to make a comment?

8                   Operator, is there anyone else on  
9 the listener's line?

10                  THE OPERATOR: Not at this time.

11                  MS. WILBON: Okay. Thank you.

12                  CO-CHAIR JEFFRIES: So, we're going  
13 to continue with - let's do another outcome  
14 measure. So, why don't we go back to the  
15 start of the outcome measure group which was  
16 Number 12.

17                  Patricia Galvin is the primary  
18 presenter for that.

19                  MS. GALVIN: So Number 12, the  
20 measure is the use of an expanded pre-  
21 procedural or post-procedural time out. There  
22 is basically four elements to this

1 recommendation that the conventional pre-  
2 procedural time out which includes the  
3 identification of the patient, the op site,  
4 procedure and history of any allergies is one  
5 measure or one indicator.

6           A pre-procedural briefing wherein  
7 the surgeon shares with all members of the  
8 operating room team the essential elements of  
9 the operative plan, including diagnosis, plan  
10 procedure, outline of essentials in  
11 anesthesia, bypass strategies, anticipated or  
12 planned implants or device applications and  
13 anticipated challenges.

14           That there would be a post-  
15 procedural debriefing wherein the surgeon  
16 succinctly reviews all members of the team the  
17 essential elements of the operative plan  
18 identifying successful components and  
19 opportunities for improvement.

20           The debriefing ideally would take  
21 place in the operating room and may be  
22 followed by a more in depth dialog at a later

1 time.

2           A briefing or a handoff protocol  
3 at the time of transfer or arrival to the  
4 intensive care unit, a clinician-to-clinician  
5 handoff, if you will, at the end of the  
6 operation involving the anesthesiologist,  
7 surgeon, physician staff of the intensive care  
8 unit, including critical care and cardiology  
9 and nursing.

10           The discussion centered around --  
11 I think everybody felt that this was  
12 important, it's in line with national patient  
13 safety goals, it's been well documented in the  
14 literature, and that those parts of the  
15 measure were without question.

16           There was a brief discussion about  
17 the ability to - the feasibility of how the  
18 data would be collected that if you are saying  
19 yes, you are saying yes to all of the elements  
20 that are included in each separate section.

21           But the workgroup discussed that  
22 and felt that this measure was feasible,

1 usable and worthy of voting.

2 CO-CHAIR JEFFRIES: Okay. Are  
3 there any comments from either group?

4 DR. GHANAYEM: Actually, I have a  
5 question.

6 I'm interested in how the group  
7 thought this would be feasible. In  
8 practicality, this would be great to do, but  
9 oftentimes the surgeon is starting the next  
10 case in the next room, the cardiologist is off  
11 somewhere else, there's an intensivist at the  
12 bedside.

13 So if you don't have all of the  
14 elements, which is unlikely to happen a lot of  
15 the time, how does that get measured?

16 I think this would be great if it  
17 could happen. But in an era where we have  
18 more and more work with fewer resources, I'm  
19 not quite sure how this is possible.

20 CO-CHAIR JEFFRIES: And are you  
21 commenting on -

22 DR. GHANAYEM: The post-procedural

1 handoff.

2 CO-CHAIR JEFFRIES: The briefing.

3 DR. GHANAYEM: Yes.

4 CO-CHAIR JEFFRIES: And the  
5 handoff?

6 DR. GHANAYEM: Well, the - yes.

7 The handoff also specifies that all those  
8 people need to be there.

9 CO-CHAIR JEFFRIES: Okay.

10 MS. GALVIN: So in our discussion,  
11 we talked about in clinician-clinician to  
12 handoff, a lot of places are implementing  
13 this. That at the bedside once the patient is  
14 settled, there is a brief discussion, takes  
15 five or ten minutes, where the operative  
16 procedure is sort of recapped and a lot of  
17 information is shared.

18 DR. GHANAYEM: But not to this  
19 degree of rigidity. So, you might have a  
20 surgical PA, you might have a surgical  
21 resident, you might not have a surgeon there  
22 at that moment, you might have an anesthesia

1 fellow.

2 MS. GALVIN: Well, we talked about  
3 whether it would be an attending or a  
4 resident. And in our situation -- or in our  
5 discussion, either would be fine as long as it  
6 was a surgeon who was at the procedure, who  
7 participated in the procedure.

