

NATIONAL QUALITY FORUM

TO: Consensus Standards Approval Committee

FR: Ashlie Wilbon, MPH, BSN, Project Manager
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RE: *National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report*

DA: January 10, 2011

The Consensus Standards Approval Committee (CSAC) will be reviewing the draft report, *National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report*, during the January 10, 2011, conference call. This memo includes summary information about the project and the recommended measures. The complete [voting draft report](#) and supplemental materials are available on the [project webpage](#).

CSAC ACTION REQUIRED

Pursuant to the Consensus Development Process (CDP), the CSAC may consider approval of 13 candidate consensus standards, 11 of which will be time-limited, as specified in the “voting draft” of *National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report*. This project followed NQF’s version 1.8 of the CDP. NQF Member voting closes at 6 p.m. ET on Monday, November 15, 2010. The Member voting results will be sent to the CSAC via email after the close of the voting period and CSAC members will be asked for vote on the 13 candidate consensus standards at that time.

BACKGROUND

In October 2009, the 12-member Pediatric Cardiac Surgery Steering Committee met in person to evaluate 21 measures in the topic areas of mortality, programmatic structure, and antibiotic use and make recommendations across the spectrum of pediatric cardiac surgery performance measurement. After the meeting, eight of the measures (seven outcomes, one structure) were withdrawn by the developers.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 that time.

Both developers [Children’s Hospital, Boston (CHB) and Society of Thoracic Surgeons (STS)] whose measures were under consideration, were provided an opportunity to submit additional information to further support the reliability and validity of the measures. Subsequently, the Steering Committee was convened again in May 2010 to re-evaluate the 13 remaining measures. All 13 measures are recommended for endorsement with 11 of the 13 measures recommended for time-limited endorsement.

NATIONAL QUALITY FORUM

Comments and Their Disposition

NQF received 43 comments about the draft report from 11 organizations. All measure-specific comments were forwarded to the measure developers, who were invited to respond to the comments. A [table](#) of detailed comments received during the review period, with responses and actions taken by the Steering Committee, is posted on the project's web page in the voting section.

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 in the specifications, exclusion criteria, and the level of analysis designated for some measures. The strengths and weaknesses of the competing mortality measures PCS-018-09 and PCS-021-09 were also addressed in the comments. These topics were discussed by the Committee and are summarized below.

General Comments

Administrative Data versus Clinical Data

Comments regarding the use of administrative data versus clinical data were submitted, particularly around PCS-021-09 which was specified for use of both administrative claims data and clinical data.

Action taken: Given the current environment and the growing use of electronic health records, the Steering Committee supported the endorsement of both claims-based and clinically based measures in this project.

Structural Measures

Most of the untested measures are structural measures, which indicate only the existence of a particular care process such as a preoperative planning conference or multidisciplinary rounds – not whether each patient received the recommended care process. As the initial Steering Committee evaluations and some comments reflect, the measure specifications leave room for interpretation and might be more indicative of quality as process measures applied to each patient. They are untested so it is unknown whether they can be implemented as submitted. The Steering Committee recommended the measures for time-limited endorsement because these structural components should be present in all cardiac surgery programs.

Measure-Specific Comments

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

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

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

NATIONAL QUALITY FORUM

For each of these measures, similar concerns were raised about the lack of specificity of the specifications of these measures in identifying the components of these conferences and rounds. The usefulness of these measures as a structure measures rather than process measures was also questioned, recognizing the challenges in implementation for some components of the measures.

Action Taken: After some discussion, the Committee affirmed its previous recommendation for these measures to move forward for endorsement and agreed that the measures are sufficient “as is.” The Committee preferred that the specifications for the conference/round components allow for institutional variation in practice. The Committee agreed that specifying these measures as process measures would be very difficult and not feasible within the timeframe of this project.

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

One comment questioned the usefulness of this measure as a structural 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 was 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 echocardiography when TEE is contraindicated (see Appendix A in draft report).

