NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** PCS-008-09 **NQF Project:** Pediatric Cardiac Surgery 2009

MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Surgical Volume for Pediatric and Congenital Heart Surgery: Total Programmatic Volume and Programmatic Volume Stratified by the Five STS-EACTS Mortality Levels
De.2 **Brief description of measure:** 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
1.1-2 **Type of Measure:** Structure De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** Safety De.5 **IOM Quality Domain**: Safety De.6 **Consumer Care Need:** Getting better

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** Society of Thoracic Surgeons_2010-634141161804340024.pdf	**A** **Y**☐ **N**☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1 **Testing:** No, testing will be completed within 12 months D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. ***Measures must be judged to be important to measure and report*** *in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** High resource use 1a.2 1a.3 **Summary of Evidence of High Impact:** Congenital heart disease is a common birth defect that affects approximately 1 in 125 live births [1]. Pediatric and congenital heart surgery is a subspecialty of high resource utilization that has the potential to repair or palliate the majority of patients with pediatric and congenital cardiac disease. 1a.4 **Citations for Evidence of High Impact:** 1. Tchervenkov CI, Jacobs JP, Bernier P-L, Stellin G, Kurosawa H, Mavroudis C, Jonas RA, Cicek SM, Al-Halees Z, J. Elliott MJ, Jatene MB, Kinsley RH, Kreutzer C, Leon-Wyss J, Liu J, Maruszewski B, Nunn GR, Ramirez-Marroquin S, Sandoval N, Sano S, Sarris GE, Sharma R, Shoeb A, Spray TL, Ungerleider RM, Yangni-Angate H, Ziemer G. The improvement of care for paediatric and congenital cardiac disease across the World: a challenge for the World Society for Pediatric and Congenital Heart Surgery. In: 2008 Supplement to Cardiology in the Young: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 63-69, December 9, 2008.	**1a** C☐ P☐ M☐ N☐
1b. Opportunity for Improvement 1b.1 **Benefits (improvements in quality) envisioned by use of this measure:** The incidence of mortality	**1b** C☐ P☐

stratified by complexity varies between centers, as demonstrated in the STS Congenital Heart Surgery Database.

Over the past decade, mortality after pediatric cardiac surgery has been declining and currently stands at 4%. Nevertheless, operative mortality remains a significant indicator of programmatic quality. Because case mix varies between programs, operative mortality must be stratified by case mix [1, 2, 3, 4, 5]. In addition, in order to track a variety of outcomes represented in other proposed Quality Indicators, one must have a firm grasp on the volume of pediatric and congenital cardiac surgery performed at a center over both 1 year and 4 year time intervals, stratified by complexity, as required by this measure (Surgical Volume for Pediatric and Congenital Heart Surgery, Stratified by the five STS-EACTS Mortality Levels)

Tracking this structure measure is necessary in order to track other outcome measures that use this structure measure as a denominator. Furthermore, the very act of tracking this structure measure should in and of itself lead to improvements in quality.

References:

1. Jacobs ML, Jacobs JP, Jenkins KJ, Gauvreau K, Clarke DR, Lacour-Gayet FL. Stratification of complexity: The Risk Adjustment for Congenital Heart Surgery-1 Method and The Aristotle Complexity Score – past, present, and future. In: 2008 Cardiology in the Young Supplement: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 163–168, December 9, 2008.
2. Clarke DR, Lacour-Gayet F, Jacobs JP, Jacobs ML, Maruszewski B, Pizarro C, Edwards FH, Mavroudis C. The assessment of complexity in congenital cardiac surgery based on objective data. In: 2008 Cardiology in the Young Supplement: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 169–176, December 9, 2008.
3. O´Brien SM, Jacobs JP, Clarke DR, Maruszewski B, Jacobs ML, Walters HL 3rd, Tchervenkov CI, Welke KF, Tobota Z, Stellin G, Mavroudis C, Hamilton JR, Gaynor JW, Pozzi M, Lacour-Gayet FG. Accuracy of the Aristotle Basic Complexity Score for classifying the mortality and morbidity potential of congenital heart surgery operations. The Annals of Thoracic Surgery, 84(6):2027-37, PMID: 18036930, December 2007.
4. 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.
5. Jacobs JP, Jacobs ML, Lacour-Gayet FG, Jenkins KJ, Gauvreau K, Bacha EA, Maruszewski B, Clarke DR, Tchervenkov CI, Gaynor JW, Spray, TL, Stellin G, O´Brien SM, Elliott MJ, Mavroudis C. Stratification of Complexity Improves Utility and Accuracy of Outcomes Analysis in a Multi-institutional Congenital Heart Surgery Database – Application of the RACHS-1 and Aristotle Systems in the STS Congenital Heart Surgery Database. Pediatric Cardiology, accepted for publication, in press.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

Data is currently being collected in the STS Congenital Heart Surgery Database. Data will be provided within 24 months after endorsement is received. We know that 82 out of 122 pediatric heart surgery centers in the USA participate in the STS Congenital Heart Surgery Database.

1b.3 Citations for data on performance gap:

Jacobs JP, Jacobs ML, Mavroudis C, Lacour-Gayet FG, Tchervenkov CI. Executive Summary: The Society of Thoracic Surgeons Congenital Heart Surgery Database - Tenth Harvest – (January 1, 2005 – December 31, 2008). The Society of Thoracic Surgeons (STS) and Duke Clinical Research Institute (DCRI), Duke University Medical Center, Durham, North Carolina, United States, Spring 2009 Harvest.

1b.4 Summary of Data on disparities by population group:

No formal testing of disparities has been done. Disparities and trends could be tested for many of these metrics using the STS Database.