8 DR. GHANAYEM: I'm just concerned  
9 that the way this is written leaves room for  
10 more times this not happening to the letter of  
11 the law than it does happen to the letter of  
12 the law.

13 So, it would need to be, I think,  
14 reworded to some degree.

15 MS. GALVIN: I think what we  
16 discussed was that there would be what I think  
17 Dr. Mayer referred to as escapes. That yes,  
18 that in the document, in the auditing, that  
19 yes, you did or no, you didn't because the  
20 patient was unstable, that there was a reason  
21 why it wasn't done.

22 And we all know that this is a

1 critical time and there's a lot going on. And  
2 so we need to - as you said, we need to take  
3 that into account and that would be in the  
4 documentation.

5 CO-CHAIR JEFFRIES: Marshall.

6 DR. M. JACOBS: I think Nancy's  
7 point is very important and very practical.  
8 In putting the measure together though, we  
9 thought that the collaboration between the  
10 compartments in a multi-disciplinary team is  
11 what makes the transition successful.

12 I think that there are a lot of  
13 rules that are delegatable. Some things by  
14 law, are undelegatable like informed consent.  
15 There's nothing in this measure that says  
16 roles are not delegatable. That if the  
17 attending surgeon is doing a case in another  
18 room, the resident surgeon or PA stands in, in  
19 the role of surgeon during the debriefing and  
20 the transfer.

21 So, I think it was in that spirit  
22 that this measure was put together.



1     Somebody's got to participate in those roles,  
2     but several of them are delegatable as  
3     necessary.

4                   CO-CHAIR JEFFRIES: And then we  
5     also had some discussion about the numerator,  
6     about the numerator being all or none.

7                   So if you don't do any of these  
8     elements, it would be a zero. If you do all  
9     four, then you get a one and that the measure  
10    is a rate.

11                   Other comments?

12                   DR. HOYER: I guess I would also  
13    have a few concerns that Nancy voiced about  
14    just the rigidity of this. And we had some  
15    discussion in our meetings about some of the  
16    ways that if these kinds of things are tracked  
17    and then - it's an effort to raise the bar for  
18    sure. It's an effort to raise the bar to a  
19    higher standard.

20                   And I don't know that anybody is  
21    in actuality doing that all of the time, and  
22    probably not very often, at least all four

1 components of that.

2           The number one component is things  
3 that are required now, obviously. But the  
4 additional things obviously would raise the  
5 standard.

6           And then if those are looked at by  
7 outside parties, again it becomes a way of  
8 potentially, for lack of a better term,  
9 dictating the way one practices medicine and  
10 practices these things.

11           Now again, they're all noble and  
12 worthwhile ideas, but it does kind of put a  
13 little bit of if you don't meet the standard,  
14 you did three-and-a-half out of four, is that  
15 something that's going to ding you at some  
16 point if it does become something that is  
17 adopted as a standard of care.

18           I mean we should all strive to do  
19 these things at every and any point in time,  
20 but I personally haven't seen a surgeon - and  
21 this is no knock on anybody, but I haven't  
22 seen one do a post-procedural debriefing. I

1 have not seen that, witnessed that yet.

2 MS. GALVIN: From a nursing  
3 perspective, I would agree that we have a  
4 formal debriefing. But at the end of a  
5 procedure, we do ask what was the procedure  
6 that you did, because we have to document that  
7 in the medical record. So, there are pieces  
8 of this that are already in place.

9 The one that I would agree with in  
10 Number 3 was if there was something that went  
11 wrong, and then what we discussed in the group  
12 was it doesn't have to happen right then, it  
13 just needs to be acknowledged at that point,  
14 and then a debriefing, you know, we need to  
15 talk about this at a later date because, you  
16 know, again the patient - you're getting ready  
17 to transfer the patient out of the room, it's  
18 a critical time.

19 So, the idea of having that  
20 conversation is the intent of the measure as  
21 we saw it.

22 DR. GHANAYEM: Actually, I think,

1 Lisa, you brought this up at our session. If  
2 we keep the wording like this, then we run  
3 into the same problem as Mark has alluded to  
4 with the third-party payers that - like  
5 central line-associated infection, ventilator-  
6 associated pneumonia, if you have that, that  
7 is a reason for them not to pay you.

8           If we put the wording in here and  
9 we don't document that each of these four  
10 points have not been thoroughly accomplished  
11 regardless of the rationale, third party payer  
12 can still say we're not going to pay you. You  
13 haven't met the NQF measure.

