NATIONAL QUALITY FORUM

In-Person Meeting for the Pediatric Cardiac Surgery Steering Committee

October 21-22, 2009

A two-day meeting of the Pediatric Cardiac Surgery Steering Committee took place on October 21-22, 2009, at the Hyatt Regency Hotel in Washington, D.C.

Steering Committee Members Present: Howard Jeffries, MD, MPH, MBA (*Co-Chair*); Lisa Kohr, MS, MPN, RN, CPNP (*Co-Chair*); Schonay Barnett-Jones, MBA; Patricia Galvin, RN, BSN, CNOR; Nancy Ghanayem, MD; Darryl Gray, MD, ScD; Allen Hinkle, MD; Mark Hoyer, MD; John Mayer, MD; Constantine Mavroudis, MD; Lisa Nugent, MFA

Measure Developers Present: Dr. Kimberly Gauvreau, MD (Children's Hospital, Boston); Kathy Jenkins, MD, FACC, MPH (Children's Hospital, Boston); Jeffrey Jacobs, MD (Society of Thoracic Surgeons); Marshall Jacobs, MD, STS

National Quality Forum (NQF) Staff Present: Lisa Hines, MS, BSN; Helen Burstin, MD, MPH; Tina Grannis, RN, BSN; Ashlie Wilbon, RN, MPH; Sarah Fanta

Other Attendees Present: Joel Harder, Society for Cardiovascular Angiography and Interventions

Dr. Jeffries and Ms. Kohr began the meeting by welcoming the Committee and asking the Committee members to introduce themselves and disclose any conflicts of interests. Ms. Wilbon provided an overview of the charge and scope of the project and the NQF process. Dr. Burstin summarized several NQF strategic issues for the Committee to take into consideration in its deliberations.

The Steering Committee was divided into two work groups; one reviewed the structural and process measures, and the other reviewed the outcome measures. Written transcripts from the Steering Committee's discussions can be found on the project webpage under Candidate Consensus Standards Review. Once the work groups discussed and voted on the measures, the full Committee was reconvened to discuss each measure individually. Representatives from the two measure developers that submitted measures to this project were present, and during the discussion they were given the opportunity to answer questions posed by the work groups.

Recommendations for each of the 21 measures reviewed by the Committee are presented in the table that follows, as well as any conditions that the Committee specified must be met by the measure developer (e.g., changes to the measures as submitted) prior to recommendation. The table indicates the Committee's evaluation of each measure against the following criteria:

- Importance
- Scientific Acceptability
- Usability
- Feasibility

The work groups rated each measure as “high,” “moderate,” or “low” on each of the above criteria. The full Committee then voted on each measure to be recommended, recommended as time-limited, recommended with conditions, or not recommended.

NATIONAL QUALITY FORUM

Pediatric Cardiac Surgery

Summary of Steering Committee Review of Measures, October 21-22, 2009

NQF Evaluation Criteria: I=Importance; **SA**=Scientific acceptability; **U**=Usability; **F**=Feasibility

Extent to which the NQF evaluation criteria are met: H=High rating, highly; **M**=middle rating, moderately; **L**=low rating, minimally

# / Title/ Owner	I	SA	U	F	Steering Committee Comments and Recommendation
PCS-001-09 Participation in a national database for pediatric and congenital heart surgery (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	M	H	H	**Importance:** • To have quality improvement, there is a need for quality assessment and data analysis. STS fulfills this need. Participation in a national registry is associated with improved outcomes. Institutional or surgical practice has agreement with STS. Data is harvested every 6 months. Data quality reports are generated by DRI (Duke Research Institute), and opportunity is given to clean own data. Most institutions go through three iterations of data harvesting and cleaning before an outcome report generated. Data is not available for marketing. Data is only available for quality improvement. Outcome report by volume—low, medium, or high. • If an institution doesn't measure outcomes then it doesn't have a premise to improve quality. So waiting for a defined outcome is not necessary. There is however science that already shows the quality benefit in participating in databases. Because the numbers are there in single institutions, there is a need to pool multi-institutional data to study outcomes and improve quality. **Scientific Acceptability:** • The Committee would like to clarify what participation actually means, because it is not defined in the submission of data. The measure is only described as participation; there are no specific criteria for performance. If the center participates, then it counts as participation. **Usability:** • Aggregate data is in the public domain. The public could learn relative frequency of diagnosis and outcomes related to specific procedures. STS probably has the most accurate description of which congenital heart surgeries are occurring in the United States.