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 count as not having met the numerator instead of the denominator because incomplete documentation signals a need for quality improvement.

Action Taken: The Committee agreed this exclusion issue should be addressed, but recognized that changing the measure’s exclusion criteria at this point would require additional time for the developers to do so. In response to this concern, the developer did not change the exclusion criteria, but did agree to modify the measure description and numerator statement to denote that the measure only includes those cases with documentation of antibiotic administration (i.e. the measure is not intended to include patients with incomplete documentation) (see Appendix A in draft report). The

NATIONAL QUALITY FORUM

Committee agreed this was an acceptable interim approach given the measure is untested.

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

One comment 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 be updated quickly 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 also of concern.

Action Taken: The measure developer recognized that it will be a challenge to maintain the measure's list of approved antibiotics. In response to the concern regarding the measure's exclusion criteria, as done with PCS-010-09, the developers 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 in the draft report). The Committee agreed this was an acceptable interim approach to address the exclusions given the limited time for the developers to re-work the measure specifications during this project.

PCS-012-09: Use of an expanded pre-procedural and post-procedural time-out (STS) (Time-limited)

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 was 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 commenters noted that this measure as specified could not be supported as an accountability measure at the clinician level. In one [comment letter](#), a detailed comparison of PCS-018-09 (STS) and this measure was provided along with several other concerns with the measure.

Action Taken: The measure developer agreed and modified the specifications to indicate that this measure is recommended for use at the facility level only (see Appendix A). In response to the concerns expressed in the letter, [CHB submitted a response letter](#)

NATIONAL QUALITY FORUM

addressing each of the concerns. The Committee accepted these responses and the decision to recommend the competing mortality measures for endorsement.

Competing Mortality and Volume Measures

In 2008 NQF endorsed pediatric cardiac surgery measures of volume (0340 by AHRQ) and risk-adjusted mortality (0339 by AHRQ). Two mortality measures were submitted to this current project: one, a measure of operative mortality stratified by the STS-EACTS complexity tool (PCS-018-09 by STS), and the other, a standardized mortality ratio (SMR) [PCS-021-09 by Children's Hospital, Boston (CHB)] using the RACHS-1 method in a statistical risk-adjustment model. Although these measures focus on the same outcome in the same target population of patients, there are some differences in data source, exclusions, and risk adjustment methodology.

Prior to the comment period, the Committee determined that the submitted measures met the criteria and sought comments to inform selecting one measure from among the competing measures. While the draft report called for comments specific to the competing measures, the comments submitted only addressed the mortality measures, PCS-018-09 by STS and PCS-021-09 by CHB and the competing volume measures and the endorsed AHRQ mortality measure were not addressed by the commenters. Ultimately, all the measures were put forward for voting as explained below.

Justification for Multiple Measures

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 one standardized measure and promoting public reporting and improvement on quality using two or more measures need to be weighed. Measures based on different data sources may be needed to promote the greatest scope of measurement, reporting, and improvement. Additionally, there may not be a way to definitively determine the best among competing measures. It may be difficult for steering committees to compare measures, where the advantages and disadvantages of one measure may be offset by those of a competing measure. Currently, head-to-head comparisons of measures based on different data sources are generally not feasible.

The STS measure (PCS-018-09) is based on clinical data submitted according to the STS registry specifications; it produces a rate for each 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 a standardized mortality ratio. The endorsed AHRQ measure (#0339) is based on claims data and produces a risk adjusted rate per 1000 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. For all three measures, evidence of risk model validation was presented. The reported C-statistics indicate adequate discrimination: AHRQ measure 0339: 0.875; STS measure PCS-018-09: 0.778-0.812; CHB measure PCS-021-09: 0.809 - 0.854.

NATIONAL QUALITY FORUM

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 using registry data. The third volume measure, PCS-008-09, stratifies volume for five complex risk categories also using registry data.

The table starting on page 14 of this memo provides a side-by-side comparison of the competing measures for volume and mortality.