M☐
N☐

The incidence of mortality stratified by complexity varies between centers, as demonstrated in the STS Congenital Heart Surgery Database

1b.5 Citations for data on Disparities:
Jacobs JP, Jacobs ML, Mavroudis C, Lacour-Gayet FG, Tchervenkov CI. Executive Summary: The Society of Thoracic Surgeons Congenital Heart Surgery Database - Tenth Harvest – (January 1, 2005 – December 31, 2008). The Society of Thoracic Surgeons (STS) and Duke Clinical Research Institute (DCRI), Duke University Medical Center, Durham, North Carolina, United States, Spring 2009 Harvest.

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Please see section 1c.4

1c.2-3. Type of Evidence: Systematic synthesis of research

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
The relationship between the volume of pediatric and congenital cardiac surgery performed at a center and quality of care is unclear and controversial at best [1, 2, 3, 4, 5, 6, 7]. Nevertheless, in order to track a variety of outcomes represented in other proposed Quality Indicators, one must have a firm grasp on the volume of pediatric and congenital cardiac surgery performed at a center over both 1 year and 4 year time intervals. The very act of tracking this structure measure is necessary in order to track other outcome measures that use this structure measure as a denominator. Furthermore, the very act of tracking this structure measure can, in and of itself, lead to improvements in quality.

In addition to capturing total programmatic volume, it should also be stratified by complexity [8, 9, 10, 11, 13]. The selection of the proper tool for complexity stratification tool can be controversial. Suitable multi-institutional validated complexity stratification tools include the 5 functional RACHS-1 classifications, the 4 Aristotle Basic Complexity Score Levels, and the five STS-EACTS Mortality Levels. When comparing RACHS-1 and Aristotle, the Aristotle methodology allows classification of more operations while the RACHS-1 system discriminates better at the higher end of complexity.

The discrimination of any complexity stratification tool as a predictor of mortality can be quantified by calculating the c statistic, which is equivalent to the area under the receiver operating characteristic curve, as determined by univariable logistic regression [14]. The c statistic represents the probability that a randomly selected patient who had the outcome of interest (i.e. discharge mortality) had a higher predicted risk of the outcome compared to a randomly selected patient who did not experience the outcome. The c statistic generally ranges from 0.5 to 1.0 with 0.5 representing no discrimination (i.e. a coin flip) and 1.0 representing perfect discrimination.The model for risk-adjustment in the STS Adult Cardiac Surgery Database for predicting 30-day mortality after surgery to place coronary arterial bypass grafts, contains 28 clinical variables and has a C-statistic of 0.78 [14].

The Table below documents the c-statistic for the previously mentioned complexity stratification tools [13].

Method of Modeling Procedures	Model without patient covariates	Model with patient covariates
STS-EACTS Congenital Heart Surgery Mortality Categories (2009)	C = 0.778	C = 0.812
RACHS-1 Categories	C = 0.745	C = 0.802
Aristotle Basic Complexity Score	C = 0.687	C = 0.795

**STS recommends that only the STS-EACTS Congenital Heart Surgery Mortality Categories (2009) are used for complexity stratification of volume. The rationale for this is two-fold:
1. The C-statistic for the STS-EACTS Congenital Heart Surgery Mortality Categories (2009) is higher than those of the RACHS-1 Categories and the Aristotle Basic Complexity Score.
2. The publications provided below document that 84% of pediatric and congenital cardiac operations can be assessed by the RACHS-1 Categories, 96% by the Aristotle Basic Complexity Score, and 99% by the STS-EACTS Congenital Heart Surgery Mortality Categories (2009) [11,13,14].

Please note that the following publication was previously provided:
O´Brien SM, Clarke DR, Jacobs JP, Jacobs ML, Lacour-Gayet FG, Pizarro C, Welke KF, Maruszewski B, Tobota

1c
C☐
P☐
M☐
N☐

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.

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by whom***):** N/A

1c.6 Method for rating evidence: N/A

1c.7 Summary of Controversy/Contradictory Evidence: The selection of the proper tool for complexity stratification tool can be controversial. Suitable multi-institutional validated complexity stratification tools include the five functional RACHS-1 classifications, the four Aristotle Basic Complexity Score Levels, and the five STS-EACTS Mortality Levels [1, 2, 3, 4, 5]. When comparing RACHS-1 and Aristotle, the Aristotle methodology allows classification of more operations while the RACHS-1 system discriminates better at the higher end of complexity [5].

The discrimination of any complexity stratification tool as a predictor of mortality can be quantified by calculating the c statistic, as described in the previous section. The c-statistic represents the probability that a randomly selected patient who had the outcome of interest (i.e. discharge mortality) had a higher predicted risk of the outcome compared to a randomly selected patient who did not experience the outcome. The c-statistic generally ranges from 0.5 to 1.0 with 0.5 representing no discrimination (i.e. a coin flip) and 1.0 representing perfect discrimination. The model for risk-adjustment in the STS Adult Cardiac Surgery Database for predicting 30-day mortality after surgery to place coronary arterial bypass grafts, contains 28 clinical variables and has a C-statistic of 0.78 [5].

Table 1 displays c-statistics for the previously mentioned complexity stratification tools [4]:

Table 1: Method of Modeling Procedures	Model without patient covariates	Model with patient covariates
STS-EACTS Congenital Heart Surgery Mortality Categories (2009)	C = 0.778	C = 0.812
RACHS-1 Categories	C = 0.745	C = 0.802
Aristotle Basic Complexity Score	C = 0.687	C = 0.795

**STS recommends that only the STS-EACTS Congenital Heart Surgery Mortality Categories (2009) are used for complexity stratification of volume. The rationale for this was provided in a previous section.

References

1. Jacobs ML, Jacobs JP, Jenkins KJ, Gauvreau K, Clarke DR, Lacour-Gayet FL. Stratification of complexity: The Risk Adjustment for Congenital Heart Surgery-1 Method and The Aristotle Complexity Score – past, present, and future. In: 2008 Cardiology in the Young Supplement: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 163–168, December 9, 2008.

