NATIONAL QUALITY FORUM

TO: NQF Members

FROM: NQF Staff

RE: Voting for *National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report*

DA: October 15, 2010

This draft report is for the National Quality Forum's (NQF's) Pediatric Cardiac Surgery Project. This project seeks to identify and endorse quality measures that specifically address the pediatric cardiac surgery population for public reporting and quality improvement.

In an effort to understand the full implications of this process for NQF and other relevant stakeholders, NQF convened a Steering Committee comprised of 12 experts in the field to evaluate submitted measures and to make recommendations across the spectrum of pediatric cardiac surgery. As part of the Steering Committee's work, the group evaluated measures regarding the topic areas of mortality, programmatic structure, and antibiotic use. The Steering Committee ultimately recommended 2 measures for endorsement and 11 for time-limited endorsement.

COMMENTS AND REVISED DRAFT REPORT

The comment period for the draft document, *National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report*, concluded on September 7, 2010. NQF received 43 comments from 11 organizations. The distribution of comments from organizations by Member Councils is as follows:

Consumers-0	Health Professionals-6
Purchasers-0	Public Health/Community-0
Health Plans-0	QMRI-1
Providers-1	Supplier and Industry-0
Non-members-3	

All measure-specific comments were forwarded to the measure developers, who were invited to respond. A table of detailed comments submitted during the review period, with responses and actions taken by the Steering Committee, is posted on the Pediatric Cardiac Surgery project webpage. Revisions to the draft report and the accompanying measure specifications table (Appendix A) have been made using the track changes functionality.

NATIONAL QUALITY FORUM

COMMENTS AND THEIR DISPOSITION

In general, comments were supportive of the report and the Committee's recommendations. General comments on the report expressed concern with the use of administrative data versus clinical data for measurement. Measure-specific comments typically addressed the lack of specificity, exclusion criteria, and the level of analysis of some measures. The strengths and weaknesses of competing mortality measures PCS-021-09 and PCS-018-09 were also addressed in the comments. These topics were discussed by the Committee and are summarized below.

General Comments

Claims-based versus clinically-based databases
One comment on the measures focused on the use of administrative claims data versus clinical data for measurement and weighed the benefits of clinically based measures over claims-based measures.

> *Action Taken:* Given the current environment and the growing use of electronic health records, NQF supports the endorsement of both claims-based and clinically based measures.

Measure-Specific Comments

PCS-002-09: Multidisciplinary preoperative planning conference (STS)

One comment addressed the lack of specificity of this measure in identifying the components of this conference.

> *Action Taken*: After some discussion, the Committee affirmed its previous rationale for recommending the measure for endorsement and agreed that the measure is sufficient "as is." The Committee preferred that the specifications for the conference components allow for institutional variation in practice.

PCS-003-09: Multidisciplinary rounds involving multiple members of the healthcare team (STS)

Similar to the comment above for PCS-002-09, one comment addressed the lack of specificity of this measure in identifying what should take place during the rounds. The comment also noted that this measure would be most useful as a process measure but recognized the challenge in implementing it as such.

> *Action Taken*: The Committee agreed that the measure is sufficient "as is" and preferred that the specifications for the rounds components allow for institutional variation in practice. The Committee agreed that specifying this measure as a process measure would be very difficult and not feasible within the timeframe of this project.

PCS-004-09: Regularly scheduled quality assurance and quality improvement cardiac care conference (STS)

Similar to the comment above for PCS-002-09 and PCS-003-09, one comment addressed the lack of specificity of this measure in identifying what should take place in a quality assurance and quality improvement conference.

> *Action Taken*: The Committee agreed that the measure is sufficient "as is" and preferred that the specifications for the conference components allow for institutional variation in practice.

PCS-005-09: Availability of intraoperative transesophageal echocardiography (TEE) and epicardial echocardiography (STS)

One comment addressed the usefulness of this measure as a structure measure as specified rather than a process measure. Additionally, the comment noted that epicardial echocardiography should be available for use by facilities when TEE is contraindicated.

> *Action Taken*: The Committee discussed the re-specification of this measure as a process measure; however, it is not feasible within this timeframe for this project. The measure developer agreed to modify the measure title and description to reflect the availability of epicardial echocardiograhpy when TEE is contraindicated (see Appendix A).

PCS-010-09: Timing of antibiotic administration for pediatric and congenital cardiac surgery (STS)

A primary concern with this measure was the exclusion from the denominator of cases with incomplete documentation. It was argued that such cases should be excluded from the numerator instead of the denominator because incomplete documentation signals a need for quality improvement.

> *Action Taken*: The measure developer agreed to modify the measure description and numerator statement to denote that the measure only includes those cases with documentation of antibiotic administration (see Appendix A).

PCS-011-09: Selection of appropriate prophylactic antibiotics and weight-appropriate dosage for pediatric and congenital cardiac surgery patients (STS)

One comment noted that the measure title does not reflect the measure description and recommended that the title be changed to more accurately reflect the measure's intent. There was also concern about the measure's lack of flexibility to change as the list of approved antibiotics changes over time. As noted above, the exclusion from the denominator of patients for whom there is inadequate documentation of antibiotic administration was of concern.

> *Action Taken*: The measure developer recognized that it will be a challenge to maintain the measure's list of approved antibiotics and agreed to modify the description and numerator to reflect the intent of the measure and to denote that it measures only those cases with documentation of antibiotic administration (see Appendix A).

PCS-012-09: Use of an expanded pre-procedural and post-procedural time-out (STS)
One comment noted that this measure would be most useful as a process measure and should include a checklist as an implementation tool.

> *Action Taken*: The Committee and measure developer agreed that specifying this measure as a process measure would be most useful; however, doing so is not feasible within the timeframe of this project.

PCS-021-09: Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1 method) [Children's Hospital Boston (CHB)]
Two comments noted that this measure as specified could not be supported as an accountability measure at the clinician level.

> *Action Taken*: The measure developer agreeed and modified the specifications to indicate that this measure is recommended for use at the facility level only (see Appendix A).

COMPETING MEASURES
The draft report called for comments on competing measures for volume and mortality. However, the submitted comments only addressed 2 of the 3 competing mortality measures (PCS-018-09 and PCS-021-09) and did not address the 3 competing volume measures. After discussion with the Steering Committee co-chairs and internal NQF review, all measures will be moved forward for member voting.

NQF MEMBER VOTING
Information for electronic voting was sent to NQF Member primary contacts. Accompanying comments must be submitted by e-mail to pediatriccardiacsurgery@qualityforum.org. The e-mail must identify submitter, organization, and the specific ballot item that the comments accompany.

All votes must be submitted no later than 6:00 pm ET, November 15, 2010.

Thank you for your interest in this Consensus Development Project.

NATIONAL QUALITY FORUM

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PEDIATRIC CARDIAC SURGERY: A CONSENSUS REPORT

DRAFT REPORT FOR MEMBER VOTING

NATIONAL QUALITY FORUM

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PEDIATRIC CARDIAC SURGERY: A CONSENSUS REPORT

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EXECUTIVE SUMMARY

Heart defects are among the most common birth defects and are the leading cause of birth defect-related deaths in the United States.[1] Each year, about 35,000 infants (1 out of every 125) are born with heart defects.[2] Quality improvement strategies must be aimed not only at further reduction of mortality but also at efficient use of resources and reduction of morbidities to the maximum extent possible.

Performance measurement for healthcare quality reporting and improvement have to date focused largely on the adult population, but there are growing interest and momentum to include pediatric measures in these efforts. The National Quality Forum (NQF) has endorsed measures specific to adult cardiac surgery, pediatric heart surgery volume, and pediatric heart surgery mortality. Quality improvement strategies for pediatric cardiac surgery will benefit from specific measures aimed at further reduction of mortality, efficient use of resources, and reduction of morbidities. These goals are also directly aligned with the National Priorities Partnership's priority for safety.

In an effort to understand the full implications of measurement in this population, NQF convened the 12-member Pediatric Cardiac Surgery Committee to evaluate measures and to make recommendations across the spectrum of pediatric cardiac surgery. The Steering Committee considered measures in the topic areas of mortality, programmatic structure, and antibiotic use. This report presents the results of the re-evaluation of 13 measures considered under NQF's Consensus Development Process (CDP). Two measures are recommended for endorsement and 11 measures for time-limited endorsement as voluntary consensus standards suitable for public reporting and quality improvement.

1. Kochanek KD, Murphy SL, Anderson RN, et al., Deaths: Final data for 2002, *Natl Vit Stat Rep*, 2004;53(5):1-115.
2. National Heart, Lung, and Blood Institute (NHLBI), *Congenital Heart Defects*, Bethesda, MD: NHLBI; 2009. Available at www.nhlbi.nih.gov/health/dci/Diseases/chd/chd_what.html. Last accessed August 2010.

