

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

**FINAL REPORT**

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

## 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.<sup>1</sup> Each year, about 35,000 infants (1 out of every 125) are born with heart defects.<sup>2</sup> 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 has to date focused largely on the adult population, but interest and momentum are growing 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 Quality Strategy.

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.

### Endorsed Measures

- **Pediatric Cardiac Surgery Stratified Mortality & Volume Measure Pair: 1815**
    - **0732:** Surgical Volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by the Five STS-EACTS Mortality Categories [Society for Thoracic Surgeons (STS)]
    - **0733:** Operative Mortality Stratified by the Five STS-EACTS Mortality Categories [Society for Thoracic Surgeons (STS)]
  - **0734:** Participation in a national database for pediatric and congenital heart surgery [Society for Thoracic Surgeons (STS)]
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# **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.<sup>3</sup> Each year, about 35,000 infants (1 out of every 125) are born with heart defects.<sup>4</sup> Other children will develop heart disease later, 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.<sup>5</sup> 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.<sup>6</sup> 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 make a dramatic impact on their quality of life and that of their family members, 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.<sup>7</sup>

National efforts to promote accountability and improvement in healthcare through performance measurement and reporting have focused largely on the adult population, but interest and momentum are growing 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.<sup>8</sup>

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, one structure) were withdrawn by the developer. The seven outcome measures were submitted without testing, 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 consideration to further test and refine them for future consideration.

Following the initial evaluation, 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 support further the reliability and validity of the remaining measures. Subsequently, the Steering Committee was reconvened in May 2010 to re-evaluate the remaining measures. Upon review of the 13 measures recommended by the Steering Committee during the [January 10 conference call](#), the Consensus Standards Approval Committee (CSAC) identified several overarching measurement issues, including the use of poor documentation as exclusion criteria, the evidence required for structural measures, and the lack of specificity in the measure specifications to enable consistent implementation. The developers subsequently withdrew the following measures from the Consensus Development Process (CDP) for further refinement and testing:

- **PCS-002-09:** Multidisciplinary preoperative planning conference (Society for Thoracic Surgeons [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) (STS)
- **PCS-006-09:** Availability of institutional pediatric ECLS (extracorporeal life support) (STS)
- **PCS-010-09:** Timing of antibiotic administration for pediatric and congenital cardiac surgery (STS)
- **PCS-011-09:** 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)

The remaining measures were moved to other projects or combined with similar measures:

- The CHB measure (**PCS-021-09**: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted) was moved to the [2010 Surgery Endorsement Maintenance](#) project to be combined with a similar measure [**0339**: Pediatric Heart Surgery Mortality (PDI 6) (AHRQ)] under review and will subsequently be reviewed by the CSAC and Board of Director (BOD) within the Surgery project.
- **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* were combined into one measure. The newly combined measure [**0732**: Surgical Volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by the Five STS-EACTS Mortality Categories] is recommended as part of a pair.

This report represents the evaluation of the remaining three measures endorsed as voluntary consensus standards suitable for public reporting and quality improvement by CSAC and ratified by the BOD in November and December 2011:

- **Pediatric Cardiac Surgery Stratified Mortality & Volume Measure Pair: 1815**
  - **0732**: Surgical Volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by the Five STS-EACTS Mortality Categories (STS)
  - **0733**: Operative Mortality Stratified by the Five STS-EACTS Mortality Categories (STS)
- **0734**: Participation in a national database for pediatric and congenital heart surgery (STS).

## RELATED NQF WORK

This report does not represent the entire scope of NQF work relevant to pediatric patients. To date, NQF has endorsed more than 60 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 \(2010\)](#)
- [Surgery Endorsement Maintenance \(2010\)](#)

## 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.

## **Evaluating Potential Consensus Standards**

This report presents the evaluation of three 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 them to submit measures for this project.

The measures were evaluated using the 2008 NQF Measure Evaluation Criteria.<sup>10</sup> The 12-member, multi-stakeholder Steering Committee provided evaluations of the four main criteria of 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.

## **ENDORSED STANDARDS**

This report presents the results of the evaluation of three measures considered under NQF's CDP (see Appendix A for detailed specifications). Three measures have been endorsed as national voluntary consensus standards suitable for public reporting and quality improvement.