2. Clarke DR, Lacour-Gayet F, Jacobs JP, Jacobs ML, Maruszewski B, Pizarro C, Edwards FH, Mavroudis C. The assessment of complexity in congenital cardiac surgery based on objective data. In: 2008 Cardiology in the Young Supplement: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 169–176, December 9, 2008.

3. O´Brien SM, Jacobs JP, Clarke DR, Maruszewski B, Jacobs ML, Walters HL 3rd, Tchervenkov CI, Welke KF, Tobota Z, Stellin G, Mavroudis C, Hamilton JR, Gaynor JW, Pozzi M, Lacour-Gayet FG. Accuracy of the Aristotle Basic Complexity Score for classifying the mortality and morbidity potential of congenital heart surgery operations. The Annals of Thoracic Surgery, 84(6):2027-37, PMID: 18036930, December 2007.

4. 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

5. Jacobs JP, Jacobs ML, Lacour-Gayet FG, Jenkins KJ, Gauvreau K, Bacha EA, Maruszewski B, Clarke DR, Tchervenkov CI, Gaynor JW, Spray, TL, Stellin G, O´Brien SM, Elliott MJ, Mavroudis C. Stratification of Complexity Improves Utility and Accuracy of Outcomes Analysis in a Multi-institutional Congenital Heart Surgery Database – Application of the RACHS-1 and Aristotle Systems in the STS Congenital Heart Surgery Database. Pediatric Cardiology, accepted for publication, in press.

1c.8 Citations for Evidence (*other than guidelines***):**

1. Welke KF, O'Brien SM, Peterson ED, Ungerleider RM, Jacobs ML, Jacobs JP. The Complex Relationship between Pediatric Cardiac Surgical Case Volumes and Mortality Rates in a National Clinical Database. The Journal of Thoracic and Cardiovascular Surgery,. 2009 May;137(5):1133-40. Epub 2009 Mar 17, PMID: 19379979, May, 2009.

2. Bradley SM. Good Things in Small Packages: Meeting Challenge in the Low-volume Program. Jacobs JP, Wernovsky G, Cooper DS, Gaynor JW, Anderson RH (editors). 2009 Supplement to Cardiology in the Young: Annual Heart Week in Florida Supplement Number 7 - Innovation Associated With The Treatment Of Patients With Congenital and Pediatric Cardiac Disease, Cardiology in the Young, Volume 19, accepted for publication, in press.

3. Jenkins KJ, Newburger JW, Lock JE, et al. In-hospital mortality for surgical repair of congenital heart defects: preliminary observations of variation by hospital caseload. Pediatrics. 1995;95:323-30.

4. Hannan EL, Racz M, Kavey RE, Quagebeur JM, Williams R. Pediatric cardiac surgery: the effect of hospital and surgeon volume on in-hospital mortality. Pediatrics. 1998;101:963-9.

5. Sollano JA, Gelijns AC, Moskowitz AJ, et al. Volume-outcome relationships in cardiovascular operations: New York State, 1990-1995. J Thorac Cardiovasc Surg. 1999;117:419-28.

6. Chang RK, Klitzner TS. Can regionalization decrease the number of deaths for children who undergo cardiac surgery? A theoretical analysis. Pediatrics. 2002; 109:173-81.

7. Quintessenza JA, Jacobs JP, Morell VO. Issues in Regionalization of Pediatric Cardiovascular Care. Progress in Pediatric Cardiology 18 (2003) 49–53. Elsevier Science Ireland Ltd. 2003.

8. Jacobs JP, Lacour-Gayet FG, Jacobs ML, Clarke DR, Tchervenkov CI, Gaynor JW, Spray TL, Maruszewski B, Stellin G, Gould J, Dokholyan RS, Peterson ED, Elliott MJ, Mavroudis C. Initial application in the STS congenital database of complexity adjustment to evaluate surgical case mix and results. Ann Thorac Surg. 2005 May;79(5):1635-49.

9. Jacobs JP, Jacobs ML, Maruszewski B, Lacour-Gayet FG, Clarke DR, Tchervenkov CI, Gaynor JW, Spray TL, Stellin G, Elliott MJ, Ebels T, Mavroudis C. Current status of the European Association for Cardio-Thoracic Surgery and the Society of Thoracic Surgeons Congenital Heart Surgery Database. Ann Thorac Surg 80(6):2278-83, 2005.

10. Lacour-Gayet F., Jacobs J.P., Clarke D.R., Maruszewski B., Jacobs M.L., O'Brien S.M., Mavroudis C. Evaluation of the quality of care in congenital heart surgery: contribution of the Aristotle complexity score. Adv Pediatr. 2007;54:67-83.

11. O'Brien S.M., Jacobs J.P., Clarke D.R., Maruszewski B., Jacobs M.L., Walters H.L., Tchervenkov C.I., Welke K.F., Tobota Z., Stellin G., Mavroudis C., Hamilton J.R., Gaynor J.W., Pozzi M., Lacour-Gayet F.G. Accuracy of the Aristotle basic complexity score for classifying the mortality potential of congenital heart surgery operations. Ann Thorac Surg. 2007 Dec;84(6):2027-37.

12. Jacobs ML, Jacobs JP. Jenkins KJ, Gauvreau K, Clarke DR, Lacour-Gayet F. Stratification of complexity: The Risk Adjustment for Congenital Heart Surgery-1Method and The Aristotle Complexity Score – past, present, and future. Cardiol Young. 2008 Dec;18 Suppl 2:163-8.

13. 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.