Measures Recommended for Endorsement

- PCS-018-09: Operative mortality stratified by the five STS-EACTS Mortality Levels (Society of Thoracic Surgeons [STS])
- PCS-021-09: Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1 method) (Children's Hospital Boston [CHB])

Measures Recommended for Time-Limited Endorsement

- PCS-001-09: Participation in a national database for pediatric and congenital heart surgery (STS)
- PCS-002-09: Multidisciplinary preoperative planning conference (STS)
- PCS-003-09: Multidisciplinary rounds involving multiple members of the healthcare team (STS)
- PCS-004-09: Regularly scheduled quality assurance and quality improvement cardiac care conference (STS)
- PCS-005-09: Availability of intraoperative transesophageal echocardiography (TEE) and epicardial echocardiography (STS)
- PCS-006-09: Availability of institutional pediatric ECLS (extracorporeal life support) (STS)
- PCS-007-09: Surgical volume for pediatric and congenital heart surgery (STS)
- PCS-008-09: Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS Mortality Levels (STS)
- PCS-010-09: Timing of antibiotic administration for pediatric and congenital cardiac surgery (STS)

- PCS-011-09: Selection of appropriate prophylactic antibiotics and weight-appropriate dosage for pediatric and congenital cardiac surgery patients ~~Selection of antibiotic administration for pediatric and congenital cardiac surgery patients~~ (STS)
- PCS-012-09: Use of an expanded pre-procedural and post-procedural time-out (STS)

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PEDIATRIC CARDIAC SURGERY: A CONSENSUS REPORT

BACKGROUND

Heart defects are among the most common birth defects and are the leading cause of birth defect-related deaths in the United States.[3] Each year, about 35,000 infants (1 out of every 125) are born with heart defects.[4] Other children will develop acquired heart disease, including such conditions as arrhythmias, cardiomyopathies, Kawasaki disease, and rheumatic fever. Because of advances in diagnosis and surgical treatment of these children, the mortality rate related to surgery has decreased dramatically. Today, about 1.4 million children and adults are living with congenital heart defects.[5] And yet, a retrospective cohort study from 1992 to 1996 revealed that children with Medicaid insurance have a higher risk of dying after congenital heart surgery than those with commercial and some managed care insurance, likely because of barriers to accessing care and differential referral patterns.[6] This is significant because more than 20 million, or 25 percent, of children in the United States rely on Medicaid and SCHIP (State Children's Health Insurance Program) for health insurance coverage. Furthermore, many survivors experience morbidities that impact dramatically on their quality of life and that of their family members and on the consumption of resources, and consequently on the ultimate costs of healthcare, which are borne by society as a whole. Quality improvement strategies must be aimed not only at further reduction of mortality but also at efficient use of resources and reduction of morbidities to the maximum extent possible. Indeed, annual national charges for care currently exceed $2.2 billion for inpatient congenital cardiac surgery.[7]

National efforts to promote accountability and improvement in healthcare through performance measurement and reporting have focused largely on the adult population, but there are growing interest and momentum to include pediatric measures in these efforts. In September 2006 the Centers for Medicare & Medicaid Services issued a compendium containing primarily adult, but some pediatric, quality measures in broad categories to support states' programmatic needs in the areas of quality-based purchasing or pay-for-performance, public reporting, quality improvement, service delivery, benchmarking, and program/plan monitoring. Among the measures in the compendium was

a measure of pediatric cardiac surgery mortality developed by the Agency for Healthcare Research and Quality.[8]

In October 2009, the 12-member Pediatric Cardiac Surgery Steering Committee (Appendix B) met in person to evaluate 21 measures in the topic areas of mortality, programmatic structure, and antibiotic use and to make recommendations across the spectrum of pediatric cardiac surgery performance measurement. After the meeting, eight of the measures (seven outcomes, 1 structure) were withdrawn by the developers. The seven outcome measures were submitted without risk-adjustment or a rationale and analysis to support the lack of risk-adjustment. The developers agreed that the measures need risk-adjustment and withdrew them from further consideration at this time.

Both developers were also provided an 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.

This report presents the results of the re-evaluation of the remaining 13 measures, 2 of which are recommended for endorsement and 11 of which for time-limited endorsement as voluntary consensus standards suitable for public reporting and quality improvement.

STRATEGIC DIRECTIONS FOR NQF

NQF's mission includes three parts: 1) setting national priorities and goals for performance improvement, 2) endorsing national consensus standards for measuring and publicly reporting on performance, and 3) promoting the attainment of national goals through education and outreach programs. As greater numbers of quality measures are developed and brought to NQF for consideration of endorsement, it is incumbent on NQF to assist stakeholders to "measure what makes a difference" and address what is important to achieve the best outcomes for patients and populations. For more information see www.qualityforum.org/projects/pediatric-cardiac-surgery.aspx.

Several strategic issues have been identified to guide consideration of candidate consensus standards:

DRIVE TOWARD HIGH PERFORMANCE. Over time, the bar of performance expectations should be raised to encourage achievement of higher levels of system performance.

EMPHASIZE COMPOSITES. Composite measures provide much needed summary information pertaining to multiple dimensions of performance and are more comprehensible to patients and consumers.

MOVE TOWARD OUTCOME MEASUREMENT. Outcome measures provide information of keen interest to consumers and purchasers, and when coupled with healthcare process measures, they provide useful and actionable information to providers. Outcome measures also focus attention on much-needed system-level improvements, since achieving the best patient outcomes often requires carefully designed care process, teamwork, and coordinated action on the part of many providers.

CONSIDER DISPARITIES IN ALL THAT WE DO. Some of the greatest performance gaps relate to care of minority populations. Particular attention should be focused on identifying disparities-sensitive performance measures and on identifying the most relevant race/ethnicity/language strata for reporting purposes.

NATIONAL PRIORITIES PARTNERSHIP

NQF seeks to endorse measures that address the National Priorities and Goals of the NQF-convened National Priorities Partnership.[9] The National Priorities Partnership represents those who receive, pay for, provide, and evaluate healthcare. The National Priorities and Goals focus on these areas:

- equitable access
- patient and family engagement,
- population health,
- safety,
- care coordination,
- palliative and end-of-life care,
- overuse, and
- infrastructure support.

NQF'S CONSENSUS DEVELOPMENT PROCESS (CDP)

The purpose of the National Voluntary Consensus Standards for Pediatric Cardiac Surgery project is to identify and endorse measures for public reporting and quality improvement related to pediatric cardiac surgery processes, structure, and patient outcomes. It will establish national, multi-stakeholder voluntary consensus on performance standards that are ready for immediate implementation, as well as on recommendations for priority areas for research and measure development.

Evaluating Potential Consensus Standards

This report presents the re-evaluation of 13 pediatric cardiac surgery measures. Candidate consensus standards were solicited through a Call for Measures on July 31-August 31, 2009, and were actively sought through searches of the National Quality Measures Clearinghouse, NQF Member websites, and an environmental scan. NQF staff contacted potential measure stewards to encourage submission of measures for this project.

The measures were evaluated using NQF's standard evaluation criteria.[10] The 12-member, multi-stakeholder Steering Committee provided evaluations of the four main criteria: importance to measure and report, scientific acceptability of the measure properties, usability, and feasibility, as well as the recommendation for endorsement. Measure developers responded to Committee questions and clarified any issues or concerns.

RELATIONSHIP TO OTHER NQF-ENDORSED CONSENSUS STANDARDS

This report does not represent the entire scope of NQF work relevant to pediatric patients. To date, NQF has endorsed more than a sixty quality measures specific to pediatric patients through past projects and continues work in this area with upcoming projects:

- Hospital Care: Additional Measures (2007)
- Perinatal Care (2008)
- Child Health Outcomes (Patient Outcomes Measures-Phase III) (2009)
- Child Health Quality Measures Project (2010)

RECOMMENDATIONS FOR ENDORSEMENT

This report presents the results of the re-evaluation of 13 measures considered under NQF's CDP (see Appendix A for detailed specifications). Two measures are recommended for endorsement and 11 are recommended for time-limited endorsement as national voluntary consensus standards suitable for public reporting and quality improvement.

Competing Measures

~~NQF has previously endorsed pediatric cardiac surgery measures of volume (#0340) and mortality (#0339). For this project, measures similar to these were recommended by the Steering Committee. NQF aims to have a portfolio of parsimonious and harmonized endorsed measures that represent the best-in-class, and typically does not endorse multiple measures with the same focus and target population. As such, the Steering Committee is seeking comment on these competing measures and will be asked to make recommendations for best-in-class for the measures considered following this comment period. Appendix C provides a side-by-side comparison of the endorsed and submitted measures.~~

~~Two outcome measures were submitted to this project: one a measure of operative mortality stratified by the STS-EACTS complexity tool (PCS-018-09), and the other a standardized mortality ratio (SMR) (PCS-021-09) using the RACHS-1 method in a statistical risk-adjustment model. Although these measure similar outcomes in the same population of patients, as per NQF procedure, the measures were evaluated and recommended for endorsement based on their individual merits and how well they meet the evaluation criteria. These two submitted measures are similar to each other and to the endorsed measure #0339. Despite the different approaches to measuring volume,the two submitted volume measures, PCS-007-09 and PCS-008-09 (volume stratified by complexity) are also similar to each other and endorsed measure #0340 in that they each measure volume in the same population. While similar, the Committee did consider whether both the volume and mortality competing measures could co-exist as endorsed measures.~~

NQF generally prefers to endorse one measure for a specific focus and target population unless there is a justification for endorsing multiple measures. The NQF evaluation process calls for a competing measures to be evaluated first individually on the four criteria to determine if it is suitable to be recommended for endorsement and then compared to competing measures. If multiple measures meet the criteria, they are compared to determine best in class or, to determine, whether there is justification for more than one measure.

In 2008 NQF endorsed pediatric cardiac surgery measures of risk-adjusted mortality (0339 by the Agency for Health Research and Quality [AHRQ]) and of volume (0340 by AHRQ). During this current project, the Steering Committee recommended the following similar mortality and volume measures (See Appendix C for detailed specifications of competing measures):

- PCS-018-09: Operative mortality stratified by the STS-EACTS Mortality Levels (STS)
- PCS-021-09: Standardized mortality ratio for congenital heart surgery, RACHS-1 method (CHB)
- PCS-007-09: Surgical volume for pediatric and congenital heart surgery
- PCS-008-09: Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS Mortality Levels (STS)

Although these measures focus on the same outcome (or volume) in the same target population of patients as do the endorsed measures, they include some differences in data source, exclusion, and risk--adjustment methodology.