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					Feasibility: • Health centers will be unlikely to participate in databases if there isn't significant volume. The key piece is the quality of data and who is entering it. It is important to take into account how often the database is checked for completeness/accuracy. Some centers may not enter data for fear that they will be compared with larger centers (regardless of comparable outcomes). • It is difficult to determine which database to enter information into. When databases eventually merge, it will be more feasible. Currently what is being done is to adopt basic codes into each other's database (e.g., STS codes in the ICU VPS database). Drilling down specifics regarding surgery and complications requires a multidisciplinary approach. Currently providers and centers are being asked to do more with less. • General concerns regarding the database are human error and lack of incentive to participate. The data collected must be reported in a way that is understandable to the public. Reporting institutions must develop skills in data visualization. This measure would be structured to look at outcomes, with the numerator eventually becoming the denominator. **Response from Measure Developer:** None **Voting Options:** • **VOTE to recommend for time-limited endorsement on the condition that STS provides a definition of "participation" based on the STS database - 12/12** • **VOTE to not recommend - 0**
PCS-002-09 Multidisciplinary conference to plan pediatric and congenital heart surgery cases (Society of Thoracic Surgeons)	H	L	L	M	**Importance:** • It is important to note how this activity will impact outcomes; no data are currently available to support this. **Scientific Acceptability:** • This measures a dichotomous variable; there is a need to distinguish between conferences versus a one-on-one discussion when determining whether a conference has occurred. It must be specified how the conference is documented. • The Committee wanted to know how to measure and compare a conference that involves a small number of non-clinicians versus a

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RECOMMEND FOR TIME-LIMITED ENDORSEMENT					designated group of specialists. • This is a programmatic measure, not an individual patient measure. • Perhaps the measure should be reworded to be limited to cardiology and cardiac surgery, which are the key stakeholders. • This measure simply specifies whether a conference is occurring, not whether each patient is discussed at a conference. • There is no description of who should be at the table; the measure must be more specific regarding criteria so that data are comparable and have the essential components. • A framework for the series of tasks that occur in the meeting must be created. **Usability:** • Tracking this measure is problematic due to lack of documentation. If an organization is audited and picked up by the public domain, it could be problematic if the institution falls short of the documented measure (which would be an unintended consequence). • Concerns exist regarding the dissemination of information to the public. **Feasibility:** • Documentation of this measure is a limiting factor. It would be interesting to understand how this measure works within the health system (in terms of reporting) and where the information is reported. • This information does not normally appear in a medical record but perhaps as a brief note; there are limited ways to track this information. • Not all conferences are the same; not the same topics are covered. How will these differences and measures be reconciled? **Recommendations:** • In the future this measure would be most useful if it were linked to mortality. Linking every measure to outcomes is limited to mortality, whereas linking to longer term chronic conditions is more important. Hence linking this measure to an outcome that is not measureable on paper will limit this measure. **Response from Measure Developer:** • Some existing programs do not cover the communication aspects of care coordination. Communication is an important structural component of the measure; this should be submitted as an expected level of care