14. Jacobs JP, Jacobs ML, Lacour-Gayet FG, Jenkins KJ, Gauvreau K, Bacha EA, Maruszewski B, Clarke DR, Tchervenkov CI, Gaynor JW, Spray, TL, Stellin G, O´Brien SM, Elliott MJ, Mavroudis C. Stratification of Complexity Improves Utility and Accuracy of Outcomes Analysis in a Multi-institutional Congenital Heart Surgery Database – Application of the RACHS-1 and Aristotle Systems in the STS Congenital Heart Surgery Database. Pediatric Cardiology, accepted for publication, in press.

1c.9 Quote the Specific guideline recommendation (*including guideline number and/or page number***):**
N/A

1c.10 Clinical Practice Guideline Citation: At the current time no uniform practice guidelines are in place for pediatric and congenital cardiac surgery. Clinical care rationale mainly depends on the consensus of a panel of experts in the field. In lieu of guideline support for the measures, published consensus opinion and supporting clinical data from the STS Congenital Heart Surgery Database will be used.

1c.11 National Guideline Clearinghouse or other URL: N/A

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom***):**
N/A

1c.13 Method for rating strength of recommendation (*If different from USPSTF system, also describe rating and how it relates to USPSTF)***:**
N/A

1c.14 Rationale for using this guideline over others:
N/A

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report*?	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, met? **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** 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 **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the numerator***):** 12 months **2a.3 Numerator Details (***All information required to collect/calculate the numerator, including all codes,*	**2a-specs** **C☐** **P☐** **M☐** **N☐**

logic, and definitions):
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 <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.

The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications (http://www.sts.org/sites/default/files/documents/pdf/CongenitalDataSpecificationsV3_0_20090904.pdf). Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease:

10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860

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.

References:
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.
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).

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. The Journal of Thoracic and Cardiovascular Surgery, 2009 Nov;138(5):1139-53.PMID: 19837218, November 2009.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
N/A

2a.5 Target population gender: Female, Male
2a.6 Target population age range: Pediatric heart surgery: patients <18 years of age. Congenital heart surgery: patients of any age to treat congenital cardiac disease

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
N/A

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
N/A

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** 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.) [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.

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.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
N/A

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
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

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Count
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
N/A

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
N/A

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)***:**
Electronic Clinical Data : Registry

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
The Society of Thoracic Surgeons Congenital Heart Surgery Database, Version 3.0

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL Data Collection Form - http://www.sts.org/sites/default/files/documents/pdf/ndb/CongenitalDataCollectionForm3_0_Annotated_20090916.pdf

2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.sts.org/sites/default/files/documents/pdf/CongenitalDataSpecificationsV3_0_20090904.pdf

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*

Clinician : Group/Practice, Facility, Population : County or City, Population : National, Population : Regional, Population : State

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Hospital/Acute Care Facility

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)
Clinicians: Physicians (MD/DO)

TESTING/ANALYSIS

2b. Reliability testing

2b.1 Data/sample *(description of data/sample and size)*: "Reliability is the extent to which an experiment, test, or any measuring procedure yields the same result on repeated trials. Without the agreement of independent observers able to replicate research procedures, or the ability to use research tools and procedures that yield consistent measurements, researchers would be unable to satisfactorily draw conclusions, formulate theories, or make claims about the generalizability of their research." [http://writing.colostate.edu/guides/research/relval/]

The reliability of the STS-EACTS Congenital Heart Surgery Mortality Categories (2009) is documented in detail in the following manuscript:

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.

Accuracy and Completeness of the STS Congenital Heart Surgery Database data

The audit process assures the accuracy and completeness of STS Congenital data through a combination of two strategies:

1. Intrinsic data verification – designed to rectify inconsistencies of data and missing elements of data)
2. Site visits with "Source Data Verification" – in other words, verification of the data at the primary source of the data

This process of verification of data has demonstrated that the STS Congenital Heart Surgery Database is very complete and accurate, as documented in the STS Congenital Heart Surgery Database Report Overview, as well as in the following peer-reviewed publication:

Clarke DR, Breen LS, Jacobs ML, Franklin RCG, Tobota Z, Maruszewski B, Jacobs JP. Verification of data in congenital cardiac surgery. In: 2008 Cardiology in the Young Supplement: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 177–187, December 9, 2008.

2b.2 Analytic Method *(type of reliability & rationale, method for testing)*:

2b.3 Testing Results *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:

2b
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2c. Validity testing

2c.1 Data/sample *(description of data/sample and size)*: "Validity refers to the degree to which a study accurately reflects or assesses the specific concept that the researcher is attempting to measure. While reliability is concerned with the accuracy of the actual measuring instrument or procedure, validity is

2c
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concerned with the study´s success at measuring what the researchers set out to measure.

Researchers should be concerned with both external and internal validity. External validity refers to the extent to which the results of a study are generalizable or transferable.

Internal validity refers to (1) the rigor with which the study was conducted (e.g., the study´s design, the care taken to conduct measurements, and decisions concerning what was and wasn´t measured) and (2) the extent to which the designers of a study have taken into account alternative explanations for any causal relationships they explore (Huitt, 1998). In studies that do not explore causal relationships, only the first of these definitions should be considered when assessing internal validity.

Scholars discuss several types of internal validity:

- Face Validity
- Criterion Related Validity
- Construct Validity
- Content Validity"

[http://writing.colostate.edu/guides/research/relval/]

This measure has been developed by a multi-institutional, multi-subspecialty panels of experts made up of international leaders in the medical and surgical care of patients with pediatric and congenital heart disease. This process is described in detail in the following publications:

1. Jacobs JP. (Editor). 2008 Supplement to Cardiology in the Young: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Cardiology in the Young, Volume 18, Supplement S2, pages 1 –530, December 9, 2008.

2. Jacobs JP. Introduction – Databases and the assessment of complications associated with the treatment of patients with congenital cardiac disease. In: 2008 Supplement to Cardiology in the Young: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 1-37, December 9, 2008.