Justification for Multiple Measures

In comparing the competing mortality measures, the STS measure (PCS-018-09) is based on clinical data submitted according to the STS registry specifications; it produces a 30-day mortality rate for each European Association for Cardio-Thoracic Surgery (EACTS) risk category. The CHB measure (PCS-021-09) is based on either claims data or clinical record data; it is risk--adjusted and produces an in-hospital standardized mortality ratio. The endorsed AHRQ measure (0339) is based on claims

data and produces an in-hospital risk--adjusted mortality rate per 1,000 patients. Ideally, NQF would prefer to endorse the measure that provides the best representation of quality of care. Unfortunately, there is no definitive way to make that determination at this time. Evidence of risk model validation was presented for all three measures. The reported C-statistics indicate adequate discrimination: STS measure: 0.778-0.812; CHB measure: 0.809-0.854; AHRQ measure: 0.875.

The differences in the volume measures also lie in the data sources and the methodologies used. Endorsed measure #0340 is a measure of raw volume using administrative claims data. Most similar to this measure is submitted measure PCS-007-09, which also measures raw volume, but uses registry data. The third volume measure, PCS-008-09, stratifies volume for the five EACSTS risk categories and uses registry data.

After review and consultation with the Steering Committee and CSAC Co-Chairs, all of the measures are recommended to move forward for member voting. In addition to the above considerations, there is a noted lack of consensus on the best methodology, and no new information emerged from the public comment period. In the current environment without widespread adoption of electronic health records that are capable of using clinical data to generate quality measure scores, the competing interests of having a standardized measure and promoting widespread public reporting and improvement on quality need to be weighed. Measures based on different data sources may be needed to promote the greatest scope of measurement and improvement. Currently, head-to-head comparisons of measures based on different data sources are generally not feasible. There is also an urgent need to place volume and mortality data for pediatric cardiac surgery into public view, even though there is not objective evidence to support one proposed measure over another.

The NQF three-year maintenance cycle allows for time to use measures in the field and to gather additional evidence and data about their use for analysis and re-evaluation at the time of endorsement maintenance review. As part of the endorsement maintenance cardiovascular project, the AHRQ PDI 6 mortality measure (0339) will be reviewed within the coming months in the context of this Committee's discussions and challenges and along with any revisions and data about its current use.

Candidate Consensus Standards Recommended for Endorsement

PCS-018-09 Operative mortality stratified by the five STS-EACTS Mortality Levels *Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool* (STS)

The initial specifications for this operative mortality measure were reviewed during the October 2009 Steering Committee meeting and included three methods for stratifying or adjusting the population (Aristotle, RACHS-1, and STS-EACTS), allowing the user of the measure to select the method for each use. However, in an effort to standardize this measure and to improve comparability, NQF asked the measure developer to select one method of risk-stratification and to resubmit the measure with support of the method. The measure that is presented in this report was resubmitted by the developer as a measure of operative mortality within 30 days after surgery or prior to discharge for patients who undergo pediatric and congenital open heart surgery, stratified for complexity using only the STS-EACTS Mortality Levels. The use of this measure relies on the STS registry database staff or statisticians to calculate the mortality for each level of complexity. The Committee agreed that understanding of comparative mortality following congenital and pediatric cardiac surgery across institutions is immensely important. The Committee also emphasized the importance of capturing post-discharge mortality, especially for distant referrals, which needs to be assured for this measure to work. The Committee ultimately recommended this measure for endorsement based on the agreement that the measure is important for the field.

PCS-021-09 Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) method *Adjusted ratio of observed to expected rate of in-hospital mortality following surgical repair of congenital heart defect among patients <18 years of age, risk-adjusted using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method* (CHB)

This measure uses the RACHS-1 system of risk analysis to compute an observed-to-expected (O/E) standardized mortality ratio (SMR). A score of greater than 1.0 indicates that the observed mortality is greater than the expected mortality. The risk analysis method (RACHS-1) incorporates five clinical characteristics: six predefined risk categories, age at surgery, prematurity, presence of a major non-cardiac structural anomaly, and combinations of cardiac procedures performed. The data required for this measure can be collected through manual chart abstraction or administrative data (ICD-9-CM codes) to determine the RACHS-1 score. During its initial evaluation of this measure in October

2009, the Committee voted to recommend this measure for endorsement on the condition that the risk analysis method used in the SMR is harmonized with the three methods used in the initial submission for PCS-018-09. The Committee was reluctant to determine a best-in-class among these three methods (Aristotle, RACHS-1, and STS-EACTS), given that the field has yet to determine which method is best.

The Committee expressed concerns about the use of administrative data to calculate this measure and noted references that have demonstrated the shortcomings of the use of administrative data in congenital heart disease. The concerns about data also extended to potential issues resulting from the conversion from ICD-9-CM to ICD-10-CM/PCS codes; however, the measure developer confirmed that this mapping process has already begun and no major issues are anticipated. This measure was ultimately recommended for endorsement without conditions following its second review.

During the comment period, the issue of administrative data versus clinical data was raised again in a comparative analysis between this measure and PCS-018-09. In response to this comment, the developer pointed out that this measure has been tested in both administrative databases and clinical databases such as the Pediatric Cardiac Care Consortium (PCCC) data-base and has been specified and tested using both types of data with comparable results. Other comments expressed concern with the level of analysis indicated for this measure, which was specified at all levels. Upon review of the comment, the developer agreed that mortality should not be attributed at the surgeon level and changed the measure submission form to indicate that it should only be applied at the facility level. The developer also responded to detailed comments submitted via letter, all of which are available on the project webpage for review.

Candidate Consensus Standards Recommended for Time-Limited Endorsement

These untested measures were submitted prior to the December 2009 policy change restricting time-limited endorsement. Should these measures be endorsed, testing results must be submitted within 12

months. The Steering Committee recommended 11 of the submitted measures for time-limited endorsement. These measures include both structure and process measures.

Structure Measures

Each of the following structure measures seeks to measure quality at the programmatic level, not at the patient level. They are dichotomous and require a "Yes" or "No" response to complete the measure.

PCS-001-09 Participation in a national database for pediatric and congenital heart surgery
Participation in at least one multi-center, standardized, data collection, and feedback program that provides benchmarking of the physician's data relative to national and regional programs and uses process and outcome measures (STS)

This structure measure requires a "Yes" or "No" response to whether the facility or program participates in a national database for pediatric and congenital heart surgery. Based on the condition for recommendation put forth by the Committee at the October 2009 meeting, "participation" is defined as "submission of all congenital and pediatric operations performed by the database." The Steering Committee agreed that this activity is important to measure and report. Research has shown that participation in multi-institutional databases/registries improves patient outcomes. Given the volume of pediatric surgeries performed, the Committee agreed it is important to track them via a database and to collect feedback as to what types of interventions increase the likelihood of positive outcomes, which enhances the ability to identify opportunities for improvement. Although the measure does not specify the sole use of the STS registry, the measure developer noted that the STS registry database is already used by a large number of programs and includes more than 90 percent of the active programs in the United States. Although the Committee members agreed that this measure is feasible for those who already participate in the STS database, and that the required information is most likely already maintained within the institutions, several expressed concern that it may be more difficult for smaller institutions to adhere to this measure. Other members raised concerns about how the submission of data to a registry would work with electronic health records (EHRs), as well as about the expenses that might be incurred to implement a measure that requires a high level of administrative commitment. This measure was recommended for time-limited endorsement by the Committee.

PCS-002-09 Multidisciplinary preoperative planning conference *Occurrence of a pre-operative multidisciplinary planning conference to plan pediatric and congenital heart surgery cases. This conference will involve multiple members of the healthcare team, with recommended participation including but not limited to cardiology, cardiac surgery, anesthesia, and critical care.* (STS)

The intent of this measure is to determine whether a facility or program has in place a multidisciplinary pre-operative planning conference involving multiple members of the healthcare team. Although this type of conference has not been evaluated in research studies, the Steering Committee thought it was reasonable to expect that this type of conference would allow for issues to be aired and discussed before surgery is performed, leading to better outcomes. Due to the lack of evidence supporting the relationship of this structure measure to an outcome at this point, support for importance is based on expert opinion. Experts on the Committee agreed that pre-operative conferences enhance both the process of the operation and the education for trainees. The Committee raised the question of what constitutes this type of meeting. Furthermore, it was unclear from the measure specifications which components of this meeting should be in place before an institution can answer "Yes." As such, the ratings for scientific acceptability varied widely among the Committee members. Most Committee members thought that because of its dichotomous structure this measure will be fairly simple to implement. However, the Committee agreed that some type of record of the meeting must be maintained to enable assessment of the measure and monitoring of the extent to which cases are discussed. This type of record would not necessarily be available from electronic sources unless there is a hospital-specific documentation requirement. The Committee agreed that these types of meetings are important for institutions to implement, but, without more specific specifications, ensuring that standards for conferences are maintained across centers will be challenging. NQF received comments that echoed this concern and requested additional guidance in the specifications on the frequency and the components of this meeting. In order to allow flexibility for facility variations in practice the Committee maintained that the components of this meeting be left up to the individual institution. One comment suggested that family members be involved in this conference. The Committee disagreed and suggested that family participation would be more appropriate at the multidisciplinary rounds. The Committee agreed that this is an important measure, even as a starting point for the field, and recommended it for time-limited endorsement.