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					quality. **Voting Options:** • **VOTE to recommend for time-limited endorsement on the condition that STS changes the measure title to be more descriptive of the conference - <u>12/12</u>** • **VOTE to not recommend - <u>0</u>**
PCS-003-09 Multidisciplinary rounds involving cardiology, cardiac surgery, and critical care (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	M	**Scientific Acceptability:** • The measure needs to include family, along with other health-related disciplines. It is very important for the family to know what the plan of the day is. Family participation in rounds allows for recognition of care needs and improves outcomes. • Which patients are included in this measure? Only patients in critical care? This is not listed in the measure specifications. • The Committee may want to request a change from cardiologist to cardiovascular service. **Feasibility:** • All providers should document this activity for billing purposes. This activity can be billed and time recorded. **Response from Measure Developer:** • This measure would not apply to daily rounds, because cardiologists are not available on a daily basis. It would simply ensure that someone on the team is looking after the patient. The measure developer would like to change to "multi-disciplinary rounds (daily review of patient care, family participation is welcome and encouraged)". Rounds are a bed-side discussion with the parents' involvement; they have to be inclusive. • The final change to this measure should be: "multidisciplinary rounds including 'multiple members of the healthcare team', family participation is welcome and encouraged– it is recommended but not limited to people present: family, primary care giver etc." The measure developer will include this language in the description, including the individuals listed, but not limited to include only them. The measure should also specify who the ideal members of the team should include. **Voting Options:** • **VOTE to recommend for time-limited endorsement on the conditions that STS changes the description to "Implementation of**

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					multidisciplinary rounds involving the healthcare team, recommended but not limited to: cardiology, cardiac surgery, critical care, primary care giver, family, nurses, pharmacist and respiratory therapist" and that STS changes the title to "Multidisciplinary rounds involving multiple members of the healthcare team"- 12/12 • **VOTE to not recommend – 0**
PCS-004-09 Regularly scheduled peer review quality assurance conference (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	M	M	L	H	**Importance:** • The Committee agreed that a regularly scheduled peer review is essential for high-level care. • The Committee agreed that having a meaningful conference within a structured time-frame may be enough. Peer review is very different from an M&M (morbidity and mortality); peer review implies that another pediatric cardiac surgeon is involved as a reviewer. **Scientific Acceptability:** • The Committee had concerns similar to those for PCS-003-09. • The Committee discussed the recommendation to insert "surgical" into the title. • The language of this measure is inconsistent with The Joint Commission (TJC) requirements for M&M conferences. • The term used is "regularly scheduled," but is once a year enough? • By using the word "peer," we may or may not be able to determine if people are performing tasks accurately and efficiently, but everyone is looking at the same result. In that context, the intensive care doctor would appear to have an idea of what the outcome will be. Peer review is really about clinical judgment; a physician and a pharmacist don't speak the same language. **Response from Measure Developer:** • This is proposed as a structure measure, TJC mandates hospitals and healthcare facilities hold M&M conferences; however, this measure requires a separate peer review. It is not an M&M, but rather a cardiac care schedule meeting, which requires a different level of commitment from merely fulfilling the TJC mandate. Peer review is misleading, but it should appear somewhere because the intent is for the content process to be protected under peer review. The conference should be regularly scheduled so that all of the team members can come together to

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					explain their cases. • This measure does not specify a timeframe. The timeframe should be quarterly at a minimum; every six months is not frequent enough. The measure developer suggested changing the title to "Regularly scheduled quarterly QA review" and omitting from the specifications a list of exactly who should be there, because the idea is that these meetings should be occurring. **Voting Options:** • **VOTE to recommend for time-limited endorsement based on the condition that STS changes the title to "Regularly Scheduled Quality Assurance and Quality Improvement Cardiac Care Conference" and that STS changes the description and numerator to reflect the change to the title (i.e., removal of "peer review") and to clarify "regularly scheduled" to mean at least quarterly - 12/12** • **VOTE to not recommend - 0**
PCS-005-09 Availability of intraoperative transesophageal echocardiography (TEE) (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Importance:** • This measure is important for patient care. • Overall the measure embodies well-accepted technology in the field. All institutions have this technology. **Scientific Acceptability:** • This is a structural measure designed to determine whether TEE is available in a facility and not necessarily whether it is being used. **Response from Measure Developer:** None . **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**
PCS-006-09 Availability of institutional pediatric ECLS (extracorporeal life support) (Society of	H	H	H	H	**Importance:** • ECLS is an important adjunct support device for a pediatric surgery program. Data support the importance of having ECLS in cardiac surgery programs, and its importance is not limited to heart disease. • How does this overlap with the Extracorporeal Life Support Organization (ELSO) registry? It is possible to have an Extracorporeal