3. Jacobs JP, Jacobs ML, Mavroudis C, Backer CL, Lacour-Gayet FG, Tchervenkov CI, Franklin RCG, Béland MJ, Jenkins KJ, Walters III H, Bacha EA, Maruszewski B, Kurosawa H, Clarke DR, Gaynor JW, Spray TL, Stellin G, Ebels T, Krogmann ON, Aiello VD, Colan SD, Weinberg P, Giroud JM, Everett A, Wernovsky G, Martin J. Elliott MJ, Edwards FH. Nomenclature and databases for the surgical treatment of congenital cardiac disease – an updated primer and an analysis of opportunities for improvement. In: 2008 Supplement to Cardiology in the Young: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 38–62, December 9, 2008.

Mortality and morbidity related to pediatric and congenital heart surgery are defined in detail in the following publications:

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.

2. Jacobs JP, Jacobs ML, Mavroudis C, Maruszewski B, Tchervenkov CI, Lacour-Gayet FG, Clarke DR, Yeh T, Walters HL 3rd, Kurosawa H, Stellin G, Ebels T, Elliott MJ, Vener DF, Barach P, Benavidez OJ, Bacha EA.. What is Operative Morbidity? Defining Complications 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; 84:1416-1421, October 2007.

Due to the process used to develop these measures, we believe they have exceptional face validity. These metrics have external validity because they are clearly generalizable or transferable, as documented in the publications mentioned above. When used in the STS Congenital Heart Surgery Database, these metrics have internal validity due to (1) the rigor of the analyses conducted and (2) the extent to which the STS Congenital Heart Surgery Database Task Force has recognized and considered alternative explanations for any causal relationships reported, as documented in the STS Congenital Heart Surgery Database Feedback Report and Report Overview, which has been sent to the National Quality Forum in a separate e-mail. Finally, as these outcome metrics encompass a broad and comprehensive range of outcomes that are all directly related to pediatric cardiac surgery performance, we believe they have strong content and construct validity.

As stated above, extensive testing has also been performed within the STS Congenital Heart Surgery Database that confirms the validity and reliability of the three multi-institutional validated complexity stratification tools (the five functional RACHS-1 classifications, the four Aristotle Basic Complexity Score Levels, or the five STS-EACTS Congenital Heart Surgery Mortality Categories [2009]). This testing is summarized in the following manuscripts:

1. O´Brien SM, Jacobs JP, Clarke DR, Maruszewski B, Jacobs ML, Walters HL 3rd, Tchervenkov CI, Welke KF, Tobota Z, Stellin G, Mavroudis C, Hamilton JR, Gaynor JW, Pozzi M, Lacour-Gayet FG. Accuracy of the Aristotle Basic Complexity Score for classifying the mortality and morbidity potential of congenital heart surgery operations. The Annals of Thoracic Surgery, 84(6):2027-37, PMID: 18036930, December 2007.

2. Jacobs JP, Jacobs ML, Lacour-Gayet FG, Jenkins KJ, Gauvreau K, Bacha E, Maruszewski B, Clarke DR, Tchervenkov CI, Gaynor JW, Spray TL, Stellin G, O´Brien SM, Elliott MJ, Mavroudis C. Stratification of complexity improves the utility and accuracy of outcomes analysis in a Multi-Institutional Congenital Heart Surgery Database: Application of the Risk Adjustment in Congenital Heart Surgery (RACHS-1) and Aristotle Systems in the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database. Pediatric Cardiology, 2009, DOI 10.1007/s00246-009-9496-0.

3. 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.

The third manuscript in the list above describes the development of the "STS-EACTS Congenital Heart Surgery Mortality Categories (2009)" using data from 77,294 operations entered into the European Association for Cardiothoracic Surgery (EACTS) Congenital Heart Surgery Database (33,360 operations) and the STS Congenital Heart Surgery Database (43,934 patients) between 2002 and 2007. This manuscript clearly states that: "Model performance was subsequently assessed in an independent validation sample (n = 27,700) and compared with 2 existing methods: Risk Adjustment for Congenital Heart Surgery (RACHS-1) categories and Aristotle Basis Complexity scores." This peer-reviewed and published validity testing using "an independent validation sample (n = 27,700 operations)" generated the c-statistics shown in Table 1 below and should satisfy the requirements for validity and reliability testing for our outcome metrics. The technical details of this validity and reliability testing is described in reference number 3 above. This publication is also provided as STS Attachment 1 (of 2) - O´Brien et al, JTCVS, Nov 2009.

Table 1: Method of Modeling Procedures	Model without patient covariates	Model with patient covariates
STS-EACTS Congenital Heart Surgery Mortality Categories (2009)	C = 0.778	C = 0.812
RACHS-1 Categories	C = 0.745	C = 0.802
Aristotle Basic Complexity Score	C = 0.687	C = 0.795

2c.2 Analytic Method *(type of validity & rationale, method for testing)***:**

2c.3 Testing Results *(statistical results, assessment of adequacy in the context of norms for the test conducted)***:**

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):

STS excludes 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]. In addition, STS exclude sany 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.

This measure is designed to track total surgical volume and volume stratified by the five STS-EACTS Mortality Levels, which is a multi-institutional validated complexity stratification tool. Published methodology is available that describes the proper techniques for gathering this information based on the consensus of a panel of experts.