PCS-003-09 Multidisciplinary rounds involving multiple members of the healthcare team *Occurrence of multidisciplinary rounds for pediatric and congenital cardiac surgery patients*

involving multiple members of the healthcare team, with recommended participation including but not limited to cardiology, cardiac surgery, critical care, primary caregiver, family, nurses, pharmacist, and respiratory therapist. Involvement of the family is encouraged. (STS)

The purpose of this measure is to determine whether a program holds multidisciplinary rounds with a multidisciplinary healthcare team. Clear and detailed rounds help with planning of therapeutic interventions. The literature supporting the importance of this measure provides strong evidence that multidisciplinary rounds lead to improved clinical outcomes. As such, there was general consensus among the Committee members that this activity is important to measure and report. The Committee agreed that this measure is of particular importance in advancing the partnership between families and healthcare providers. In particular, given the nature of children with cardiac-related issues, it is usually their families and/or caregivers who need to be fully engaged in the care plan to ensure effective communication among all entities involved. Despite agreement on the measure's importance, the Committee had concerns with this measure's specifications similar to those for the previous measure, PCS-002-09. Although the measure specifies that rounds should take place daily, there is no definition or description of a "round" and its components. This concern of lack of specificity of this measure was also addressed in the comments as was a suggestion for this measure to be specified as a process measure. After further discussion, the Committee affirmed its initial recommendation to allow for inistitutional flexibility. In addition, re-specifying the measure as a process measure would at this point is not feasible. Related to concerns regarding the measure's feasibility, the Committee agreed that this type of activity can be easily tracked through progress notes in the patients' charts. The Committee agreed that the measure is important for the field and voted to recommend it for time-limited endorsement.

PCS-004-09 Regularly scheduled quality assurance and quality improvement cardiac care conference *Occurrence of a regularly scheduled quality assurance and quality improvement cardiac care conference to discuss care provided to patients who undergo pediatric and congenital cardiac surgery operations and to discuss opportunities for improvement. This conference should be held at least every three months (quarterly).* (STS)

The purpose of this measure is to determine whether a facility or pediatric/congenital heart surgery program implements regularly scheduled quality assurance and quality improvement cardiac care conferences. The purpose of the conference is to discuss opportunities for improvement. Although there is no direct evidence linking this activity to patient outcomes, there is indirect evidence from

other fields that shows that such conferences improve quality. Based on the conditions for recommendation put forth by the Committee in October 2009, the measure developer changed the specifications to reflect that these meetings should occur quarterly. The Steering Committee agreed that this measure addresses an important aspect of healthcare, but similar to the two previous measures (PCS-002-09, PCS-003-09), its specifications do not clearly identify the components of a quality assurance and quality improvement care conference and the criteria for selecting the patients to be discussed during the conference. This concern was also addressed during the comment period. The Committee clarified that the intent of this meeting is to discuss opportunities for improvement, adverse outcomes, and complications, and as such additional specifications were not needed. The Committee voted to recommend the measure for time-limited endorsement.

PCS-005-09 Availability of intraoperative transesophageal echocardiography (TEE) and epicardial echocardiography *Availability of intraoperative transesophageal echocardiography (TEE) for pediatric and congenital heart operations. Epicardial echocardiography should be readily available for those with patients in whom TEE is contraindicated or less informative.* (STS)

The purpose of this measure is to determine whether a facility or program has a TEE available for use. The Committee agreed that TEE is a well-known and well-documented imaging technique that has been shown to positively affect the outcome of operations for congenital heart disease. However, the accessibility of this tool by facilities and its range of appropriate use are unclear. The Committee's discussion of this measure revolved around the many publications that support the use of TEE. Because this is not a patient-level measure, it will be used to determine the availability of TEE, not necessarily whether it is being used for patients who need it. Some Committee members stated that the measure will be more useful if it calculates a percentage of patients for whom TEE is used appropriately, and they recommended that a future version should specify the measure in this way. The Committee agreed that this measure will be easy to report. Although not required because this is a structure measure, patient-level data should be available from clinical sources to determine the presence of this tool. Commenters noted that these measures would be more appropriate as a process measure rather than a structure measure since most centers have this technology available. Commenters also noted that it would be a more valuable measure if it could provide information on the relationship between the availability of the TEE, using it appropriately, and associated outcomes. In cases where TEE is contraindicated, a commenter noted that epicardial echocardiography should

also be available. The measure developers agreed with this comment and changed the measure title and description accordingly. While the use of TEE or epicardial echocardiography in individual patients can be captured, consistent availability cannot be implied. These concerns were ultimately outweighed by the Committee's assessment that this is an important measure for the field, and it was recommended for time-limited endorsement.

PCS-006-09 Availability of institutional pediatric ECLS (extracorporeal life support) *Availability of an institutional pediatric extracorporeal life support (ECLS) program for pediatric and congenital cardiac surgery patients* (STS)

Similar to the previous measure, PCS-005-09, the purpose of this measure is to determine the availability of an ECLS program at a facility. During its discussion, the Steering Committee cited multiple manuscripts that document the importance of ECLS, which can rehabilitate hearts, save lives, and in the end serve as a bridge to transplantation. Clear evidence exists that ties improved outcomes to ECLS therapy in cardiac surgery patients with an estimated 50 to 60 percent chance of survival. Some Committee members expressed concern about the overlap of ECLS and extracorporeal membrane oxygenation (ECMO) programs: Does one program produce better outcomes than the other for cardiac patients? Similar to the concerns of the previous measures, the Committee pointed out that the specifications of this measure do not clearly delineate the criteria for answering "Yes" and for what having a "program" actually means (e.g., having any ECLS capability at all, existing program components). The Committee discussed the issue of capturing the measure data. Data on ECLS use for individual patients can be retrieved by the STS database and EHRs. However, the measure does not require patient-level data because it is a structure measure focused only on the availability of the program. The Committee believed that this was an important measure for the field and voted to recommend it for time-limited endorsement.

PCS-007-09 Surgical volume for pediatric and congenital heart surgery *Surgical volume for pediatric and congenital heart surgery* (STS)

The purpose of this measure is to provide a count of cases at a facility that provides pediatric or congenital heart surgery. The Committee agreed that the relationship between volume and outcome is unclear, although there is likely a volume below which outcome suffers. In its discussions, the

Committee identified the following issues: 1) the need to review procedure codes to remove noncardiac surgical and nonsurgical procedures; 2) the capture of surgery in adults with congenital versus acquired disease; and 3) the requirement that those who do not participate in the STS database use a crosswalk from STS codes to ICD-9-CM to identify cases that should be included in the count. This measure is similar to and considered to compete with NQF-endorsed measure 0340, Pediatric Heart Surgery Volume (PDI 7). In discussions of best-in-class between these two measures, several Committee members stated that data derived from a clinical dataset more validly represent the number of procedures than do the administrative data used in the NQF-endorsed measure. The Committee questioned the measure developer to determine why both this measure and the following measure, PCS-008-09, which stratifies volume by complexity, are needed. The developer responded that although this measure can be calculated with simple addition, a roll-up of the cases at each mortality level in PCS-008-09 would not equal the total cases for this measure. This measure was ultimately recommended for time-limited endorsement.

PCS-008-09 Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS Mortality Levels *Surgical volume for pediatric and congenital heart surgery stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool* (STS)

This is a volume measure similar to the previous measure, but it stratifies the cases by complexity level using the STS-EACTS Mortality Levels in a stratified schema based on data in the STS database. This measure can be used in conjunction with PCS-018-09, Operative mortality stratified by the five STS-EACTS Mortality Levels, to determine the denominator. The method of risk-stratification used for this measure requires the use of STS codes and registry data. The Committee agreed that this measure will provide a useful comparison across centers, rated it highly for usability, and ultimately recommended it for time-limited endorsement.

PCS-012-09 Use of an expanded pre-procedural and post-procedural time-out *Use of an expanded pre-procedural and post-procedural "time-out" that includes the following elements: 1) The conventional pre-procedural "time-out", which includes identification of patient, operative site, procedure, and history of any allergies; 2) 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, planned procedure, outline of essentials of anesthesia and bypass strategies, anticipated or planned implants or device applications, and anticipated challenges; 3) A post-procedural debriefing wherein the surgeon succinctly reviews with all members of the operating room team the essential elements of the operative plan, identifying both the successful components and the opportunities for improvement. This debriefing should take place prior to the patient leaving the operating room or its equivalent, and may be followed by a more in-depth dialogue involving team members at a later time. (The actual debriefing in the operating room is intentionally and importantly brief, in recognition of the fact that periods of transition may be times of instability or vulnerability for the patient.); 4) A briefing or hand-off protocol at the time of transfer (arrival) to the Intensive Care Unit at the end of the operation, involving the anesthesiologist, surgeon, physician staff of the Intensive Care Unit (including critical care and cardiology) and nursing. (STS)

The purpose of this measure is to determine whether a facility with a congenital/pediatric heart surgery program implements pre- and post-procedural timeouts for surgical cases. There is an emerging area of research focused on linking "time-outs" to improved outcomes. Although data are not yet amassed to determine whether this measure yields improved outcomes, the Committee's expert opinion was that this activity is important to measure and report, because a time-out is a critical component of knowledge sharing for the healthcare team. Its importance is supported by the implementation of this activity as policy by most centers around the country. The Committee sought to clarify whether or not this measure is specified as an "all-or-none" (i.e., all four elements must be in place for the institution to answer "Yes") to ensure consistency and usability of the results. Although the Committee was in agreement about this measure's importance, some members questioned the feasibility of measuring the presence of time-outs in a program. They argued that such information is not routinely documented, and it is unclear from the measure specifications if time-outs must occur for every patient. In support of this opinion, one comment noted that although it would be difficult to track time-outs on a patient-level, this measure would be most useful as a process measure that includes the use of a checklist. The Committee and measure developers agreed that this measure is sufficient as a structure measure at this point in time, and the Committee voted to recommend the measure for time-limited endorsement.

Process Measures

Both of the submitted process measures are untested, and therefore reliability or validity data are not available. Consequently, the evaluation of scientific acceptability is limited to review of the measure

specifications. Although evidence was provided to show that the reliability and validity of the current STS database have been verified, the measure developer acknowledged that the measures have not yet been added to the database. Therefore, these measures are only eligible for time-limited endorsement.