Action taken: After internal review and consultation with the CSAC Co-Chairs and Steering Committee Co-Chairs, NQF staff recommended that all of the measures move forward for member voting. In addition to the above considerations, there was a noted lack of consensus on the best methodology and no new information emerged from the public comment period. The NQF three-year endorsement maintenance cycle allows time for measures to be used in the field and for gathering additional evidence and data on their use that can be submitted at the time of maintenance. The AHRQ PDI 6 mortality measure (#0339) will undergo review within the Cardiovascular Endorsement Maintenance 2010 project in the coming months. During its evaluation, it will be reviewed in the context of this Committee's discussions and challenges, along with any revisions and data on the measure's current use.

NQF MEMBER VOTING

The 30-day voting period for the Pediatric Cardiac Surgery project closed on Monday, November 15, 2010. Sixteen member organizations voted; no votes were received from the Consumer, Purchaser or Supplier/Industry councils. One comment was received from the Association for Professionals in Infections Control and Epidemiology and six comments were received from WellPoint. The comments received are under the voting results for each measure.

VOTING RESULTS

Voting results for the 13 candidate consensus standards are provided below.

Measure PCS-001-09: Participation in a national database for pediatric and congenital heart surgery

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	0	1	17	100%

NATIONAL QUALITY FORUM

Percentage of councils approving (<50%)			100%
Average council percentage approval			100%

*equation: Yes/ (Total - Abstain)

Measure PCS-002-09: Multidisciplinary conference to plan pediatric and congenital heart surgery cases

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	1	0	1	0%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	1	0	1	0%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	14	2	1	17	88%
Percentage of councils approving (<50%)					60%
Average council percentage approval					60%

*equation: Yes/ (Total - Abstain)

Voting Comment:

- **Wellpoint:**

Both 002 and 003 raise the same question regarding appropriate documentation. The processes of pre-operative planning and rounding can be highly variable both between institutions and between cases within an institution. We cannot support this measure without more clarification regarding the content of these meetings and the consistency of documenting the process and discussion.

Measure PCS-003-09: Multidisciplinary rounds involving multiple members of the healthcare team

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	1	0	1	0%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	0	1	0	1	0%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%

NATIONAL QUALITY FORUM

Supplier/Industry	0	0	0	0	
All Councils	14	2	1	17	88%
Percentage of councils approving (<50%)					60%
Average council percentage approval					60%

*equation: Yes/ (Total - Abstain)

Voting Comment:

- **Wellpoint:**

Both 002 and 003 raise the same question regarding appropriate documentation. The processes of pre-operative planning and rounding can be highly variable both between institutions and between cases within an institution. We cannot support this measure without more clarification regarding the content of these meetings and the consistency of documenting the process and discussion.

Measure PCS-004-09: Regularly scheduled quality assurance and quality improvement cardiac care conference

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	0	1	17	100%
Percentage of councils approving (<50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure PCS-005-09: Availability of Intraoperative Transesophageal echocardiography (TEE)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%

NATIONAL QUALITY FORUM

Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	0	1	17	100%
Percentage of councils approving (<50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure PCS-006-09: Availability of Institutional Pediatric ECLS (Extracorporeal Life Support) Program

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	0	1	17	100%
Percentage of councils approving (<50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure PCS-007-09: Surgical Volume for Pediatric and Congenital Heart Surgery

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	1	0	1	0%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	15	1	1	17	94%

NATIONAL QUALITY FORUM

Percentage of councils approving (<50%)	80%
Average council percentage approval	80%

*equation: Yes/ (Total - Abstain)

Voting Comment:

- **WellPoint:**
Appears redundant with the following measure #008.