Furthermore, it is important to understand that the Society of Thoracic Surgeons advocates utilization of a systematic multi-institutional clinical database (registry) for the analysis of cardiac surgical outcomes and the assessment of quality. Evidence from three recent investigations suggests that the validity of coding of lesions seen in the congenitally malformed heart via the International Classification of Diseases as used in Administrative Databases is likely to be poor[2, 3, 4]. First, in a series of 373 infants with congenital cardiac defects at Children's Hospital of Wisconsin, investigators report that only 52% of the cardiac diagnoses in the medical records had a corresponding code from the International Classification of Diseases in the hospital discharge database [2]. Second, the Hennepin County Medical Center discharge database in Minnesota identified all infants born during 2001 with a code for congenital cardiac disease using the International Classification of Diseases. A review of these 66 medical records by physicians was able to confirm only 41% of the codes contained in the administrative database from the International Classification of Diseases [3]. Third, the Metropolitan Atlanta Congenital Defect Program of the Birth Defect Branch of the Centers for Disease Control and Prevention of the federal government of the United States of America carried out surveillance of infants and fetuses with cardiac defects delivered to mothers residing in Atlanta during the years 1988 through 2003 [4]. These records were reviewed and classified using both administrative coding and the clinical nomenclature used in the Society of Thoracic Surgeons Congenital Heart Surgery Database. This study concluded that analyses based on the codes available in the International Classification of Diseases are likely to "have substantial misclassification" of congenital cardiac disease.

Several potential reasons can explain the poor diagnostic accuracy of Administrative Databases and codes from the International Classification of Diseases:
1) accidental miscoding
2) coding performed by medical records clerks who have never seen the actual patient
3) contradictory or poorly described information in the medical record
4) lack of diagnostic specificity for congenital cardiac disease in the codes of the of International Classification of Diseases
5) inadequately trained medical coders

2d.2 Citations for Evidence:

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.

2. Cronk CE, Malloy ME, Pelech AN, et al. Completeness of state administrative databases for surveillance of congenital heart disease. Birth Defects Res A Clin Mol Teratol 2003; 67: 597-603.

3. Frohnert BK, Lussky RC, Alms MA, Mendelsohn NJ, Symonik DM, Falken MC. Validity of hospital discharge data for identifying infants with cardiac defects. J Perinatol 2005; 25: 737-742.

4. Strickland MJ, Riehle-Colarusso TJ, Jacobs JP, Reller MD, Mahle WT, Botto LD, Tolbert PE, Jacobs ML, Lacour-Gayet FG, Tchervenkov CI, Mavroudis C, Correa A. The importance of nomenclature for congenital cardiac disease: implications for research and evaluation. In: 2008 Supplement to Cardiology in the Young:

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NA ☐

Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 92-100, December 9, 2008. 2d.3 **Data/sample** *(description of data/sample and size)*: 2d.4 **Analytic Method** *(type analysis & rationale)*: 2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:	
2e. Risk Adjustment for Outcomes/ Resource Use Measures 2e.1 **Data/sample** *(description of data/sample and size)*: None 2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*: 2e.3 **Testing Results** *(risk model performance metrics)*: 2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:**	**2e** C☐ P☐ M☐ N☐ NA ☐
2f. Identification of Meaningful Differences in Performance 2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: The STS Congenital Heart Surgery Database 2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*: Outliers can be identified with 95% confidence intervals based on the sample size, with complexity stratification for one and four-year time intervals. Data will be available when the STS Congenital Heart Surgery Database National Report is published in May 2010. 2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*: Currently being collected in the STS Congenital Heart Surgery Database. We do not have this data. We know that 82 out of 122 pediatric heart surgery centers in the USA participate in the STS Congenital Heart Surgery Database.	**2f** C☐ P☐ M☐ N☐
2g. Comparability of Multiple Data Sources/Methods 2g.1 **Data/sample** *(description of data/sample and size)*: Clinical data abstraction is the only method utilized 2g.2 **Analytic Method** *(type of analysis & rationale)*: 2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:	**2g** C☐ P☐ M☐ N☐ NA ☐
2h. Disparities in Care 2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: 2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**	**2h** C☐ P☐ M☐ N☐ NA

	☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties*?	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, met? **Rationale:**	***2*** **C☐** **P☐** **M☐** **N☐**
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information **3a.1 Current Use:** In use **3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*)**:** **3a.3 If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) **3a.4 Data/sample** *(description of data/sample and size)***:** Post-operative mortality and morbidity data are currently being collected voluntarily by The Society of Thoracic Surgeons Congenital Cardiac Surgery Database. All of the outcome metrics are used by clinicians as performance feedback and are tracked in the STS Database. No focused consumer testing has been done to date on any of these metrics. No public reporting has been done on any of these metrics to date. Pediatric and congenital heart surgery is very different from adult heart surgery. Separate metrics are necessary. **3a.5 Methods** *(e.g., focus group, survey, QI project)***:** **3a.6 Results** *(qualitative and/or quantitative results and conclusions)***:**	**3a** **C☐** **P☐** **M☐** **N☐**
3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): **3b.2 Are the measure specifications harmonized? If not, why?** This measure has been harmonized with PCS-007-09 Surgical Volume for Pediatric and Congenital Heart Surgery at the request of the NQF Surgery Steering Committee. It has not been harmonized with # 0340. It is STS´s understanding that the NQF Surgery Steering Committee is in agreement that harmonization with #340 is not necessary.	**3b** **C☐** **P☐** **M☐** **N☐** **NA☐**

(Provided in original STS submission in 2009):
NQF # 0340 and NQF # 0339 are both suboptimal. The limitations of each of these measures will be reviewed below:

NQF # 0340
Title: Pediatric Heart Surgery Volume (PDI 7)
Status: Endorsed
Endorsed on: MAY 15, 2008
Steward(s): Agency for Healthcare Research and Quality
Description: Raw volume compared to annual thresholds (100 procedures)

The relationship between the volume of pediatric and congenital cardiac surgery performed at a center and quality of care is unclear and controversial at best [1, 2, 3, 4, 5, 6, 7]. Evidence simply does not exist to support an annual volume threshold of 100 procedures.