PCS-010-09 Timing of antibiotic administration for pediatric and congenital cardiac surgery
Percentage of patients undergoing pediatric and congenital cardiac surgery who were documented as having received prophylactic antibiotics within one hour of surgical incision (two hours if receiving Vancomycin) (STS)

This measure is intended to determine the rate at which congenital and pediatric heart surgery patients are receiving prophylactic antibiotics within the appropriate timeframe (one hour prior to surgical incision). The Steering Committee agreed that this measure is clinically relevant and has a clear linkage to improved outcomes; there is evidence that timely administration of antibiotics prevents infections. There is also evidence that adherence to timing improves outcomes in pediatric cardiac surgery, although on a limited basis. The Committee did, however, express some concerns with the specifications related to coding and exclusions. For example, the Committee believed that the number of patients for whom documentation of such things as incision and/or antibiotic start time should be captured in some way rather than excluded from the measure. Comments on this measure echoed this concern. In response, the measure developer agreed to change the measure description and numerator to clarify that the intent of the measure is to include only those patients whose antibiotic administration is documented. There was also concern that the codes, particularly for congenital surgery, were too inclusive and could result in the inadvertent counting of patients with acquired heart disease requiring surgery rather than counting only the patients with congenital heart disease requiring surgery. Other comments expressed concern about the guidelines for redosing, because the numerator indicates that redosing should be done only "if clinically appropriate" when the surgery is delayed. Those comments sought additional specificity for acceptable redosing procedures and reasons for delay. The Committee and developer agreed that redosing procedures should be determined by the institution because of patient variability and lack of consistency in the literature on this practice.

A significant amount of Committee discussion, during and subsequent to the October 2009 meeting, focused on this measure as it relates to measure PCS-011-09, Selection of antibiotic administration

for pediatric and congenital heart surgery patients. The Committee was divided over whether measurement of appropriate antibiotic administration should include both timely administration combined with appropriate antibiotic selection and weight-based dosing. Proponents of this approach believed that the selection and administration of the appropriate antibiotic is pointless if it is not done in a timely manner and is not weight appropriate. Opponents argued that for quality improvement purposes it would be better to keep the measures separate to determine whether the issues occurred at selection or administration. The Committee ultimately recommended this measure for time-limited endorsement as an individual measure.

PCS-011-09 Selection of appropriate prophylactic antibiotics and weight-appropriate dosage ~~antibiotic administration~~ for pediatric and congenital cardiac surgery patients *Percentage of patients undergoing pediatric and congenital cardiac surgery who were documented as having received body weight appropriate prophylactic antibiotics recommended for the operation* (STS)

This measure is intended to measure both the selection of the appropriate prophylactic antibiotic and the appropriate weight-based dose administration. The Steering Committee agreed that this is a relevant measure with high impact because surgical site infection in cardiac patients is a major complication. The Committee was concerned, however, that the list of appropriate antibiotics specified in this measure may be subject to debate. There are many acceptable antibiotics that can be used, and they change often. Nationwide variations in the types of antibiotics used may make it difficult to meet this measure's requirements. The Committee acknowledged that experience with measures in other fields indicates that options for quickly changing the approved drug list in the specifications must be in place. Public comments echoed this concern, and the measure developer agreed that maintaining the list will be a challenge. Several Committee members asserted that body weight is not the only factor that determines the appropriate dosages of antibiotics in high-risk patients: Clinicians also take into account renal/liver dysfunction and anticipated drug clearance, which are not accounted for in the measure. Other comments noted the lack of specificity about how clinicians should calculate the dose and recommended the use of an algorithm as guidance for this measure as well as for PCS-010-09. Furthermore, the measure does not clearly identify who is responsible for selecting the dose. Similar to PCS-010-09, comments expressed concerned about the exclusion of patients for whom documentation is incomplete; the developer agreed to change the measure description and numerator to clarify that the intent of the measure is to include only those

patients for whom antibiotic administration is documented. In response to comments that the measure title does not reflect the intent of the measure, the developer changed the title to indicate that both administration of the antibiotic and weight-appropriate dosing are being measured. In terms of feasibility, the Committee agreed that the required information can be feasibly obtained from electronic medical records. The Steering Committee ultimately recommended time-limited endorsement of the measure as an individual measure.

Candidate Consensus Standards Withdrawn from Consideration

As discussed above in the Background section, the following 8 of the originally submitted 21 measures were withdrawn from consideration by the developer.

- PCS-009-09 Surgical volume for six pediatric and congenital heart operations (STS)
- PCS-013-09 Mediastinitis after pediatric and congenital heart surgery (STS)
- PCS-014-09 Stroke/cerebrovascular accident after pediatric and congenital heart surgery (STS)
- PCS-015-09 Post-operative renal failure requiring dialysis at hospital discharge (STS)
- PCS-016-09 Arrhythmia necessitating permanent pacemaker insertion (STS)
- PCS-017-09 Surgical re-exploration (STS)
- PCS-019-09 Operative mortality for six benchmark operations (STS)
- PCS-020-09 Operative survival free of major complication (STS)

NOTES

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3. Kochanek, KD, Murphy SL, Anderson RN, et al., Deaths: final data for 2002, *Natl Vit Stat Rep*, 2004;53(5):1-115.
4. March of Dimes. *Quick references: fact sheets. Congenital health defects.* White Plains, NY: March of Dimes; 2010. Available at www.marchofdimes.com/professionals/14332_1212.asp. Last accessed July 2010.
5. Ibid.
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NATIONAL QUALITY FORUM

APPENDIX A: SPECIFICATIONS OF THE NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PEDIATRIC CARDIAC SURGERY

The following table presents the detailed specifications for the National Quality Forum (NQF)-endorsed® *National Voluntary Consensus Standards for Pediatric Cardiac Surgery*. All information presented has been derived directly from measure sources/developers without modification or alteration (except when the measure developer agreed to such modification during the NQF Consensus Development Process) and is current as of ~~July 22~~October 13, 2010. All NQF-endorsed voluntary consensus standards are open source, meaning they are fully accessible and disclosed. Measures were developed by Children's Hospital Boston (CHB) and The Society of Thoracic Surgeons (STS).

***Note: Denotes measures recommended for time-limited endorsement.**

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PCS-001-09*	Participation in a national database for pediatric and congenital heart surgery	Participation in at least one multi-center, standardized data collection, and feedback program that provides benchmarking of the physician's data relative to national and regional programs and uses process and outcome measures.	STS	Whether or not there is participation in at least one multi-center, data collection, and feedback program for pediatric and congenital heart surgery.	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".	Electronic Health/Medical Record, Clinical Database, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Clinical Registry, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database ~~Electronic Clinical Database, Electronic Clinical Registry,~~ Electronic Claims, Paper Medical Records	Group of clinicians, Facility, Integrated delivery system, Health plan, Community/Population

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Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PCS-002-09*	Multidisciplinary preoperative planning conference	Occurrence of a pre-operative multidisciplinary planning conference to plan pediatric and congenital heart surgery cases. This conference will involve multiple members of the healthcare team, with recommended participation including but not limited to cardiology, cardiac surgery, anesthesia, and critical care.	STS	Whether or not there is a pre-operative multidisciplinary conference involving cardiology, cardiac surgery, anesthesia, and critical care to plan surgical cases for pediatric and congenital heart surgery.	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".	Electronic Health/Medical Record,~~,~~ Electronic Claims, Paper Medical Record, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection and analysis	Group of clinicians, Facility, Integrated delivery system, Health plan, Community/Population
PCS-003-09*	Multidisciplinary rounds involving multiple	Occurrence of multidisciplinary rounds	STS	Whether or not the facility implements	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac	Electronic Health/Medical Record, Electronic Claims, Paper Medical Record, Other: Upon receiving NQF	Group of clinicians, Facility, Integrated

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
	members of the healthcare team	for pediatric and congenital cardiac surgery patients involving multiple members of the healthcare team, with recommended participation including but not limited to cardiology, cardiac surgery, critical care, primary caregiver, family, nurses, pharmacist and respiratory therapist. Involvement of the family is encouraged.		multidisciplinary rounds involving cardiology, cardiac surgery, and critical care professionals for pediatric and congenital cardiac surgery patients.		operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular"."	endorsement will be added to the STS congenital heart surgery database for collection and analysis	delivery system, Health plan, Community/Population

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PCS-004-09*	Regularly scheduled quality assurance and quality improvement cardiac care conference	Occurrence of a regularly scheduled quality assurance and quality improvement cardiac care conference to discuss care provided to patients who undergo pediatric and congenital cardiac surgery operations and to discuss opportunities for improvement. This conference should be held at least every three months (quarterly).	STS	Whether or not the facility holds a regularly scheduled quality assurance and quality improvement cardiac care conference to discuss care provided to patients who undergo pediatric and congenital cardiac surgery operations and to discuss opportunities for improvement. This conference should be held at least every three months (quarterly).	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular". (CPB is cardiopulmonary bypass.)	Electronic Health/Medical Record, Electronic Claims, Clinical Database, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Clinical Registry, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database ~~Electronic Clinical Database, Electronic Clinical Registry~~Paper Medical Record, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection and analysis	Group of clinicians, Facility, Integrated delivery system, Health plan, Community/Population
PCS-005-09*	Availability of	Availability of	STS	Whether or not	N/A	Any operation that is not a pediatric or	Electronic Health/Medical Record, Electronic Claims,	Group of clinicians,