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Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT					Membrane Oxygenation (ECMO) program without a cardiac program. ELSO regularly reports data to contributing institutions. • Is access to a mobile ECMO center enough? Should the focus of the measure be appropriate use? • The Committee agreed that the literature support the effectiveness of ECLS in increasing survival of pediatric and congenital heart patients. **Scientific Acceptability:** • This is a dichotomous variable measure, requiring a yes or no response; the program either has it or not. **Usability:** • The workgroup that discussed this measure expressed some concern about this measure overlapping with ELSO efforts; which also tracks this information. • The work group/Committee agreed that the information derived from this measure, i.e., knowing what centers have the program in place, is important for patient safety and for public information when complex cases occur. **Response from Measure Developer:** None **Voting Options:** • **VOTE to recommend for time-limited endorsement - 11/11** • **VOTE to not recommend – 0**
PCS-007-09 Surgical volume for pediatric and congenital heart surgery (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Importance:** • Higher volume does not always lead to better quality; however, it can be tracked for future reference. **Scientific Acceptability:** • This measure is not intended to imply that higher volume equals higher quality. It is simply a structure measure. **Usability:** • The Committee would prefer CPT codes rather than ICD-9 and STS codes. • This measure is intended to be the denominator for the complication outcome measures that were previously discussed. Volume itself doesn't really mean anything unless it is paired with something. • The Committee asked the measure developer to explain the need for both this measure and PCS-008-09, which stratifies volume by

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					complexity. Is there any benefit of one over the other? • The Committee also expressed concern about the comparability of this measure to the existing NQF-endorsed measure 0340 from AHRQ. Although the AHRQ measure uses administrative data, there are efforts to map the codes between this measure and the STS codes to determine where gaps and misclassifications exist. **Response from Measure Developer:** • The difference between the two measures is that one provides the scope of patients that can then be stratified (PCS-007-09). It also allows the user to figure out how many cases have been excluded from the complexity volume measure. • The STS measure uses clinical data and NQF-endorsed measure 0340 from AHRQ uses administrative data to count. There are data that have shown that counting cases using administrative data can be inaccurate. **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**
#PCS-008-09 Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS mortality levels (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Importance:** • See the discussion for PCS-007-09. **Scientific Acceptability:** • See the discussion for PCS-007-09. **Usability:** • See the discussion for PCS-007-09. • This measure should be reported with PCS-018-09. **Response from Measure Developer:** None **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**

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PCS-009-09 Surgical volume for six pediatric and congenital heart operations (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Importance:** • Six procedures represent surgeries most commonly performed. **Scientific Acceptability:** • See discussion for PCS-007-09. **Usability:** • This measure should be reported with PCS-019-09. • The Committee agreed that the volume measures should be used in conjunction with the mortality measures. **Response from Measure Developer:** None **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**
PCS-010-09 Timing of antibiotic administration for pediatric and congenital cardiac surgery patients (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Scientific Acceptability:** • This measure should include timing and dose. Weight-based dosing is mentioned in PCS-011-09. PCS-010-09 and PCS-011-09 should be combined. • If the incorrect dose is given, then it doesn't matter if it is given at the right time. This measure should be combined with PCS-011-09. The person who gave the dose may be different from the person who ordered the dose. **Usability:** • Is this measure intended to measure individual compliance or programmatic performance? If combined with PCS-011-09, then this measure is more of a programmatic measurement. If separate, then it is implied that the measures are intended to track to an individual who is responsible for that process occurring as it should. • Some Committee members also expressed concern that there may be payment implications for these measures, and combining them may have unintended consequences on fairness. • Ultimately, it was decided to keep the measures separate. **Feasibility:** • The data required for this measure and PCS-011-9 are generally documented in the same place in the EHR or patient record, and so it is