Measure PCS-008-09: Surgical Volume for Pediatric and Congenital Heart Surgery Stratified by the Five STS-EACTS Mortality Levels

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	0	1	17	100%
Percentage of councils approving (<50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure PCS-010-09: Timing of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	1	0	1	0%
Health Professional	7	0	0	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	1	0	17	94%
Percentage of councils approving (<50%)					80%

NATIONAL QUALITY FORUM

Average council percentage approval	80%
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*equation: Yes/ (Total - Abstain)

Voting Comment:

- **WellPoint:**

We are concerned about the handling inadequate or incomplete documentation. This type of measure has been used for 5 years by CMS and Joint Commission as a quality process measure for various types of adult surgeries. One clear result of the inclusion of incompletely documented cases in the denominator has been the drive toward improved documentation including the use of electronic documentation with reminders for appropriate timing and selection. As facilities and providers recognize that inadequate documentation is reflected in poor process scoring, their documentation is regularly shown to improve.

Measure PCS-011-09: Selection of Appropriate Prophylactic Antibiotics and Weight-Appropriate Dosage for Pediatric and Congenital Cardiac Surgery Patients

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	1	0	1	0%
Health Professional	6	1	0	7	86%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	15	2	0	17	88%
Percentage of councils approving (<50%)					80%
Average council percentage approval					77%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- **Association for Professionals in Infection Control and Epidemiology:**

The SCIP antibiotic selection criteria may not always be applied to the pediatric population. The science was taken from and applied to the adult population.

- **WellPoint:**

We are concerned about the handling inadequate or incomplete documentation. This type of measure has been used for 5 years by CMS and Joint Commission as a quality process measure for various types of adult surgeries. One clear result of the inclusion of incompletely documented cases in the denominator has been the drive toward improved documentation including the use of electronic documentation with reminders for appropriate timing and selection. As facilities and

NATIONAL QUALITY FORUM

providers recognize that inadequate documentation is reflected in poor process scoring, their documentation is regularly shown to improve.

Measure PCS-012-09: Use of an expanded pre-procedural and post-procedural “time-out”

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	0	1	17	100%
Percentage of councils approving (<50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure PCS-018-09: Operative Mortality Stratified by the Five STS-EACTS Mortality Levels

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	1	0	0	1	100%
Health Professional	6	0	1	7	100%
Provider Organizations	4	0	0	4	100%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	4	0	0	4	100%
Supplier/Industry	0	0	0	0	
All Councils	16	0	1	17	100%
Percentage of councils approving (<50%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

NATIONAL QUALITY FORUM

Measure PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	1	0	1	0%
Health Professional	5	0	2	7	100%
Provider Organizations	3	1	0	4	75%
Public/Community Health Agency	1	0	0	1	100%
Purchaser	0	0	0	0	
QMRI	3	1	0	4	75%
Supplier/Industry	0	0	0	0	
All Councils	12	3	2	17	80%
Percentage of councils approving (<50%)					80%
Average council percentage approval					70%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- **WellPoint:**
We are concerned about the option of using either chart abstraction or administrative data. While both methodologies have been tested and found adequate, it is not clear that having a mix of methodologies within one database will provide valid results
- **Society of Thoracic Surgeons:**
On behalf of STS surgeon leadership for this project, I would like to take this opportunity to address our concerns regarding the highest C-statistic provided for the CHB measure. The C-statistic of 0.854 was derived from a study of surgical procedures performed in Guatemala from 1997 to 2004 [1]. While informative, this figure is based solely on a study from an institution outside of the US, and thus, it is clearly not representative of the state of pediatric and congenital heart surgery in this country. In addition, we would like to pose to NQF whether it wishes to put this C-statistic forth as part of the validation of the CHB measure for the proposed use (i.e., a *national* consensus standard for performance measurement).