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
	intraoperative transesophageal echocardiography (TEE) and Epicardial echocardiography	intraoperative transesophageal echocardiography (TEE) for pediatric and congenital heart operations. Epicardial echocardiography should be readily available for those patients whom TEE is contraindicated or less informative.		intraoperative transesophageal echocardiography (TEE) is available for pediatric and congenital cardiac surgery operations. Epicardial echocardiography should be readily available for those patients whom TEE is contraindicated or less informative.		congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular". " (CPB is cardiopulmonary bypass.).	Paper Medical Record, Hospital Records, Electronic Clinical Database, Electronic Clinical Registry, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection & and analysis	Facility, Integrated delivery system, Health plan, Community/Population
PCS-006-09*	Availability of institutional pediatric ECLS (extracorporeal life support)	Availability of an institutional pediatric extracorporeal life support (ECLS) program for pediatric and congenital cardiac surgery patients.	STS	Whether or not the facility has available an institutional pediatric extracorporeal life support (ECLS) program for pediatric and congenital cardiac surgery	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular". (CPB is cardiopulmonary bypass.)	Electronic Health/Medical Record, Electronic Claims, Electronic Pharmacy Data, Paper Medical Record, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection and analysis	Facility, Integrated delivery system

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				operations.				
PCS-007-09*	Surgical volume for pediatric and congenital heart surgery	Surgical volume for pediatric and congenital heart surgery.	STS	Number of pediatric and congenital heart surgery operations.	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular". (CPB is cardiopulmonary bypass.)	Electronic Health/Medical Record, Clinical Database, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Clinical Registry, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Claims, Paper Medical Record	Group of clinicians, Facility, Integrated facility, integrated delivery system, Health plan, Community/ Population
PCS-008-09*	Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS mortality levels	Surgical volume for pediatric and congenital heart surgery stratified by the five STS-EACTS mortality levels, a multi-institutional validated complexity stratification tool.	STS	Number of pediatric and congenital cardiac surgery operations (types "CPB" and "No CPB cardiovascular") in each of the strata of complexity specified by the five STS-EACTS mortality levels, a multi-institutional validated complexity stratification	N/A	Any operation that is a pediatric or congenital open heart surgery (operation types of "CPB" or "No CPB cardiovascular") that cannot be classified into a level of complexity by the five STS-EACTS mortality levels.	Electronic Health/Medical Record, Clinical Database, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Clinical Registry, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Claims, Paper Medical Record, Other: http://www.sts.org/documents/pdf/ndb/CongenitalDataCollectionForm3_0_NonAnnotated_20090916.pdf	Group of clinicians, Facility, Integrated Delivery System, Community/Population

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				tool.				
PCS-010-09*	Timing of antibiotic administration for pediatric and congenital cardiac surgery patients	Percentage of patients undergoing pediatric and congenital cardiac surgery who were documented as having received prophylactic antibiotics within one hour of surgical incision (two hours if receiving Vancomycin).	STS	Number of pediatric and congenital cardiac surgery patients who were documented as having received prophylactic antibiotics within one hour of surgical incision (two hours if Vancomycin). In the event that surgery is delayed, as long as the patient is re-dosed (if clinically appropriate) the patient should be included in the numerator.	All patients undergoing pediatric and congenital cardiac surgery operations.	Patients who: • had principal or admission diagnosis of preoperative infectious disease • were receiving antibiotics at time of admission • have medical records that do not include antibiotic start date/time or incision date/time • were receiving antibiotics more than 24 hours prior to surgery • have physician documentation of infection prior to surgical procedure. Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular"." (CPB is cardiopulmonary bypass.)}	Electronic Health/Medical Record, Electronic Claims, Paper Medical Record, Electronic Pharmacy Data, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection and analysis	Individual clinician, Group of clinicians, Facility
PCS-011-	Selection of	Percentage	STS	Number of	Number of	Patients who:	Electronic Health/Medical	Individual

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
09*	appropriate prophylactic antibiotics and weight-appropriate dosage ~~antibiotic administration~~ for pediatric and congenital cardiac surgery patients	of patients undergoing pediatric and congenital cardiac surgery who were documented as having received body weight appropriate prophylactic antibiotics recommended for the operation.		pediatric and congenital cardiac surgery patients who were documented as having received body weight appropriate prophylactic antibiotics recommended for the operation.	pediatric and congenital cardiac surgery operations.	• had principal or admission diagnosis of preoperative infectious disease • were receiving antibiotics at time of admission • have medical records that do not include antibiotic start date/time or incision date/time • were receiving antibiotics more than 24 hours prior to surgery • have physician documentation of infection prior to surgical procedure. Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".~~"~~ (CPB is cardiopulmonary bypass.)~~)~~	Record, Electronic Claims, Paper Medical Record, Electronic Pharmacy Data, Paper Medical Records, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection ~~&~~ and analysis	clinician, Group of clinicians, facility~~,~~
PCS-012-09*	Use of an expanded pre-procedural	Use of an expanded pre-procedural	STS	Whether or not the facility implements	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac	Electronic Health/Medical Record, Clinical Database, Electronic Claims, Paper Medical Record, Electronic	Individual clinicians, Group of clinicians,

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
	and post-procedural time-out	and post-procedural "time-out" that includes the following elements: 1. The conventional pre-procedural "time-out", which includes identification of patient, operative site, procedure and history of any allergies. 2. A pre-procedural briefing wherein the surgeon shares with all members of the operating room team the essential elements of the operative plan,~~;~~ including		an expanded pre-procedural and post-procedural "time-out" for all patients undergoing pediatric and congenital heart surgery operations. Pre-procedural and post-procedural time-out includes the following elements: 1. The conventional pre-procedural "time-out", which includes identification of patient, operative site, procedure and history of any allergies.		operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".″ (CPB is cardiopulmonary bypass.)	Pharmacy Data, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection & analysis	Facility

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Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		diagnosis, planned procedure, outline of essentials of anesthesia and bypass strategies, anticipated or planned implants or device applications, and anticipated challenges. 3. A post-procedural debriefing wherein the surgeon succinctly reviews with all members of the operating room team the essential elements of the operative plan, identifying both the successful components and the opportunitie		2. 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, planned procedure, outline of essentials of anesthesia and bypass strategies, anticipated or planned implants or device applications, and anticipated challenges. 3. A post-procedural debriefing wherein the surgeon succinctly				

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Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		s for improvement. This debriefing should take place prior to the patient leaving the operating room or its equivalent, and may be followed by a more in-depth dialogue involving team members at a later time. (The actual debriefing in the operating room is intentionally and importantly brief~~,~~ in recognition of the fact that periods of transition may be times of instability or		reviews with all members of the operating room team the essential elements of the operative plan, identifying both the successful components and the opportunities for improvement. This debriefing should take place prior to the patient leaving the operating room or its equivalent, and may be followed by a more in-depth dialogue involving team members at a later time. (The actual				

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		vulnerability for the patient.). 4. A briefing or hand-off protocol at the time of transfer (arrival) to the Intensive Care Unit at the end of the operation, involving the anesthesiologist, surgeon, physician staff of the Intensive Care Unit (including critical care and cardiology) and nursing.		debriefing in the operating room is intentionally and importantly brief, in recognition of the fact that periods of transition may be times of instability or vulnerability for the patient). 4. A briefing or hand-off protocol at the time of transfer (arrival) to the Intensive Care Unit at the end of the operation, involving the anesthesiologist, surgeon, physician staff of the Intensive				

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				Care Unit (including critical care and cardiology) and nursing.				
PCS-018-09	Operative mortality stratified by the five STS-EACTS Mortality Levels	Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	STS	Number of patients who undergo pediatric and congenital open heart surgery in a given level of complexity stratification and die during either of the following two time intervals: 1. Prior to hospital discharge 2. Within 30 days of the date of surgery.	Number of index cardiac operations in each level of complexity stratification using the five STS-EACTS mortality levels, a multi-institutional validated complexity stratification tool.	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular"." (CPB is cardiopulmonary bypass.) Any operation that is a pediatric or congenital open heart surgery (operation types of "CPB" or ""No CPB cardiovascular"") that cannot be classified into a level of complexity by the five STS-EACTS mortality levels.	Electronic Health/Medical Record, Clinical Database, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Clinical Registry, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Claims, Paper Medical Record, Other: http://www.sts.org/documents/pdf/ndb/CongenitalDataCollectionForm3_0_NonAnnotated_20090916.pdf	Group of clinicians, Facility, Integrated facility, Integrated delivery system, Health plan, Community/Population
PCS-021-09	Standardized mortality ratio for congenital heart surgery, Risk	Ratio of observed to expected rate of in-hospital mortality	CHB	Cases of congenital heart surgery among patients <18	Total cases of congenital heart surgery among patients <18 years of age.	Patients ≥ 18 years of age, those undergoing heart transplantation, neonates or premature infants with patent ductus arteriosus repair	Electronic Health/Medical Record, Electronic Clinical Database, Paper Medical Records, Other: Data elements may be obtained from an administrative database (e.g.,	~~Can be measured at all levels~~ Facility

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
	Adjustment for Congenital Heart Surgery (RACHS-1)	following surgical repair of congenital heart defect among patients <18 years of age, risk-adjusted using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method.		years of age resulting in in-hospital death.		as the only cardiac surgical procedure, transcatheter interventions, surgical cases unable to be assigned to a RACHS-1 risk category.	Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient Database (KID), Pediatric Health Information System (PHIS)); from a clinical database (e.g., Pediatric Cardiac Care Consortium (PCCC), Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database)*; from hospital-specific electronic medical records; or from paper medical records. * The STS database does not currently include all variables, but there are plans to add them.	