### **Endorsed Candidate Consensus Standards**

#### **Pediatric Cardiac Surgery Stratified Mortality & Volume Measure Pair: 1815**

##### **0732: Surgical Volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by the Five STS-EACTS Mortality Categories (STS)**

This volume measure stratifies the cases by complexity categories using the STS-EACTS mortality categories in a stratified schema based on data in the STS database. The method of risk stratification used for this measure requires using STS codes and registry data. During its initial review, the Steering Committee agreed that while the relationship between volume and outcome is unclear, there is likely a volume below which outcome suffers, making the combination of the mortality and volume measure results useful as a pair. In its discussions, the Committee pointed out that the measure captures surgical

cases in adults with congenital heart defects in addition to pediatric patients, and that those who do not participate in the STS database will be required to use a crosswalk from STS codes to ICD-9-CM codes to identify cases that should be included in the count. To determine best in class between this measure and a competing endorsed pediatric cardiac volume measure under maintenance review [#0340: Pediatric Heart Surgery Volume (PDI 7)], the 2010 Surgery Steering Committee was asked to provide guidance to CSAC on best in class. The Surgery Steering Committee recommended that this measure be combined with PCS-007-09: Surgical Volume for Pediatric and Congenital Heart Surgery (AHRQ), adding total volume strata to the measure. The developers agreed and resubmitted the final measure, which included total programmatic volume strata. In comparison to measure 0340, the Committee agreed that due to the differences in data sources, one relying on administrative and the other clinical registry data, these measures are “complementary” rather than competing and should co-exist in the NQF portfolio as such to meet the needs of different users with access to different types of data. Additionally, they recommended that this measure be paired with the stratified mortality measure.

### **0733: Operative Mortality Stratified by the Five STS-EACTS Mortality Categories (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 improve comparability, NQF asked the measure developer to select one method of risk stratification and 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 categories. 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 comparative mortality following congenital and pediatric cardiac surgery across institutions is immensely important to measure and report. 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 Steering Committee recommended this measure for endorsement.

Subsequently, to determine best-in-class between this measure and a competing endorsed pediatric cardiac mortality measure under maintenance review [#0339: Pediatric Heart Surgery Mortality (PDI 6)], the 2010 Surgery Steering Committee was asked to provide guidance to CSAC on best in class. The



Surgery Committee agreed that due to the differences in data sources, one relying on administrative and the other on clinical registry data, these measures are “complementary” rather than competing and should co-exist in the NQF portfolio as such to meet the needs of different users with access to different types of data. Additionally, they recommended this measure be paired with the stratified volume measure.

**(0734) Participation in a National Database for Pediatric and Congenital Heart Surgery (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. The Committee discussed the use of registries for other patient populations, including the adult cardiac surgery population, where participation in multi-institutional databases/registries has been shown to improve research, measurement, and reporting capabilities. 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 it. 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. The CSAC considered the benefits and limitations of structural measures related to registry participation. The Board of Directors ratified endorsement of the pediatric cardiac surgery registry-participation measure but provided policy guidance that additional structural measures of registry participation would not be endorsed in the future.

**Candidate Consensus Standards Withdrawn from Consideration**

As discussed above in the Background section, the following 16 of the 21 originally submitted measures were withdrawn from consideration by the developer. The Committee encouraged the developer to resubmit many of these measures when testing and analysis on the need for risk adjustment is completed.

- 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) (STS)
- PCS-006-09: Availability of institutional pediatric ECLS (extracorporeal life support) (STS)
- PCS-009-09: Surgical volume for six pediatric and congenital heart operations (STS)
- PCS-010-09: Timing of antibiotic administration for pediatric and congenital cardiac surgery (STS)
- PCS-011-09: 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)
- 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

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](http://www.nhlbi.nih.gov/health/dci/Diseases/chd/chd_what.html). Last accessed August 2010.
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](http://www.marchofdimes.com/professionals/14332_1212.asp). Last accessed July 2010.
5. Ibid.
6. DeMone JA, Gonzalez PC, Gauvreau K, et al., Risk of death for Medicaid recipients undergoing congenital heart surgery, *Pediatr Cardiol*, 2006;24(2):97-102.
7. American Heart Association (AHA), *Congenital Heart Disease in Children Fact Sheet*, Dallas, TX: AHA; 2009. Available at [www.americanheart.org/presenter.jhtml?identifier=12012](http://www.americanheart.org/presenter.jhtml?identifier=12012). Last accessed August 2010.