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					feasible to collect the data needed for this measure. **Response from Measure Developer:** • The measure developer explained that presenting this measure and PCS-011-09 separately was done to follow the way similar measures for the adult population have been submitted and endorsed. **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**
PCS-011-09 Selection of antibiotic administration for pediatric and congenital cardiac surgery patients (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	See discussion for PCS-010-09. **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**
# / Title/ Owner	**I**	**SA**	**U**	**F**	**Steering Committee Comments and Recommendation**
PCS-012-09 Use of an expanded pre-procedural and post-procedural "time-out" (Society of Thoracic Surgeons) RECOMMENDED	H	H	H	H	**Importance:** • The Committee generally agreed about the importance of this process to improving quality. **Scientific Acceptability:** • There was discussion about the definition of the numerator and the importance of calculating a rate of adherence to all four elements (all or none). • This measure incorporates the clinician to clinician hand-off, brief discussion, recap of the procedure, and sharing of information. Either an attending or resident or whoever participated in the procedure could

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FOR TIME-LIMITED ENDORSEMENT					fulfill this role. The idea of having this conversation is the intent of the measure. **Usability:** • Most payers in this market would be open and excited about the prospects that someone is paying attention to this matter. Metrics are moving forward based on this concept. Payers may look at these measures when increasing payments; it would be a discussion point. It should be a collaborative process between payers and providers. **Feasibility:** • The Committee discussed the tracking of all four proposed elements and explanations for omissions of one or more elements, e.g., unstable patient condition precluding post-procedure time-out. Concerns were raised about a proposed process measure to have a post-procedure debriefing in the OR because of patient instability, etc. This will be a new process. • There was discussion about feasibility and how data would be collected. • The Committee wanted to know how measurement will be feasible; this activity does not occur with this level of depth on a daily basis. There was concern that meeting the measure criteria would be unattainable if the specifications remain as is; most centers are unlikely to have all the people that are required at the bed-side. **Response from Measure Developer:** • The collaboration between partners and the medical team is what makes the procedure successful. Every measure NQF endorses has the potential to dictate how people practice with compliance. If you want to make quality systematic, you need to dictate. Time-outs have been proven by circumstances to save lives and reduce errors, as there are only so many ways to relax that patient and medical team. • The measure developer anticipates, on a case-by-case basis, that there will be four check boxes. If you say "no" for steps 2 and 3, you can go to a drop down to give a reason why. Step 2 and 3 will allow the individual entering information to offer a reasonable explanation, such as an unstable patient, etc.). **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12**

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					• **VOTE to not recommend - <u>0</u>**
PCS-013-09 Mediastinitis after pediatric and congenital heart surgery (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Importance:** • Although evidence in the measure's submission did not clearly make the case for variation in mediastinitis rates, the Committee was satisfied with the measure developer's response that variation in this indicator does exist in the STS database for those who submit data. **Scientific Acceptability:** • STS will need to develop risk-adjustment models (or exclusion criteria) for variables associated with this complication to help identify or adjust for patients with tracheostomy or gastrostomy, for example. • The measure uses the CDC definition for mediastinitis. • The Committee wanted to clarify the ICD-9 codes. Procedures on heart and great vessels may include thoracic vascular procedures. **Response from Measure Developer:** • The scope of operations and specifications can be specified through ICD- 9 or basic terminology; currently it is specified with CPT codes. **Voting Options:** • **VOTE to recommend for time-limited endorsement - <u>12/12</u>** • **VOTE to not recommend - <u>0</u>**
PCS-014-09 Stroke/cerebrovascular accident (CVA) after pediatric and congenital heart surgery (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	M	H	H	**Scientific Acceptability:** • This outcome measure is not stratified or risk-adjusted. Similar to PCS-013-09, the Committee agreed that this measure should use risk models developed for this measure. • Patients who have a neurologic deficit without systemic sequelae would not meet this. The issue of timing was discussed; the measure definition specifies that stroke is a neurological deficit that is not resolved within 24 hours. This is the definition used by the American College of Cardiology. • Most of the discussion was about the at-risk population. It won't be evident that a patient has had an event until he/she has symptoms,