APPENDIX B: PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE AND NQF STAFF

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APPENDIX C: COMPETING MEASURES

Competing Mortality Measures

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF--0339
Title	Pre-Operative mortality stratified by the five STS-EACTS Mortality Levels	Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) method	Pediatric heart surgery mortality (PDI 6) (risk adjusted)
Status	Under Review	Under Review 9/18/2009	Endorsed 5/15/2008 (Maintenance review begins Oct 2010 in Cardiovascular Project)
Steward	Society of Thoracic Surgeons	Program for Patient Safety and Quality, Children's Hospital Boston	Agency for Healthcare Research and Quality
Description	Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Ratio of observed to expected rate of in-hospital mortality following surgical repair of congenital heart defect among patients <18 years of age, risk-adjusted using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method.	Number of in-hospital deaths in patients undergoing surgery for congenital heart disease per 1000 patients.
Numerator	Number of patients who undergo pediatric and congenital open heart surgery and die during either of the following two time intervals: 1. Prior to hospital discharge 2. Within 30 days of the date of surgery	Cases of congenital heart surgery among patients <18 years of age resulting in in-hospital death.	Number of deaths, age under 18 years, with a code of pediatric heart surgery in any procedure field with an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code of congenital heart disease in any field.
Denominator	Number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool	Total cases of congenital heart surgery among patients <18 years of age.	All discharges age under 18 years with ICD-9-CM procedure codes for congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD-9-CM diagnosis of congenital heart disease (2D) in any field.
Exclusions	Any operation that is not a pediatric or congenital Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB	Patients ≥18 years of age, those undergoing heart transplantation, neonates or premature infants with patent ductus arteriosus repair as the only cardiac surgical procedure, transcatheter	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF--0339
	Cardiovascular" (CPB is cardiopulmonary bypass.) [1]. Any operation that is a pediatric or congenital open heart surgery (operation types of "CPB" or "No CPB Cardiovascular") that cannot be classified into a level of complexity by the five STS-EACTS Mortality Levels.	interventions, surgical cases unable to be assigned to a RACHS-1 risk category.	procedures without bypass; heart transplant; premature infants with PDA closure as only cardiac procedure; age less than 30 days with PDA closure as only cardiac procedure; missing discharge disposition; transferring to another short-term hospital and newborns less than 500 grams.
Methods and~~&~~ Risk Adjustment	Stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Uses a statistical risk model RACHS-1 risk categories, age at surgery, prematurity, presence of major non-cardiac structural anomaly, combinations of cardiac procedures performed.	The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, birthweight (500g groups), age in days (29-60, 61-90, 91+), age in years (in 5-year age groups), modified CMS DRG and AHRQ CCS comorbidities. The reference population used in the regression is the universe of discharges for states that participate in the HCUP State Inpatient Data (SID) for the years 2002-2004 (combined), a database consisting of 37 states and approximately 20 million pediatric discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., hospital, state, and region). The risk adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate. The model includes additional covariates for RACHS-1 risk categories.
Risk Model Performance Statistics	C-statistics: STS-EACTS Congenital Heart Surgery Mortality Categories (2009)	I -- Validation of Risk Adjustment Model Original derivation of RACHS-1: (1) Pediatric Cardiac Care Consortium (PCCC)	Risk model C-statistic: 0.875

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF--0339
	Model without patient covariates: C = 0.778 Model with patient covariates: C = 0.812	database 1996; 4370 cases from 32 institutions. (2) Hospital discharge data from three states (Illinois 1994, Massachusetts 1995, California 1995); 3646 total cases. Subsequent validation: (3) 1996 hospital discharge data from six states (California, Illinois, Massachusetts, New York, Pennsylvania, Washington); 4318 total cases. (4) Retrospectively collected primary data from a newly created pediatric cardiac care program in Guatemala, 1997-2004; 1215 total cases. (5) Kids' Inpatient Database (KID) 2000; 12717 total cases. Other uses: (6) Kids' Inpatient Database (KID) 2003; 11395 total cases. (7) Pediatric Health Information System (PHIS) 2002-2006; 45621 total cases. Risk Model C-Statistics: (1) Area under the ROC curve for the full RACHS-1 model 0.811; p value for Hosmer-Lemeshow test 0.34. (2) Area under the ROC curve 0.814; p value for Hosmer-Lemeshow test 0.21. (3) Area under the ROC curve 0.818; p value for	

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF--0339
		Hosmer-Lemeshow test 0.83. (4) Area under the ROC curve 0.854. (5) Area under the ROC curve 0.828; p value for Hosmer-Lemeshow test 0.66. (6) Area under the ROC curve 0.809; p value for Hosmer-Lemeshow test 0.18. (7) Area under the ROC curve 0.822; p value for Hosmer-Lemeshow test 0.08.	
Numerator Details		Number of cases of congenital heart surgery among patients <18 years of age able to be placed into a RACHS-1 risk category (see item 8 below) where patient disposition is death prior to hospital discharge.	
Denominator Details	As demonstrated in the following publication (STS Attachment 1 (of 2) - O'Brien et al, JTCVS, Nov 2009), the five STS-EACTS Mortality Levels constitute an objective and empirically based tool for complexity stratification. In addition, it represents an improvement over existing consensus-based tools. Definition: The number of patients who undergo pediatric and congenital Cardiac Operation - Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1]. Definition: The number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity	Pediatric cases <18 years of age undergoing surgical repair of a congenital heart defect and able to be placed into a RACHS-1 risk category (see item 8 below).	

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF--0339
	stratification tool. The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease: STS Denominator Codes: 10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780,		

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF--0339
	1790, 1802, 1804, 1830, 1860 **Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions. Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease		
Exclusion Details		Neonates are defined as patients ≤30 days of age at surgery; premature infants are defined as <37 weeks gestation. See item 8 for RACHS-1 risk categories.	Exclude patients with MDC 14 (Pregnancy, Childbirth, Pueperium); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass; heart transplant; premature infants with PDA closure as only cardiac procedure; age less than 30 days with PDA closure as only cardiac procedure; missing discharge disposition; transferring to another short-term hospital and newborns less than 500 grams.
Data Source	Paper Medical Record, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Clinical Database, Electronic Health/Medical Record, Other	Electronic Claims
Level	Community/Population, Health Plan, Group of clinicians (facility, dept/unit, group), Facility	Facility (e.g., hospital, nursing home)	Facility (e.g., hospital, nursing home)

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF--0339
	(e.g., hospital, nursing home)		
Setting	Hospital	Hospital	Hospital

Competing Volume Measures

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF- 0340
Title	Surgical volume for pediatric and congenital heart surgery	Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS Mortality Levels	Pediatric heart surgery volume (PDI 7)
Status	Under Review	Under Review	Endorsed 5/15/2008 (Maintenance Review begins Oct 2010 in Cardiovascular Project)
Steward	Society of Thoracic Surgeons	Society of Thoracic Surgeons	Agency for Healthcare Research and Quality
Description	Surgical volume for pediatric and congenital heart surgery	Surgical volume for pediatric and congenital heart surgery stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool	Raw volume compared to annual thresholds (100 procedures)
Numerator	Number of pediatric and congenital heart surgery operations	Number of pediatric and congenital cardiac surgery operations (types "CPB" and "No-CPB Cardiovascular") in each of the strata of complexity specified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Discharges, age under 18 years, with an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) code for either congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD-9-CM diagnosis of congenital heart disease (2D) in any field.
Denominator	N/A	N/A	N/A
Exclusions	Measure Exclusions: Any operation that is not a pediatric or congenital Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary	Any operation that is not a pediatric or congenital Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular" (CPB is	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF- 0340
	bypass.) [1].	cardiopulmonary bypass.) [1]. Any operation that is a pediatric or congenital open heart surgery (operation types of "CPB" or "No CPB Cardiovascular") that cannot be classified into a level of complexity by the five STS-EACTS Mortality Levels.	procedures without bypass.
Methods & Risk Adjustment	N/A	N/A	N/A
Numerator Details	Cardiac operations are defined as operations that are of operation types "CPB" or "No CPB Cardiovascular" (CPB is cardiopulmonary bypass.) [1]. The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease: 10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630,	There are currently three validated systems of Complexity Stratification in use to categorize operations for pediatric and congenital heart disease on the basis of complexity. Each of these is used in some registry databases, and data is currently stratified using each of the three systems in the most recent outcome reports of the Society of Thoracic Surgery Congenital Heart Surgery database. The three systems are: 1. the RACHS-1 (Risk Adjustment in Congenital Heart Surgery) System with 5 functional levels; 2. The Aristotle Basic Complexity Score with 4 levels; and 3. STS-EACTS Mortality Levels (5 levels). As demonstrated in the following publication (STS Attachment 1 (of 2) - O'Brien et al, JTCVS, Nov 2009), the five STS-EACTS Mortality Levels constitute an objective and empirically based tool for complexity stratification. In addition, it represents an improvement over existing consensus-based tools.	N/A

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF- 0340
	640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 **Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions. Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease	Numerator definition: The number of patients who undergo pediatric and congenital Cardiac Operation - Cardiac operations are defined as operations that are of operation types of “CPB” or “No CPB Cardiovascular”. (CPB is cardiopulmonary bypass.) [1].Numerator definition: The number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool. The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease: 10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600,	

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF- 0340
	2. heart surgery on patients of any age to treat congenital cardiac disease	1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 **Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions. Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease	
Denominator Details	N/A	N/A	N/A
Exclusion Details	N/A	N/A	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass.
Data Source	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Electronic Claims

NATIONAL QUALITY FORUM

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF- 0340
Level	Community/Population, Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home), Integrated delivery system	Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home), Integrated delivery system	Facility (e.g., hospital, nursing home)
Setting	Hospital	Hospital	Hospital