14           And I think we actually put  
15 ourselves in jeopardy unless we reword this.

16           CO-CHAIR JEFFRIES: Marshall.

17           DR. M. JACOBS: I think this is a  
18 fascinating discussion, but I'm not sure it  
19 pertains specifically to this measure anymore  
20 than it does generically to the whole process.

21           I mean I heard a certain reticence  
22 or fear about raising the bar, which I think

1 we ought to be very anxious to raise the bar.

2           And I heard an articulation of if  
3 we endorse something, then it's going to  
4 dictate how people practice, which it can be  
5 looked at from two perspectives.

6           I'm asking very honestly and  
7 innocently, doesn't every measure that the NQF  
8 endorses dictate how people are going to  
9 practice in the sense that payers are going to  
10 look for compliance, parents are going to look  
11 for compliance, referring physicians are going  
12 to look for compliance, administrators are  
13 going to look for compliance?

14           And unfortunately if you want to  
15 make quality systematic rather than just  
16 altruistic, you really are dictating how  
17 people are going to practice, but you're  
18 trying to raise the bar in a rational way.

19           I'm an outsider to this process  
20 and I'm confused by the dialog.

21           DR. GHANAYEM: This one can't be  
22 met though. With the resources we have

1 available to us right now, we cannot meet this  
2 one as it's laid out.

3 Yes, there should be debriefings,  
4 but to have all these people at the bedside is  
5 a problem.

6 DR. M. JACOBS: Well, this sort of  
7 stuff comes from models like how Air Force  
8 pilots interact with the crews on aircraft  
9 carriers and how airline pilots interact with  
10 control towers and ground crews, and it has  
11 been proved in those circumstances to save  
12 lives.

13 And in the pilot studies done in  
14 adult cardiac surgery at the Mayo Clinic, it's  
15 been proved to reduce errors.

16 I think there's only so much that  
17 you can relax the proposal if you intend to  
18 achieve the desired end.

19 CO-CHAIR JEFFRIES: Dr. Mayer.

20 DR. MAYER: Well, I think the other  
21 thing is maybe we don't need to think about  
22 this as a black/white sort of issue. I think

1 that many of - I'm pretty sure this is right:  
2 There are some of the metrics that are in the  
3 adult STS cardiac database and the measure set  
4 that do require accomplishing several things  
5 in order to get credit, if you will, and I  
6 think the data are that nobody is at a hundred  
7 percent.

8           And so the notion that somehow or  
9 another your local insurance payer or whatever  
10 would deny payment for the whole case because  
11 you didn't meet all four of the - or didn't  
12 use some percentage, I mean that's a little  
13 bit outside this process because that's a  
14 subject of negotiation between you and your  
15 payer.

16           And I can tell you that from our  
17 own personal experience in a different realm  
18 with one of our local payers, we had a quite  
19 involved negotiation about what we were going  
20 to do with blood stream infections and  
21 recognizing things like the asymptote problem,  
22 you know, you can't get the infection rate

1 below zero, as an example. Here, you couldn't  
2 get above a hundred percent compliance.

3           And I think there's a recognition  
4 that we're never going to get this a hundred  
5 percent of the time. We've tried pretty hard,  
6 and I would say most of the time we would get  
7 three out of four. We do the ICU  
8 brief/handoff thing. We do the timeouts  
9 beforehand and stuff.

10           The debrief in the operating room  
11 I think the way it's phrased, is to be pretty  
12 succinct and brief. And that if there were  
13 issues during the case, that all you do is you  
14 said this was an issue, not that you resolve  
15 it, that you figure out well, it's because  
16 somebody forgot to call for this or something  
17 like that.

18           So, I guess I'm not so  
19 uncomfortable with this with those caveats  
20 that if as we're collecting the data we say  
21 sorry, we didn't have time or weren't capable  
22 or doing the debrief because the patient was



1 pretty unstable and we thought the best thing  
2 was to get the child to the unit and get  
3 settled and then let the dust settle, that  
4 that would be a legitimate escape that you  
5 wouldn't necessarily be penalized for that.

6           And so I think rather than  
7 thinking about this in black and white terms,  
8 I think if it's viewed as something that we're  
9 trying to get to that there is a recognition  
10 that we're not going to get it a hundred  
11 percent of the time, maybe that would give you  
12 a little bit more comfort with this measure.

