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

10:04 a.m.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

implemented.

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

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

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

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

DR. HINKLE: My name is Dr. Allen

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(Laughter.)

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

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

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

So, bear with me briefly while I relocate.

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

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

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

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

We're a 400-plus-member

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

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

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

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

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

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

So, here is a condensed version of

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

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

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

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

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

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

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

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

recommendations to NQF on how the measures should move forward.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have to have a steward who

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

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

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

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

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

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

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

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

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

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

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

This is a must-pass criteria. This is a change from when we updated the criteria last year.

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

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

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

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

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

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

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

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

What we don't want is things that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I'm sorry. Go ahead.

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

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

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

As John mentioned, this work

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

methodology.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

these books.

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

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

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

within our quality improvement metrics.

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

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

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

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

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

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

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

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

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

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

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

practice hospitals.

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

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

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

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

The two books will provide a lot

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

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

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

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

So, I think I'll stop talking now.

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

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

(Off the record comments.)

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

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

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

This multi-societal group had, on

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

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

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

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

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

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

So, we consulted infectious disease experts for the infectious complications, we consulted pulmonary experts for the pulmonary complications.

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

neurology societies.

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

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

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

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

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

DR. J. JACOBS: It's really a

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

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

DR. BURSTIN: Yes.

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

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

DR. BURSTIN: I was actually

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

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

DR. J. JACOBS: Absolutely.

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

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

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

DR. BURSTIN: Yes.

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

(Off-the-record comment.)

DR. J. JACOBS: Thanks.

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

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

So everyone is aware, I'm sure, at

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

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

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

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

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

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

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

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

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

So, if everyone is comfortable

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

DR. HINKLE: Yes, just real quick.

MS. WILBON: Okay.

DR. HINKLE: I think I understand. For the developers, we will have one of each, I guess, in each of our rooms. That's why there's four people here.

That's all. Just for clarification purposes.

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

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

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

(This portion of the meeting

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

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

OPEN SESSION RECONVENED

3:47 p.m.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

I think like I said before, the

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

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

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

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

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

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

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

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

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

separate set of codes.

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

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

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

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

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

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

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

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

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

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

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

Do you agree with that, Jeff?

DR. J. JACOBS: 100 percent.

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

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

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

So my guess, and I wasn't part of

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

(Off the record comments.)

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

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

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

DR. GRAY: The diagnosis codes.

DR. J. JACOBS: Diagnosis codes.

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

So, codes for adults with

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

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

CO-CHAIR JEFFRIES: Other comments?

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

CO-CHAIR JEFFRIES: Yes.

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

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

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

DR. MAYER: So moved.

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

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

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

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

So, if we can move now to Measure 21?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

was also free from contention.

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

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

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

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

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

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

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

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

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

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

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

about it.

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

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

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

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

It could be that RACHS-2 when it

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

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

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

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

But we should continue this. We

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

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

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

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

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

I'm finished.

(Laughter.)

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

DR. MAVROUDIS: Long winded.

CO-CHAIR JEFFRIES: Kathy.

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

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

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

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

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

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

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

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

CO-CHAIR JEFFRIES: Marshall.

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

terse response after Dr. Mavroudis' soliloquy.

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. HINES: Just to recap on that,

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

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

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

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

measure that has all three versus one.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. JENKINS: No, not data sources.

MS. HINES: Well, the different models.

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

MS. HINES: Right.

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

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

(Off-mic comment.)

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

generated in other ways.

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

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

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

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

DR. JENKINS: Well, the other

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

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

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

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

DR. MAVROUDIS: If I may offer a suggestion -

DR. J. JACOBS: And excellent flexibility -

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

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

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

allowing us to.

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

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

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

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

metric and the group supports that?

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

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

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

DR. HINKLE: In the committee?

CO-CHAIR JEFFRIES: Yes.

DR. HINKLE: The whole committee?

CO-CHAIR JEFFRIES: Yes.

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

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

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

otherwise -

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

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

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

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

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

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

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

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

DR. MAVROUDIS: Yes.

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

Did I reflect the discussion correctly?

CO-CHAIR JEFFRIES: That's my understanding.

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

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

I believe that that's what we -

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

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

DR. MAVROUDIS: Agreed.

DR. MAYER: That's all.

CO-CHAIR JEFFRIES: Yes, Marshall.

DR. M. JACOBS: May I just supplement what John said?

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

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

Is that correct?

DR. MAVROUDIS: That's correct.

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

Is that what seems to be on the table?

CO-CHAIR JEFFRIES: Yes.

DR. M. JACOBS: Okay.

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

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

CO-CHAIR JEFFRIES: Correct.

DR. HOYER: Or are we voting right

now with -

CO-CHAIR JEFFRIES: No.

DR. HOYER: - the three choices?

CO-CHAIR JEFFRIES: We're voting as if it was reconciled so they know that the work they're doing is not going to be in vain. Okay.

Straw. So, we have 11 straw votes, and the one not in the room. Okay.

DR. MAVROUDIS: That was easy.

CO-CHAIR JEFFRIES: Yes. The workgroup clearly dealt with all the issues.

So, we have time for a public comment, for the public who hasn't commented.

(Laughter.)

MS. WILBON: Operator, are you there on the conference line?

THE OPERATOR: Yes, I am.

MS. WILBON: Is there anyone on the participant's line for the public?

THE OPERATOR: Yes, Boston is on.

MS. WILBON: I'm sorry?

THE OPERATOR: Boston is on.

MS. WILBON: Oh, Boston is on.

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

THE OPERATOR: Please press Star 1.

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

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

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

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

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

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

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

THE OPERATOR: Not at this time.

MS. WILBON: Okay. Thank you.

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

Patricia Galvin is the primary presenter for that.

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

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

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

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

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

time.

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

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

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

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

usable and worthy of voting.

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

DR. GHANAYEM: Actually, I have a question.

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

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

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

CO-CHAIR JEFFRIES: And are you commenting on -

DR. GHANAYEM: The post-procedural

handoff.

CO-CHAIR JEFFRIES: The briefing.

DR. GHANAYEM: Yes.

CO-CHAIR JEFFRIES: And the handoff?

DR. GHANAYEM: Well, the - yes. The handoff also specifies that all those people need to be there.

CO-CHAIR JEFFRIES: Okay.

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

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

fellow.

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

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

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

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

And we all know that this is a

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

CO-CHAIR JEFFRIES: Marshall.

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

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

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

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

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

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

Other comments?

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

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

components of that.

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

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

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

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

have not seen that, witnessed that yet.

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

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

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

DR. GHANAYEM: Actually, I think,

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

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

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

CO-CHAIR JEFFRIES: Marshall.

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

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

we ought to be very anxious to raise the bar.

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

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

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

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

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

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

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

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

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

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

CO-CHAIR JEFFRIES: Dr. Mayer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. GALVIN: Right.

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

MS. GALVIN: Right.

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

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

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

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

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

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

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

providers.

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

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

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

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

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

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

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

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

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

They may look at these NQF

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

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

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

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

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

control of this moving it forward.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

delineated?

DR. MAYER: So moved.

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

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

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

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

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

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