8. Centers for Medicare & Medicaid Services (CMS), *The Guide to Quality Measures: A Compendium, Medicaid and SCHIP Quality Improvement, Volume 1*, Bethesda, MD: CMS; 2006. Available at: [www.cms.hhs.gov/MedicaidSCHIPQualPrac/Downloads/pmfinalaugust06.pdf](http://www.cms.hhs.gov/MedicaidSCHIPQualPrac/Downloads/pmfinalaugust06.pdf). Last accessed May 2007.
9. National Quality Forum (NQF), *National Priorities Partnership*, Washington, DC: NQF. Available at [www.nationalprioritiespartnership.org](http://www.nationalprioritiespartnership.org). Last accessed June 2010.
10. NQF, *Measure Evaluation Criteria*, Washington, DC: NQF; 2008. Available at [www.qualityforum.org/docs/measure\\_evaluation\\_criteria.aspx](http://www.qualityforum.org/docs/measure_evaluation_criteria.aspx). Last accessed June 2010.

## 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<sup>®</sup> *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 December 12, 2011. All NQF-endorsed voluntary consensus standards are open source, meaning they are fully accessible and disclosed. All measures were developed by The Society of Thoracic Surgeons (STS).

|                          | <b>Measure 0734: Participation in a National Database for Pediatric and Congenital Heart Surgery (The Society of Thoracic Surgeons [STS])</b>  |
|--------------------------|--|
| <b>Description</b>       | 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.   |
| <b>Numerator</b>         | Whether or not there is participation in at least one multi-center data collection and feedback program for pediatric and congenital heart surgery.  |
| <b>Numerator Details</b> | <p>Participation is defined as submission of all congenital and pediatric operations performed to the database.</p> <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, 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><b>**Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions.</b></p> <p>Pediatric heart surgery is heart surgery on patients &lt;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</p> |

|                              |  |
|------------------------------|--|
|                              | following operations:<br>1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease<br>2. heart surgery on patients of any age to treat congenital cardiac disease                           |
| <b>Denominator</b>           | NA   |
| <b>Denominator Details</b>   | NA   |
| <b>Exclusions</b>            | 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 bypass.) |
| <b>Exclusion details</b>     | NA   |
| <b>Risk Adjustment</b>       | No risk adjustment necessary   |
| <b>Stratification</b>        |  |
| <b>Numerator Time window</b> | Time Window: One year (12 months) and 4 years (48 months)  |
| <b>Type</b>                  | Structure  |
| <b>Type of Score</b>         | Other Dichotomous (Yes/No)   |
| <b>Data Source</b>           | Electronic administrative data/claims, Electronic Clinical Data, Electronic Health/Medical Record, Paper medical record/flow-sheet, Registry data  |
| <b>Level</b>                 | Clinicians : Group, Facility/Agency, Health Plan, Integrated Delivery System, Population : Counties or cities  |
| <b>Setting</b>               | Hospital   |