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					particularly while the brain is recovering and the patient is sedated. As such, some of the Committee expressed a preference for a 72-hour window versus a 24-hour window. Others, however, believed it was negligible since the measure is aimed at long-term survival. **Response from Measure Developer:** • We usually don't know when the brain disturbance occurred. If symptoms persist after 24 hours, the definition can't be based on the time frame of the blood flow; there is no way to tell. Definitions are based on either resolving or not resolving the issue. **Voting Options:** • **VOTE to recommend for time-limited endorsement on the condition that STS changes the numerator from 24 hours to 72 hours - 12/12** • **VOTE to not recommend - 0**
PCS-015-09 **Post-operative renal failure requiring dialysis at hospital discharge** **(Society of Thoracic Surgeons)** RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Importance:** • An important point to note is that the variable refers specifically to the status at the time of discharge (or death). The Committee suggested looking specifically at the patients who require mechanical circulatory support going forward with attention to incidence of renal failure. Another issue is that this complication is quite uncommon. • The complication is rare, but it is an enduring complication and it is important to note when it occurs for quality improvement purposes. **Scientific Acceptability:** • With regard to the specified exclusions, they are not included in the first place. Patients who had pre-operative renal failure are excluded; on the subset these individuals are excluded. **Usability:** • The numbers associated with this are very small; children tend to die when sent home on dialysis. From a public reporting perspective, it is a very small number. • From a quality metric standpoint, it is important to follow this complication independent of mortality even though they are coincidences. As a quality indicator, it is important to know that there are renal failures even if the patients expire. If renal failure is not a component of the reasons people die, the two variables will segregate at

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#PCS-015-09 (cont'd)	H	H	H	H	some point. This measure is important as a quality indicator, not necessarily as a public reporting mechanism. If it shows up as un-reportable because it never happened, then it is not useful for public reporting. • When the numbers become fractions and lower, it doesn't mean it is not important, but the public reporting value of it will no longer be there. • The Committee considered recommending that this and the other complication measures be aggregated into a complications composite of some sort. • One Committee member, who is a parent of a child with a congenital heart defect, expressed that prior to her child's surgery she would not have thought to look for this type of measure. However, having been through the experience of her child's surgery, this type of measure would be of importance. • There was some discussion of who the public encompasses. There are many dimensions of the "public." The public may be health professionals, families, insurers, etc. • Time-limited endorsement will give the measure developer enough time to test and determine the rate of incidence relative to the small numbers issue. **Feasibility:** • This complication is already tracked in the STS database and gives the opportunity to compare institutions in the country. **Response from Measure Developer:** • Pediatric patients can go home on dialysis, which may cost the healthcare system a lot of money; it is important to track. When discussing complications and frequency, a risk of 1-4% may not be much different from 1-3%, but it still impacts quality of life. • The measure developer would like to consider a composite including this measure in the future, but it would also like to list each measure individually to be transparent to those receiving the scores. **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**

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PCS-016-09 Arrhythmia necessitating permanent pacemaker insertion (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	M	H	H	**Importance:** • The Committee discussion focused on the indications for pace maker placement and how it is variable from time to time. For the most part, indications for a pacemaker for an arrhythmia are not as controversial from center to center. **Scientific Acceptability:** • This outcome measure is not stratified or risk-adjusted. **Response from Measure Developer:** None. **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**
PCS-017-09 Surgical re-exploration (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMTED ENDORSEMENT (WITH TITLE CHANGE)					**Scientific Acceptability:** • The Committee suggested to the measure developer that not only re-operation but also catheter-based re-intervention should be included in the numerator because there are now capabilities to deal with these problems (inadequately repaired, etc.). • There was a consensus that post-operative catheterization interventions should be included along with re-operations following an initial cardiac surgical intervention. • The title is a problem and does not convey the measure. **Feasibility:** • The Committee generally agreed that the measure is feasible, and STS indicated that these data were already being collected in the STS database. **Response from Measure Developer:** • There was a consensus that post-operative catheterization interventions should be included along with re-operations following an initial cardiac surgical intervention. The measure developer agreed with this amended version and agreed to change the title to “Unplanned cardiac intervention during cardiac surgery.” Then all three points would be satisfied.