Nevertheless, in order to track a variety of outcomes represented in other proposed Quality Indicators, one must have a firm grasp on the volume of pediatric and congenital cardiac surgery performed at a center over both 1 year and 4 year time intervals. The very act of tracking this structure measure is necessary in order to track other outcome measures that use this structure measure as a denominator. Furthermore, very act of tracking this structure measure should in and of itself lead to improvements in quality.

The operations counted towards this metric must clearly be defined as 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.) [8]. Published methodology is available that describes the proper techniques for gathering this information based on the consensus of a panel of experts.

NQF # 0339
Title: Pediatric Heart Surgery Mortality (PDI 6) (risk adjusted)
Status: Endorsed
Endorsed on: MAY 15, 2008
Steward(s): Agency for Healthcare Research and Quality
Description: Number of in-hospital deaths in patients undergoing surgery for congenital heart disease per 1000 patients.

Furthermore, it is important to understand that the Society of Thoracic Surgeons advocates utilization of a systematic multi-institutional clinical database (registry) for the analysis of cardiac surgical outcomes and the assessment of quality. Evidence from three recent investigations suggests that the validity of coding of lesions seen in the congenitally malformed heart via the International Classification of Diseases as used in Administrative Databases is likely to be poor[9, 10, 11]. First, in a series of 373 infants with congenital cardiac defects at Children's Hospital of Wisconsin, investigators report that only 52% of the cardiac diagnoses in the medical records had a corresponding code from the International Classification of Diseases in the hospital discharge database [9]. Second, the Hennepin County Medical Center discharge database in Minnesota identified all infants born during 2001 with a code for congenital cardiac disease using the International Classification of Diseases. A review of these 66 medical records by physicians was able to confirm only 41% of the codes contained in the administrative database from the International Classification of Diseases [10]. Third, the Metropolitan Atlanta Congenital Defect Program of the Birth Defect Branch of the Centers for Disease Control and Prevention of the federal government of the United States of America carried out surveillance of infants and fetuses with cardiac defects delivered to mothers residing in Atlanta during the years 1988 through 2003 [11]. These records were reviewed and classified using both administrative coding and the clinical nomenclature used in the Society of Thoracic Surgeons Congenital Heart Surgery Database. This study concluded that analyses based on the codes available in the International Classification of Diseases are likely to "have substantial misclassification" of congenital cardiac disease.

Several potential reasons can explain the poor diagnostic accuracy of Administrative Databases and codes from the International Classification of Diseases:

1) accidental miscoding
2) coding performed by medical records clerks who have never seen the actual patient
3) contradictory or poorly described information in the medical record
4) lack of diagnostic specificity for congenital cardiac disease in the codes of the of International Classification of Diseases
5) inadequately trained medical coders

References:

1. Welke KF, O'Brien SM, Peterson ED, Ungerleider RM, Jacobs ML, Jacobs JP. The Complex Relationship between Pediatric Cardiac Surgical Case Volumes and Mortality Rates in a National Clinical Database. The Journal of Thoracic and Cardiovascular Surgery,. 2009 May;137(5):1133-40. Epub 2009 Mar 17, PMID: 19379979, May, 2009.

2. Bradley SM. Good Things in Small Packages: Meeting Challenge in the Low-volume Program. Jacobs JP, Wernovsky G, Cooper DS, Gaynor JW, Anderson RH (editors). 2009 Supplement to Cardiology in the Young: Annual Heart Week in Florida Supplement Number 7 - Innovation Associated With The Treatment Of Patients With Congenital and Pediatric Cardiac Disease, Cardiology in the Young, Volume 19, accepted for publication, in press.

3. Jenkins KJ, Newburger JW, Lock JE, et al. In-hospital mortality for surgical repair of congenital heart defects: preliminary observations of variation by hospital caseload. Pediatrics. 1995;95:323-30.

4. Hannan EL, Racz M, Kavey RE, Quagebeur JM, Williams R. Pediatric cardiac surgery: the effect of hospital and surgeon volume on in-hospital mortality. Pediatrics. 1998;101:963-9.

5. Sollano JA, Gelijns AC, Moskowitz AJ, et al. Volume-outcome relationships in cardiovascular operations: New York State, 1990-1995. J Thorac Cardiovasc Surg. 1999;117:419-28.

6.Chang RK, Klitzner TS. Can regionalization decrease the number of deaths for children who undergo cardiac surgery? A theoretical analysis. Pediatrics. 2002; 109:173-81.

7. Quintessenza JA, Jacobs JP, Morell VO. Issues in Regionalization of Pediatric Cardiovascular Care. Progress in Pediatric Cardiology 18 (2003) 49–53. Elsevier Science Ireland Ltd. 2003.

8. 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.

9. Cronk CE, Malloy ME, Pelech AN, et al. Completeness of state administrative databases for surveillance of congenital heart disease. Birth Defects Res A Clin Mol Teratol 2003; 67: 597-603.

10. Frohnert BK, Lussky RC, Alms MA, Mendelsohn NJ, Symonik DM, Falken MC. Validity of hospital discharge data for identifying infants with cardiac defects. J Perinatol 2005; 25: 737-742.

11. Strickland MJ, Riehle-Colarusso TJ, Jacobs JP, Reller MD, Mahle WT, Botto LD, Tolbert PE, Jacobs ML, Lacour-Gayet FG, Tchervenkov CI, Mavroudis C, Correa A. The importance of nomenclature for congenital cardiac disease: implications for research and evaluation. In: 2008 Supplement to Cardiology in the Young: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young, Volume 18, Issue S2 (Suppl. 2), pp 92–100, December 9, 2008.