13           MS. GALVIN: I think the other  
14 thing that I would add to that is that when we  
15 actually did implement that in our ICU, if you  
16 look at Number 4 and the people that are  
17 there, all of those people are at the bedside.

18           So, all we were saying was that  
19 everybody had to come together at one point  
20 and hear the same information.

21           And actually it streamlined the  
22 process because the nurse at the bedside in

1 the past, couldn't hear what the  
2 anesthesiologist had to say or didn't hear  
3 what the plan for the night would be.

4 This way it really streamlines  
5 communication so you don't have all of those  
6 questions later.

7 DR. GHANAYEM: And I absolutely  
8 agree and we do the exact same thing.  
9 However, there are some variations of what's  
10 written -

11 MS. GALVIN: Right.

12 DR. GHANAYEM: - based on the  
13 availability of the resources. So, oftentimes  
14 it is a PA, it's not a surgeon.

15 MS. GALVIN: Right.

16 DR. GHANAYEM: It is the  
17 anesthesia fellow. It's the ICU fellow. But  
18 yes, you're right. It reads a little bit too  
19 black and white.

20 Realizing that, I would hate to  
21 see a third party payer come to us and say  
22 well, you didn't have all these people here,

1 check off that they were all here, and for  
2 that reason you can't get paid for your  
3 services.

4 DR. LOPEZ: If I could just make a  
5 comment, I mean I don't work for private  
6 insurance, but I do work for a state Medicaid  
7 agency and we don't really look at whether a  
8 provider has checked every single box. We  
9 never withhold payment for anything like that.

10 What we might look at is quality  
11 and the kind of quality of care that's being  
12 provided to the patient.

13 And if we see that there's an  
14 issue with a single provider, perhaps an  
15 institution, we'll start talking to that group  
16 or that institution.

17 Occasionally we'll have some calls  
18 from other providers complaining about someone  
19 down the street and perhaps what they're  
20 doing, we get calls from patients concerned  
21 about the quality of care that they've  
22 received, so we'll start investigating those

1 providers.

2                   But we really don't withhold  
3 treatment just because something wasn't  
4 checked off - or withhold payment, I should  
5 say.

6                   DR. HINKLE: I'd like to make a  
7 quick comment. I am from one of those payers,  
8 the private payers, but I've also been a  
9 pediatric anesthesiologist.

10                   Let me just make a couple of  
11 comments. One is that measurement is here in  
12 medicine and it's moving forward. And my  
13 participation in this process, I think, has  
14 been very - I'm very enlightened by the group  
15 moving forward.

16                   Pediatric cardiac surgery I would  
17 have thought would be the last sub, sub-  
18 specialty I would have thought moving in this  
19 direction.

20                   So, I applaud the fact that you're  
21 moving forward and you own - you're going to  
22 try to own these metrics going forward.

1           And I'd hope that in most of your  
2 markets if a payer does come forward, you  
3 would meet with them.

4           I've only had, I can tell you in  
5 my experience, it's mainly primary care, but  
6 I did have an anesthesia group come forward  
7 and say we would like to be measured, we would  
8 like to have a pay for performance program to  
9 make a little more money.

10           And I met with them and they came  
11 up with the metrics. We went through them  
12 back and forth and we came to a decision on  
13 the metrics that they were under their control  
14 and they were very reasonable and now that's  
15 in place, and so we're moving forward around  
16 their metric.

17           So, I would hope that you wouldn't  
18 get - I mean I can't imagine any medical  
19 director, chief medical officer at any health  
20 plan in this country meeting with pediatric  
21 cardiac specialists and dictating measures.

22           They may look at these NQF

1 measures and say to you what do you think? If  
2 you want to even participate in upside, you  
3 know, increasing upside payments, then they  
4 would take - these would at least be a  
5 discussion point.

6           They could put them on the table  
7 and say, Nancy, what do you think of these?  
8 And then it would be a collaborative process.

9           None of these have been, you know,  
10 they've all been collaborative in primary care  
11 as much as it doesn't sound that way from the  
12 outside, you know.

13           So, I would just say  
14 congratulations that you're doing this. This  
15 is pretty impressive. You're going to see  
16 this will start a movement.

17           You do have to be aware that they  
18 sometimes do find their ways into payment.  
19 There's no question about that. But as  
20 somebody said, you know, let's move, this is  
21 what we're trying to do in healthcare, and we  
22 as physicians need to take control, more

1 control of this moving it forward.