NATIONAL QUALITY FORUM

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) Adjusted.	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 Cardiovascular" (CPB is cardiopulmonary bypass.) [1].	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;

NATIONAL QUALITY FORUM

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF -0339
	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.		missing discharge disposition; transferring to another short-term hospital and newborns less than 500 grams.
Methods & 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) Model without patient covariates: C = 0.778	I -- Validation of Risk Adjustment Model Original derivation of RACHS-1: (1) Pediatric Cardiac Care Consortium (PCCC) database 1996; 4370 cases from 32 institutions. (2) Hospital discharge data from three states	Risk model C-statistic: 0.875

NATIONAL QUALITY FORUM

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF -0339
	<p>Model with patient covariates: C = 0.812</p>	<p>(Illinois 1994, Massachusetts 1995, California 1995); 3646 total cases.</p> <p>Subsequent validation:</p> <p>(3) 1996 hospital discharge data from six states (California, Illinois, Massachusetts, New York, Pennsylvania, Washington); 4318 total cases.</p> <p>(4) Retrospectively collected primary data from a newly created pediatric cardiac care program in Guatemala, 1997-2004; 1215 total cases.</p> <p>(5) Kids' Inpatient Database (KID) 2000; 12717 total cases. Other uses:</p> <p>(6) Kids' Inpatient Database (KID) 2003; 11395 total cases.</p> <p>(7) Pediatric Health Information System (PHIS) 2002-2006; 45621 total cases.</p> <p>Risk Model C-Statistics:</p> <p>(1) Area under the ROC curve for the full RACHS-1 model 0.811; p value for Hosmer-Lemeshow test 0.34.</p> <p>(2) Area under the ROC curve 0.814; p value for Hosmer-Lemeshow test 0.21.</p> <p>(3) Area under the ROC curve 0.818; p value for Hosmer-Lemeshow test 0.83.</p>	

NATIONAL QUALITY FORUM

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF -0339
		<p>(4) Area under the ROC curve 0.854.</p> <p>(5) Area under the ROC curve 0.828; p value for Hosmer-Lemeshow test 0.66.</p> <p>(6) Area under the ROC curve 0.809; p value for Hosmer-Lemeshow test 0.18.</p> <p>(7) Area under the ROC curve 0.822; p value for Hosmer-Lemeshow test 0.08.</p>	
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	<p>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.</p> <p>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].</p> <p>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.</p>	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).	

NATIONAL QUALITY FORUM

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF -0339
	<p>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:</p> <p>STS Denominator Codes:</p> <p>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</p> <p>**Please find data definitions in STS</p>		

NATIONAL QUALITY FORUM

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF -0339
	<p>Attachment 2 (of 2) - STS Procedure Code Definitions.</p> <p>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.</p> <p>Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations:</p> <ol style="list-style-type: none"> 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, 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.
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)	Facility (e.g., hospital, nursing home)	Facility (e.g., hospital, nursing home)

NATIONAL QUALITY FORUM

	Measure# PCS-018-09	Measure# PCS-021-09	Measure # NQF -0339
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 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.

NATIONAL QUALITY FORUM

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF-0340
	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.	
Methods & Risk Adjustment	N/A	N/A	N/A
Numerator Details	<p>Cardiac operations are defined as operations that are of operation types "CPB" or "No CPB Cardiovascular" (CPB is cardiopulmonary bypass.) [1].</p> <p>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:</p> <p>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,</p>	<p>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).</p> <p>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.</p>	N/A

NATIONAL QUALITY FORUM

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF-0340
	<p>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</p> <p>**Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions.</p> <p>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.</p> <p>Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations:</p> <ol style="list-style-type: none"> 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 	<p>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.</p> <p>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:</p> <p>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,</p>	

NATIONAL QUALITY FORUM

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # NQF-0340
	2. heart surgery on patients of any age to treat congenital cardiac disease	<p>1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860</p> <p>**Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions.</p> <p>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.</p> <p>Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations:</p> <ol style="list-style-type: none"> 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

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 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 Claims, Paper Medical Records	Group of clinicians, Facility, Integrated delivery system, Health plan, Community/Population
PCS-002-09*	Multidisciplinary preoperative planning conference	Occurrence of a pre-operative multidisciplinary	STS	Whether or not there is a pre-operative multidisciplinary	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined	Electronic Health/Medical Record, Electronic Claims, Paper Medical Record, Other: Upon receiving NQF endorsement will be added to	Group of clinicians, Facility, Integrated delivery system,