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|                            | <b>Measure 0733: Operative Mortality Stratified by the Five STS-EACTS Mortality Categories (STS) (Part of measure pair #1815)</b>   |
| <b>Description</b>         | Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool   |
| <b>Numerator</b>           | Number of patients who undergo pediatric and congenital open heart surgery and die during either of the following two time intervals:<br>1. Prior to hospital discharge<br>2. Within 30 days of the date of surgery   |
| <b>Numerator Details</b>   | Reference:<br>Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee. The Annals of Thoracic Surgery, 81(5):1937-41, May 2006.  |
| <b>Denominator</b>         | 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   |
| <b>Denominator Details</b> | 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.<br><br>O'Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro C, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L, Peterson ED, Mavroudis C, Edwards FH. An empirically based tool for analyzing mortality associated with congenital heart surgery. The Journal of Thoracic and Cardiovascular Surgery, 2009 Nov;138(5):1139-53.PMID: 19837218, November 2009.<br><br>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].<br><br>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.<br><br>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:<br><br>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><b>**Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions.</b></p> <p>Pediatric heart surgery is heart surgery on patients &lt;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"> <li>1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease</li> <li>2. heart surgery on patients of any age to treat congenital cardiac disease</li> </ol> <p>References:</p> <p>1. Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee. The Annals of Thoracic Surgery, 81(5):1937-41, May 2006.</p> |
| <b>Exclusions</b>            | <p>Measure Exclusions:</p> <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 Cardiovascular" (CPB is cardiopulmonary bypass.) [1].</p> <p>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.</p> <p>1. Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STS Congenital Database Committee. The Annals of Thoracic Surgery, 81(5):1937-41, May 2006.</p>   |
| <b>Exclusion details</b>     | N/A   |
| <b>Risk Adjustment</b>       | N/A   |
| <b>Stratification</b>        |   |
| <b>Numerator Time window</b> | One year (12 months) and 4 years (48 months); Tracked at one-year and four-year time intervals  |
| <b>Type</b>                  | Outcome   |
| <b>Type of Score</b>         | Rate/proportion   |
| <b>Data Source</b>           | Electronic Clinical Data, Electronic Health/Medical Record, Paper medical record/flow-sheet, Registry data  |
| <b>Level</b>                 | Clinicians : Group, Facility/Agency, Health Plan, Population : Counties or cities   |
| <b>Setting</b>               | Hospital  |

|                          | <b>Measure 0732: Surgical Volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by the Five STS-EACTS Mortality Categories (STS) (Part of measure pair #1815)</b>  |
|--------------------------|--|
| <b>Description</b>       | Surgical volume for pediatric and congenital heart surgery: total programmatic volume and programmatic volume stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool  |
| <b>Numerator</b>         | 1) Total number of pediatric and congenital cardiac surgery operations and 2) number of pediatric and congenital cardiac surgery operations in each of the strata of complexity specified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool   |
| <b>Numerator Details</b> | <p>Cardiac operations are defined as operations that are of operation types of “CPB” or “No CPB Cardiovascular”. (CPB is cardiopulmonary bypass.) [1]. Pediatric heart surgery is heart surgery on patients &lt;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>The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications (<a href="http://www.sts.org/sites/default/files/documents/pdf/CongenitalDataSpecificationsV3_0_20090904.pdf">http://www.sts.org/sites/default/files/documents/pdf/CongenitalDataSpecificationsV3_0_20090904.pdf</a> ). 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, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860</p> <p>As demonstrated in the previously provided publication [2], 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>References:</p> <p>1. Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STC Congenital Database Committee. <i>The Annals of Thoracic Surgery</i>, 81(5):1937-41, May 2006.</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>2. O’Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro C, Welke KF, Maruszewski B, Tobota Z, Miller WJ, Hamilton L, Peterson ED, Mavroudis C, Edwards FH. An empirically based tool for analyzing mortality associated with congenital heart surgery. <i>The Journal of Thoracic and Cardiovascular Surgery</i>, 2009 Nov;138(5):1139-53.PMID: 19837218, November 2009.</p> |



|                              |   |
|------------------------------|---|
| <b>Denominator</b>           | N/A   |
| <b>Denominator Details</b>   | N/A   |
| <b>Exclusions</b>            | <p>Measure Exclusions:</p> <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 Cardiovascular" (CPB is cardiopulmonary bypass.) [1].</p> <p>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.</p> <p>1. Jacobs JP, Mavroudis C, Jacobs ML, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ. What is Operative Mortality? Defining Death in a Surgical Registry Database: A Report from the STS Congenital Database Task Force and the Joint EACTS-STC Congenital Database Committee. The Annals of Thoracic Surgery, 81(5):1937-41, May 2006.</p> |
| <b>Exclusion details</b>     | N/A   |
| <b>Risk Adjustment</b>       | No risk adjustment necessary  |
| <b>Stratification</b>        | The second component of this measure captures volume stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool. Please see information provided in numerator details section above  |
| <b>Numerator Time window</b> | 12 months   |
| <b>Type</b>                  | Structure   |
| <b>Type of Score</b>         | Count   |
| <b>Data Source</b>           | Electronic Clinical Data : Registry   |
| <b>Level</b>                 | Clinician : Group/Practice, Facility, Population : County or City, Population : National, Population : Regional, Population : State   |
| <b>Setting</b>               | Hospital/Acute Care Facility  |

## **APPENDIX B: PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE AND NQF STAFF**

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