	~~Measure Review # PCS-018-09~~	~~Measure Review # PCS-021-09~~	~~Measure ID # 0339~~
~~**Title**~~	~~Operative Mortality Stratified by the Five STS-EACTS Mortality Levels~~	~~Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1).~~	~~Pediatric heart surgery mortalityHeart Surgery Mortality (PDI 6) (risk adjusted)~~
~~**Status**~~	~~Under Review 9/18/2009~~	~~Under Review 9/18/2009~~	~~Endorsed 5/15/2008~~
~~**Steward**~~	~~Society of Thoracic Surgeons~~	~~Children's Hospital Boston~~	~~Agency for Healthcare Research and Quality~~
~~**Description**~~	~~Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.~~	~~Ratio of observed to expected rate of in-hospital mortality following surgical repair of congenital heart defect among patients <18 years of age, risk-adjusted using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method.~~	~~Number of in-hospital deaths in patients undergoing surgery for congenital heart disease per 1,0001000 patients.~~
~~**Numerator**~~	~~Number of patients who undergo pediatric and congenital open heart surgery and die during~~	~~Cases of congenital heart surgery among patients <18 years of age resulting in in-hospital death.~~	~~Number of deaths, age under 18 years, with a code of pediatric heart surgery in any procedure field with an *International Classification of Diseases, Ninth Revision, Clinical Modification*~~

	~~Measure Review # PCS-018-09~~	~~Measure Review # PCS-021-09~~	~~Measure ID # 0339~~
	~~either of the following two time intervals:~~ ~~1. Prior to hospital discharge~~ ~~2. Within 30 days of the date of surgery.~~		~~(ICD-9-CM) code of congenital heart disease in any field.~~
~~Denominator~~	~~Number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool~~	~~Total cases of congenital heart surgery among patients <18 years of age.~~	~~All discharges age under 18 years with ICD-9-CM procedure codes for congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD-9-CM diagnosis of congenital heart disease (2D) in any field.~~
~~Exclusions~~	~~Any operation that is not a pediatric or congenital cardiac operation.Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular"." (CPB is cardiopulmonary bypass.) [1]~~ ~~Any operation that is a pediatric or congenital open heart surgery (operation types of "CPB" or ""No CPB Cardiovascular")") that cannot be classified into a level of complexity by the five STS-EACTS Mortality Levels.~~	~~Patients ≥18 years of age, those undergoing heart transplantation, neonates or premature infants with patent ductus arteriosus repair as the only cardiac surgical procedure, transcatheter interventions, surgical cases unable to be assigned to a RACHS-1 risk category.~~	~~Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass; heart transplant; premature infants with PDA closure as only cardiac procedure; age less than 30 days with PDA closure as only cardiac procedure; missing discharge disposition; transferring to another short-term hospital and newborns less than 500 grams.~~
~~Methods & Risk~~	~~N/A~~	~~RACHS-1 risk categories, age at surgery, prematurity, presence of major non-cardiac~~	~~The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and~~

	Measure Review # PCS-018-09	Measure Review # PCS-021-09	Measure ID # 0339
Adjustment		structural anomaly, combinations of cardiac procedures performed.	covariates for gender, birthweight (500g groups), age in days (29-60, 61-90, 91+), age in years (in 5-year age groups), modified CMS DRG and AHRQ CCS co-morbidities. The reference population used in the regression is the universe of discharges for states that participate in the HCUP State Inpatient Data (SID) for the years 2002-2004 (combined), a database consisting of 37 states and approximately 20 million pediatric discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., hospital, state, and region). The risk-adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate.
Numerator Details	N/A	Number of cases of congenital heart surgery among patients <18 years of age able to be placed into a RACHS-1 risk category (see item 8 below) where patient disposition is death prior to hospital discharge.	N/A
Denominator Details	As demonstrated in the following publication (STS Attachment 1 (of 2)—O'Brien) - O'Brien et al., JTCVS, Nov 2009), the five STS-EACTS Mortality Levels constitute an objective and empirically based tool for complexity stratification. In addition, it represents an improvement over existing consensus-based	Pediatric cases <18 years of age undergoing surgical repair of a congenital heart defect and able to be placed into a RACHS-1 risk category (see item 8 below).	N/A

	Measure Review # PCS 018 09	Measure Review # PCS 021 09	Measure ID # 0339
	tools. Definition: The number of patients who undergo pediatric and congenital cardiac operation – Cardiac Operation Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1] Definition: The number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool. The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a		

	~~Measure Review # PCS 018 09~~	~~Measure Review # PCS 021 09~~	~~Measure ID # 0339~~
	~~patient with pediatric and/or congenital cardiac disease:~~ ~~10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095,~~		

	Measure Review # PCS 018 09	Measure Review # PCS 021 09	Measure ID # 0339
	1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease.		
Exclusion Details	N/A	Neonates are defined as patients <=30 days of age at surgery; premature infants are defined as <37 weeks gestation. See item 8 below for RACHS-1 risk	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium);; patients with transcatheter interventions as single cardiac procedures, performed without bypass but with

	Measure Review # PCS-018-09	Measure Review # PCS-021-09	Measure ID # 0339
		categories.	catheterization; patients with septal defects as single cardiac procedures without bypass; heart transplant; premature infants with PDA closure as only cardiac procedure; age less than 30 days with PDA closure as only cardiac procedure; missing discharge disposition; transferring to another short-term hospital and newborns less than 500 grams.
Data Source	Paper Medical Record, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Clinical Database, Electronic Health/Medical Record, Other	Electronic Claims
Level	Community/Population, Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home)	Can be measured at all levels	Facility (e.g., hospital, nursing home)
Setting	Hospital	Hospital	Hospital

	Measure Review # PCS-007-09	Measure Review # PCS-008-09	Measure ID # 0340
Title	Surgical volumeVolume for pediatricPediatric and congenital heart surgeryCongenital Heart Surgery	Surgical volumeVolume for pediatricPediatric and congenital heart surgery, stratifiedCongenital Heart Surgery, Stratified by the fiveFive STS-EACTS Mortality Levels	Pediatric heart surgery volumeHeart Surgery Volume (PDI 7)

NATIONAL QUALITY FORUM

	Measure Review # PCS 007 09	Measure Review # PCS 008 09	Measure ID # 0340
Status	Under Review 9/18/2009	Under Review 9/21/2009	Endorsed 5/15/2008
Steward	Society of Thoracic Surgeons	Society of Thoracic Surgeons	Agency for Healthcare Research and Quality
Description	Surgical volumeVolume for pediatricPediatric and congenital heart surgery.Congenital Heart Surgery	Surgical volume for pediatric and congenital heart surgery stratified by the five STS-EACTS Mortality Levels, a multi institutional validated complexity stratification tool.	Raw volume compared to annual thresholds (100 procedures).)
Numerator	Number of pediatric and congenital heart surgery operations.	Number of pediatric and congenital cardiac surgery operations (types "CPB" and "No CPB Cardiovascular") in each of the strata of complexity specified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Discharges, age under 18 years, with an *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) code for either congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD-9-CM diagnosis of congenital heart disease (2D) in any field.
Denominator	N/A	N/A	N/A
Exclusions	Measure Exclusions: Any operation that is not a pediatric or congenital cardiac pperation.Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1]	Any operation that is not a pediatric or congenital cardiac operation.Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular"." (CPB is cardiopulmonary bypass.) [1]	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium);); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass.

	~~Measure Review # PCS 007 09~~	~~Measure Review # PCS 008 09~~	~~Measure ID # 0340~~
		~~Any operation that is a pediatric or congenital open heart surgery (operation types of "CPB" or ""No CPB Cardiovascular")") that cannot be classified into a level of complexity by the five STS-EACTS Mortality Levels.~~	
~~Methods & Risk-Adjustment~~	~~N/A~~	~~N/A~~	~~N/A~~
~~Numerator Details~~	~~Cardiac operations are defined as operations that are of operation types "CPB" or "No CPB Cardiovascular"." (CPB is cardiopulmonary bypass.) [1]~~ ~~The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease:~~	~~There are currently three validated systems of Complexity Stratification in use to categorize operations for pediatric and congenital heart disease on the basis of complexity. Each of these is used in some registry databases, and data is currently stratified using each of the three systems in the most recent outcome reports of the Society of Thoracic Surgery Congenital Heart Surgery database. The three systems are: 1). the RACHS-1 (Risk Adjustment in Congenital Heart Surgery) System with 5 functional levels; 2). The Aristotle Basic Complexity Score with 4 levels; and 3). STS-EACTS Mortality Levels (5 levels).~~ ~~As demonstrated in the following publication (STS~~	~~N/A~~

	~~Measure Review # PCS 007 09~~	~~Measure Review # PCS 008 09~~	~~Measure ID # 0340~~
	~~10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860~~	~~Attachment 1 (of 2)—O'Brien) - O'Brien et al.,, JTCVS, Nov 2009), the five STS-EACTS Mortality Levels constitute an objective and empirically based tool for complexity stratification. In addition, it represents an improvement over existing consensus-based tools.~~ ~~Numerator definition: The number of patients who undergo pediatric and congenital cardiac operation. Congenital cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1]~~ ~~].Numerator definition: The number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.~~ ~~The following are STS procedure codes for pediatric and congenital cardiac operations per the STS~~	

	Measure Review # PCS-007-09	Measure Review # PCS-008-09	Measure ID # 0340
	Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease.	Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease: 10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350,	

	Measure Review # PCS-007-09	Measure Review # PCS-008-09	Measure ID # 0340
		1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease.	
Denominator Details	N/A	N/A	N/A

	Measure Review # PCS-007-09	Measure Review # PCS-008-09	Measure ID # 0340
Exclusion Details	N/A	N/A	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium);); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass.
Data Source	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Electronic Claims
Level	Community/Population, Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home), Integrated delivery system	Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home), Integrated delivery system	Facility (e.g., hospital, nursing home)
Setting	Hospital	Hospital	Hospital