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					Voting Options: • **VOTE to recommend for time-limited endorsement on the condition that STS changes the title to "Unplanned post-operative re-Intervention" and that STS changes the description and numerator to reflect the verbiage change in the title and add cardiac cauterizations to interventions in the numerator - 12/12** • **VOTE to not recommend - 0**
PCS-018-09 Operative mortality with complexity (Society of Thoracic Surgeons)	H	H	H	H	**Importance:** • There was general consensus among the Steering Committee that this measure is important to calculate and report. **Scientific Acceptability:** • The Committee recognized that there are three different risk-stratification systems that have essentially equivalent predictive power as reflected in the c-statistic (area under the receiver operator curve). The measure gives the user the option to select the stratification tool from Aristotle, STS-EACTS, or RACHS-1. • Concerns were raised about the ease of use and comparability for public use if there are multiple user options for complexity, resulting in varied results (for the same measure) and thus more than one way of determining the outcomes. The consensus was that the three different risk-stratification systems each have their own strengths and weaknesses, and the measure developer will report results by each system. **Usability:** • No comments. **Feasibility:** • The Committee stated that adult cases should be captured with ICD-9 codes as well. Codes that would apply to adults would also apply to this measure as well. **Response from Measure Developer:** • When preparing this measure, which is derived from the STS database, the measure developer understood that NQF staff required CPT Codes. The measure developer is in no way held to leaving the CPT codes in the measure.

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					Voting Options: • **VOTE to recommend for time-limited endorsement on the condition that STS changes from CPT codes to ICD-9 codes - 12/12** • **VOTE to not recommend - 0**
PCS-019-09 Operative mortality for six benchmark operations (Society of Thoracic Surgeons) RECOMMENDED FOR TIME-LIMITED ENDORSEMENT	H	H	H	H	**Importance:** • The general consensus of the Committee was that operative mortality was an important indicator of outcomes of congenital heart surgery. **Scientific Acceptability:** • The weakness in this measure is the assumption that this is relatively raw mortality as opposed to risk-adjusted mortality. **Usability:** • The question was raised about the value of these procedural mortality rates versus the overall risk-adjusted mortality. • There was general agreement that this type of data would be of significant interest and may be easier for the lay public to understand. • In relation to small numbers, this issue may be remedied by the fact that the measure is cumulative. The user can look at a rolling four years and get cumulative results with more cases. **Comments:** • The Committee proposed that a revised version of this measure be developed with risk-adjustment. **Response from Measure Developer:** None. **Voting Options:** • **VOTE to recommend for time-limited endorsement - 12/12** • **VOTE to not recommend - 0**
#PCS-020-09 Operative survival free of major complication (Society of Thoracic Surgeons)					**Scientific Acceptability:** • This measure can be stratified by any one of three complexity tools (EACTS-STS, RACHS-1, and Aristotle). • The patient has to go home alive to be included in this measure. • The denominator does not explicitly state that this measure only applies to those who survive the operative period and go home alive. The developer will adjust the language of the denominator to make this

# / Title/ Owner	I	SA	U	F	Steering Committee Comments and Recommendation
RECOMMENDED FOR TIME-LIMITED ENDORSEMENT					clearer. **Usability:** • This would be a useful composite outcome measure for this type of surgery because it encompasses all of the major complications. • It is very important for families to know the likelihood that the child will not have complications and the likelihood that the child will survive. • The differences between this measure and each of the individual complication measures are that this measure is a composite of all of them, is stratified, and calculates survival rather than death or complications. **Response from Measure Developer:** • This measure does not solely apply to those who go home alive; it can be modified to include that in the denominator. **Voting Options:** • **VOTE to recommend for time-limited endorsement on the condition that STS rewords the denominator to exclude patients who don't survive - 12/12** • **VOTE to not recommend - 0**
PCS-021-09 Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) (Children's Hospital Boston)	M	M	M	M	**Importance:** • Risk-adjusted mortality was recognized as a very important outcome variable. **Scientific Acceptability:** • The strengths and weaknesses of this approach were discussed at length. It was noted that the predictive value of the RACHS had a high C-statistic of 0.8 (area under the ROC). • The Committee was reluctant to select one of the stratification tools (STS-EACTS, Aristotle, RACHS) as the best tool because the field is still determining this. Across the field there is varied use of these tools within programs. Their differences are based on the type of data; some are based on expert opinion. The Committee agreed that the best tool will be naturally selected with more use of the tools. **Usability:** • It was noted that the RACHS is based on administrative claims data, which has documented accuracy limitations in both the adult and pediatric cardiac realms.