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		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.		nary conference involving cardiology, cardiac surgery, anesthesia, and critical care to plan surgical cases for pediatric and congenital heart surgery.		as operations that are of operation types of “CPB” or “No CPB cardiovascular”.	the STS congenital heart surgery database for collection and analysis	Health plan, Community/Population
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	STS	Whether or not the facility implements multidisciplinary rounds involving cardiology, cardiac surgery, and critical care professionals for	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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		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.		pediatric and congenital cardiac surgery patients.				
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	STS	Whether or not the facility holds a regularly scheduled quality assurance and quality improvement cardiac care conference to discuss care provided to	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 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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		pediatric and congenital cardiac surgery operations and to discuss opportunities for improvement. This conference should be held at least every three months (quarterly).		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).				
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 patients whom TEE is contraindicated or less informative.	STS	Whether or not 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	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, 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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				d or less informative.				
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 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, 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
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	STS	Number of pediatric and congenital cardiac surgery operations (types “CPB” and “No CPB cardiovascular”) in each of the strata	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/	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
		multi-institutional validated complexity stratification tool.		of complexity specified by the five STS-EACTS mortality levels, a multi-institutional validated complexity stratification tool.			pdf/ndb/CongenitalDataCollectionForm3_0_NonAnnotated_20090916.pdf	
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	All patients undergoing pediatric and congenital cardiac surgery operations.	<p>Patients who:</p> <ul style="list-style-type: none"> • 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. <p>Any operation that is not a pediatric or</p>	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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				appropriate) the patient should be included in the numerator.		congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular". (CPB is cardiopulmonary bypass.)		
PCS-011-09*	Selection of appropriate prophylactic antibiotics and weight-appropriate dosage 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	Number of pediatric and congenital cardiac surgery patients who were documented as having received body weight appropriate prophylactic antibiotics recommended for the operation.	Number of pediatric and congenital cardiac surgery operations.	<p>Patients who:</p> <ul style="list-style-type: none"> 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. <p>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</p>	Electronic Health/Medical 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	Individual clinician, Group of clinicians, facility

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
						cardiovascular”. (CPB is cardiopulmonary bypass.)		
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	STS	Whether or not the facility implements 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	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, 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 & analysis	Individual clinicians, Group of clinicians, Facility

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		<p>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.</p> <p>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</p>		<p>and history of any allergies.</p> <p>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.</p> <p>3. A post-procedural debriefing wherein the surgeon succinctly reviews with</p>				

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		<p>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.).</p> <p>4. A briefing or hand-off</p>		<p>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</p>				

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		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.		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.				
PCS-018-09	Operative mortality stratified by	Operative mortality stratified by	STS	Number of patients who undergo	Number of index cardiac operations in	Any operation that is not a pediatric or congenital cardiac	Electronic Health/Medical Record, Clinical Database, Name: The Society of	Group of clinicians, Facility,

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
	the five STS-EACTS Mortality Levels	the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.		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.	each level of complexity stratification using the five STS-EACTS mortality levels, a multi-institutional validated complexity stratification tool.	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.	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	Integrated facility, Integrated delivery system, Health plan, Community/Population
PCS-021-09	Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1)	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	CHB	Cases of congenital heart surgery among patients <18 years of age resulting in in-hospital death.	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 as the only cardiac surgical procedure, transcatheter interventions, surgical cases unable to be assigned to a RACHS-1 risk category.	Electronic Health/Medical Record, Electronic Clinical Database, Paper Medical Records, Other: Data elements may be obtained from an administrative database (e.g., 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	Facility

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		Congenital Heart Surgery (RACHS-1) method.					records. * The STS database does not currently include all variables, but there are plans to add them.	