2           Otherwise, it's going to -  
3 somebody is going to take control of it  
4 outside, so this is a great process.

5           And I understand your discomfort,  
6 but I just, you know, I think the likelihood  
7 of that - especially, I would say to you, go  
8 to the steps of that insurance company, walk  
9 right in, find the CMO, sit him down, because  
10 there's not going to be a pediatric cardiac  
11 specialist at that desk and you're going to be  
12 the one in control of defining what you want  
13 to be measured on.

14           CO-CHAIR JEFFRIES: Okay. Are  
15 there any other comments on this measure?

16           I mean I would just say one thing  
17 from the discussion we had, and that was  
18 around usability. And from - I guess I would  
19 also like to hear your perspective as a family  
20 that it would seem that these points that,  
21 again, as I mentioned in the meeting, that  
22 there's sort of an expectation that these are

1 done and not that this is above and beyond  
2 what is part of practice.

3 MS. BARNETT-JONES: Absolutely, and  
4 that was part of my comment in our sub-group  
5 is that we set - the goal is to set the  
6 expectation. And I know from my own  
7 experience especially when we look at Point  
8 Number 4, for me that is routine when we go to  
9 CHOP, when we come out of the cath lab.

10 It is routine that all of the  
11 persons listed here are there and that there  
12 is a debriefing.

13 At times, the family is included  
14 in that debrief. And so that is for me, a  
15 very high expectation so that there is the  
16 transfer of knowledge, there is the  
17 communication.

18 And it helps, as I said at the  
19 table, that we are all still on the same sheet  
20 of music. That everyone is on the same page.

21 And from an outcome perspective, I  
22 think that for a child that enhances the



1 safety, that there is less likely for  
2 something to go awry because the communication  
3 was there and the opportunity was available to  
4 ask questions and make sure that all the  
5 answers were laid out at the same time and  
6 everyone heard the same message.

7 CO-CHAIR JEFFRIES: Thank you. So,  
8 Jeff, I just wanted to get some clarity before  
9 we go to a vote, around the numerator.

10 And the way the numerator is  
11 stated now, it's whether or not the facility  
12 implements.

13 Is that how you want it? Is it  
14 dichotomous or do you want it on a per patient  
15 --

16 DR. J. JACOBS: So, the way we  
17 anticipate implementing this is one would have  
18 a database that's tracking all these different  
19 metrics.

20 And for this metric on a case-by-  
21 case basis, there's going to be four check  
22 boxes to check where you would document that

1 you complied with Step 1, Step 2, Step 3 and  
2 Step 4.

3           Additionally for Step 2 and 3  
4 specifically if you said no, you would have  
5 the option of going to a drop down menu and  
6 having the reason why you said no.

7           And I think Step 1 obviously  
8 always has to happen every time or you're  
9 going to go to jail, but Step 2 and 3 there's  
10 probably some reasonably good, possible  
11 explanations for why it's not done like the  
12 patient is unstable, giving CPR, things like  
13 that.

14           So, basically it's a yes-no  
15 question on a per patient basis with four  
16 check boxes. And for the Number 2 and Number  
17 3, some explanation as to why one might put  
18 no. And then you comply it in an all or none  
19 fashion like we talked about before.

20           CO-CHAIR JEFFRIES: So, can I have  
21 a motion that we vote on this with the  
22 modifications to the numerator as were just

1 delineated?

2 DR. MAYER: So moved.

3 CO-CHAIR JEFFRIES: Okay. So, if  
4 we can vote for recommendations with those  
5 modifications?

6 MS. GRANNIS: Okay. So, it's 12  
7 four recommend for time-limited endorsement.  
8 And no one did not, not recommend.

9 CO-CHAIR JEFFRIES: Okay. So, it's  
10 five o'clock. So, I think we should probably  
11 stop.

12 MS. WILBON: Just a quick note  
13 before we break for tomorrow. Breakfast  
14 starts at 7:30. I know today we started at  
15 9:00. So, just a quick note so you guys don't  
16 come two hours late.

17 We'll start the discussions at  
18 8:00 a.m. So thank you, everyone, for your  
19 participation today, and great discussions,  
20 and we'll see you tomorrow. Thank you.

21 (Whereupon, the meeting adjourned  
22 at 5:00 p.m.)

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