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					Feasibility: • There were some concerns about the level of biostatistical support necessary for implementation of this approach, but it was noted that the new version of the STS Congenital Database would allow this outcome to be calculated through the STS database. The measure developer indicated that this system could be used with more than one dataset. **Comments:** • The small work group never reached a decision on the recommendations for the measure. The work group focused on a fair approach and on harmonization with PCS-018-09. There were suggestions that this measure be harmonized with PCS-018-09 so that the SMR can be calculated using the RACHS-1, Aristotle, and STS-EACTS methods. The measure developer responded to this suggestion by stating that they do not understand what needs to be submitted because testing hasn't been done yet by STS and there are no data. • NQF reminded the Committee/work group that they must evaluate the measure as presented. Harmonization would require new development and testing and a decision between the two developers about who would own and steward the measure. Both developers are willing to talk one another in order to bring it back to the Committee for discussion. • The work group agreed that it does not know the best risk-adjustment/stratification method among RACHS, STS-EACTS, and Aristotle. Neither does the field; in many years science alone will determine which system is better. To make a selection now without the benefit of a natural selection by the field may be the wrong move for the Committee. **Response from Measure Developer:** • An standard mortality rate can be a part of either PCS-018-09 or PCS-021-09, which may result in users picking which form of measurement they want to use and base payment upon. • The measure developer proposed adding an SMR to PCS-018-09, as opposed to adding PCS-018-09 to PCS-021-09. • A measure that calculates observed to expected mortality is a useful tool and is used in the STS adult database in the fall 2008 reports as well as in the neonatal database.

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					• Another issue is whether outcome reporting by complexity stratification should rely on one, two, or three stratification tools. The Committee's vote on PCS-018-09 implies that it thinks it is important to have more than one. It is possible for CHB and STS to work together. It is not difficult to calculate the mortality ratio based on STS or Aristotle if data for a set for expected mortality are derived. If expected mortality can be sorted, then CHB and STS can develop an SMR using all three complexity tools. • Dr. Jenkins (CHB developer) would work with Drs. Marshall and O'Brien to revise this metric. Dr. Jenkins would be the primary steward. They must re-work and re-submit the measure. • PCS-021-09 does not require participation in a database, and CHB was careful to put wording in the specifications to explain this. **Voting Options:** • **VOTE to recommend for time-limited endorsement on the condition that CHB works with STS to harmonize the risk-adjustment and stratification methodologies. The measure will be re-reviewed by the Committee once it is harmonized. - 12/12** **VOTE to not recommend - 0**

Additional Recommendations:

The Committee recommended that a more comprehensive medication administration measure be developed and proposed in lieu of combining PCS-010-09 Timing of antibiotic administration for pediatric and congenital cardiac surgery patients (STS) and PCS-011-09 Selection of antibiotic administration for pediatric and congenital cardiac surgery patients (STS).

AFTERWORD:

The conditions for recommendation were met by STS developers. After this meeting, eight of the 21 submitted measures (seven outcome, and one structural) were withdrawn by the developer (PCS-009-09, PCS-013-09, PCS-014-09, PCS-015-09, PCS-016-09, PCS-017-09, PCS-019-09, and PCS-020-09). The seven outcome measures were submitted without risk adjustment or rationale and analysis supporting no risk adjustment. The developers agreed the measures need risk adjustment and withdrew them from further consideration at this time. In an effort to standardize PCS-018-09 and improve comparability, NQF asked the measure developer to select one method of risk-stratification and resubmit the measure with support of this method. At that time, both developers were also given the opportunity to submit additional information to further support the reliability and validity of their measure submissions. The Steering Committee was subsequently asked to re-evaluate the 13 remaining measures. The CHB mortality measure was reconsidered with the initial specifications, and initial conditions for recommendation were removed. The details of this subsequent evaluation of the 13 measures are reflected in the May 17, 2010 meeting summary and draft report available on the Pediatric Cardiac Surgery project page.