3c. Distinctive or Additive Value

3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:

Please see above

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P☐
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5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality: Please see above	**N☐ NA ☐**
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, met? **Rationale:**	**3** **C☐** **P☐** **M☐** **N☐**
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
4a. Data Generated as a Byproduct of Care Processes **4a.1-2 How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	**4a** **C☐** **P☐** **M☐** **N☐**
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes **4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** **C☐** **P☐** **M☐** **N☐**
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** **C☐** **P☐** **M☐** **N☐** **NA ☐**
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences **4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** Inaccuracies and Errors: This measure may be susceptible to human error (i.e., recording the measure inaccurately or not recording the measure at all) Unintended Consequences: One should be cautious in drawing conclusions from the observation of these measures, especially in circumstances where there is a declining morbidity and mortality. 1,2 1. Welke KF, Karamlou T, Ungerleider RM, Diggs BS. Mortality is not a valid indicator of quality differences between pediatric cardiac surgery programs. Ann Thoracic Surgery. (in press) 2. O'Brien SM, Gauvreau K. Statistical issues in the analysis and interpretation of outcomes for congenital cardiac surgery. In: 2008 Cardiology in the Young Supplement: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD	**4d** **C☐** **P☐** **M☐** **N☐**

(editor). Cardiology in the Young. 2008;18(Suppl.2):145–151.

naccuracies and Errors:
Each participant is responsible for the quality and accuracy of the data they submit to the database. Each participant agrees to the following quality control measures in the participation agreement:

i) "Participant hereby warrants that all data submitted for inclusion in the CHS Database will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the independent data warehouse service provider, and agrees to cooperate with and assist STS and its designees in connection with the performance of any independent audit.

ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the CHS Database, including but not limited to apprising the Director of the STS National Database and the independent data warehouse service provider about any other Participation Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named."

In addition, the Data warehouse and analysis center at Duke Clinical Research Institute, performs a series of internal quality controls on the submitted data and issues an annual data quality report

Unintended Consequences:
The Society of Thoracic Surgeons Database audit process is used. In addition, outliers can be identified with 95% confidence intervals based on the sample size with complexity stratification for one and four-year time intervals

4e. Data Collection Strategy/Implementation

4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:
Lessons Learned:
•The STS CHS database collects gender, race/ethnicity, age and geographic location information, so disparities and trends can be studied for populations at risk.
•Data elements required for the measure can be captured and the measure is actionable by the physician.
•There are no data availability issues.
•Cost to collect the data includes staff training and the use of specific software. However there are no additional costs over what a provider would pay to be a part of the STS CHS Database or other registry that collects this information.
•This measure can be used in a variety of care settings and at different levels of analysis (i.e. physician, hospital, etc.)
•Formal reliability testing was not done. Instead, the participant is bound by the participation agreement and his/her participation can be monitored by observing the data submitted on an annual basis.
•There are no confidentiality concerns. The data is de-identified, and the sites must be HIPAA compliant and obtain IRB approval for use of the database.
•The STS Congenital Quality Measures Sub-Committee meets at the STS Annual Meeting. The Subcommittee will review each STS congenital cardiac surgery measure on a yearly basis. Changes or updates to the measure will be at the recommendation of the committee.
• The STS has a yearly meeting (The Advances in Quality and Outcomes Conference) devoted to the Database for the clinicians and data coordinators.
•The audit process has demonstrated that data is very complete and accurate.1

1. Clarke DR, Breen LS, Jacobs ML, Franklin RCG, Tobota Z, Maruszewski B, Jacobs JP. Verification of data in congenital cardiac surgery. In: 2008 Cardiology in the Young Supplement: Databases and The Assessment of Complications associated with The Treatment of Patients with Congenital Cardiac Disease, Prepared by: The

4e
C☐
P☐
M☐
N☐

Multi-Societal Database Committee for Pediatric and Congenital Heart Disease, Jeffrey P. Jacobs, MD (editor). Cardiology in the Young. 2008;18(Suppl. 2):177–187. 4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** 4e.3 **Evidence for costs:** 4e.4 **Business case documentation:**	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met? **Rationale:**	**4** **C☐** **P☐** **M☐** **N☐**
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited ☐**
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y☐** **N☐** **A☐**

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner)**
Co.1 **Organization**
The Society of Thoracic Surgeons, 633 N. Saint Clair St, Floor 23, Chicago, Illinois, 60611

Co.2 **Point of Contact**
Jane, Han, MSW, jhan@sts.org, 312-202-5856-

Measure Developer If different from Measure Steward
Co.3 **Organization**
The Society of Thoracic Surgeons, 633 North Saint Clair Street, Floor 23, Chicago, Illinois, 60611

Co.4 **Point of Contact**
Jeffrey, Jacobs, M.D., FACS, FACC, FCCP, jeffjacobs@msn.com, 727-822-6666-

Co.5 **Submitter If different from Measure Steward POC**
Jane, Han, MSW, jhan@sts.org, 312-202-5856-, The Society of Thoracic Surgeons

Co.6 **Additional organizations that sponsored/participated in measure development**

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
The STS Task Force to Develop NQF Indicators for Pediatric and Congenital Cardiac Surgery members collectively formulated the numerator statement and defined its parameters in addition to identifying data elements and sources of data.

Ad.2 **If adapted, provide name of original measure:** At the NQF Surgery Steering Committee's request, this measure has been harmonized with PCS-007-09: Surgical Volume for Pediatric and Congenital Heart Surgery.

Ad.3-5 If adapted, provide original specifications URL or attachment
Measure Developer/Steward Updates and Ongoing Maintenance **Ad.6 Year the measure was first released:** 2009 **Ad.7 Month and Year of most recent revision:** 09, 2009 **Ad.8 What is your frequency for review/update of this measure?** once a year at annual meeting **Ad.9 When is the next scheduled review/update for this measure?** 01, 2012
Ad.10 Copyright statement/disclaimers:
Ad.11 -13 Additional Information web page URL or attachment:
Date of Submission (*MM/DD/YY*)**:** 07/12/2011