NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Pediatric & Congenital Cardiac Surgery

TO: Surgery Endorsement Maintenance Steering Committee
FR: Ashlie Wilbon, NQF Project Manager
SU: Competing Pediatric Cardiac Surgery Mortality & Volume Measures
DA: May 2, 2011

Purpose

This memo provides information on three mortality measures and three volume measures for the pediatric and congenital heart surgery population being evaluated to determine the best measure for NQF endorsement. The Consensus Standards Approval Committee (CSAC) has requested the Surgery Committee' recommendation on "best in class" before taking further action on the measures submitted in a prior project.

Mortality Measures

- **PCS-018-09:** Pre-Operative Mortality Stratified by the Five STS-EACTS Mortality Levels (Society for Thoracic Surgeons) [click here to view submission form]
- **PCS-021-09:** Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted (Children's Hospital, Boston) [click here to view submission form]
- **0339:** Pediatric Heart Surgery Mortality (PDI 6) (risk adjusted) (AHRQ)

Volume Measures

- **PCS-007-09:** Surgical Volume for Pediatric and Congenital Heart Surgery (Society for Thoracic Surgeons) [click here to view submission form]
- **PCS-008-09:** Surgical Volume for Pediatric and Congenital Heart Surgery, Stratified by the Five STS-EACTS Mortality Levels (Society for Thoracic Surgeons) [click here to view submission form]
- **0340:** Pediatric Heart Surgery Volume (PDI 7) (AHRQ)

Surgery Steering Committee Action:

Using the measure evaluation criteria and draft guidance on reviewing competing measures, provide guidance to the Consensus Standards Approval Committee (CSAC) on the best measure or identify specific justification for endorsing more than one measure.

Background on Competing Pediatric Cardiac Surgery Measures

In 2008 NQF endorsed a pediatric cardiac surgery risk-adjusted mortality measure (0339-PDI 6 by AHRQ) and pediatric heart surgery volume measure (0340-PDI 7 by AHRQ); both of these measures are currently under maintenance review by this Surgery Committee. In 2009, two similar mortality measures and two similar volume measures were submitted to the Pediatric Cardiac Surgery project. The similar mortality measures included a measure of operative mortality stratified by the STS-EACTS complexity stratification tool (PCS-018-09 by STS), and the other a standardized mortality ratio (SMR) [PCS-021-09 by Children's Hospital, Boston (CHB)] using the RACHS-1 method in a statistical risk-adjustment model. The similar volume measures included a surgical volume measure (PCS-007-09 by STS) and a volume

measure stratifying by mortality levels using the STS-EACTS tool (PCS-008-09 by STS). At the time of the pediatric project, the AHRQ measures were not up for endorsement maintenance.

The 2009 Pediatric Cardiac Surgery Steering Committee evaluated the two new mortality measures and the two new volume measures against the 2009 NQF measure evaluation criteria and recommended them for endorsement, but was unable to determine the best measures. The NQF Board has recently re-emphasized NQF's policy to endorse one measure on a particular topic whenever possible and the CSAC has developed guidance to assist steering committees in their review of competing measures (see attached competing measures guidance). Because the AHRQ measures are now undergoing review for endorsement maintenance, the CSAC has requested that the Surgery Steering Committee review all six measures and make recommendations regarding identification of the best measure before it takes action on the two new measures held over from the Pediatric Cardiac Surgery Project. Based on recent discussions with the Board, a clear rationale and justification would be required if more than one measure in the same topical area for the same patient population is recommended for endorsement.

Comparing the Pediatric Heart Surgery Mortality and Volume Measures

Although these measures focus on the same outcome of mortality in the same target population of patients, there are some differences in data source, exclusions, and risk adjustment methodology. The STS measure (PCS-09-018) is based on clinical data submitted according to the STS registry specifications; it produces a rate for each EACTS risk category. The CHB measure (PCS-09-021) is based on either claims data or clinical record data; it is risk adjusted and produces a standardized mortality ratio. The endorsed AHRQ measure (0339) is based on claims data and produces a risk adjusted rate per 1000 patients.

NQF aims to endorse the measure that provides the best representation of quality of care. For all three measures, evidence of risk model validation was presented. The reported C-statistics indicate adequate discrimination: AHRQ measure 0339: 0.875; STS measure PCS-09-018: 0.778-0.812; CHB measure PCS-09-021: 0.809 – 0.854.

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

The tables below provide a side-by-side comparison of the specifications for the competing mortality and volume measures.

A summary of the Pediatric Cardiac Surgery Steering Committee's evaluation of the measures follows the specs tables.

Competing Mortality Measures

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
Title	Pre-Operative Mortality Stratified by the Five STS-EACTS Mortality Levels	Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted.	Pediatric Heart Surgery Mortality (PDI 6) (risk adjusted)
Status	Recommended for Endorsement	Recommended for Endorsement	Under Endorsement-Maintenance Review
Steward	Society of Thoracic Surgeons	Program for Patient Safety and Quality, Children's Hospital Boston	Agency for Healthcare Research & Quality
Description	Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Ratio of observed to expected rate of in-hospital mortality following surgical repair of congenital heart defect among patients <18 years of age, risk-adjusted using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method.	Percentage of cases undergoing surgery for congenital heart disease with an in-hospital death.
Numerator	Number of patients who undergo pediatric and congenital open heart surgery and die during either of the following two time intervals: 1. Prior to hospital discharge 2. Within 30 days of the date of surgery	Cases of congenital heart surgery among patients <18 years of age resulting in in-hospital death.	Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator with a code of pediatric heart surgery with ICD-9-CM diagnosis of congenital heart disease in any field.
Numerator Details		Number of cases of congenital heart surgery among patients <18 years of age able to be placed into a RACHS-1 risk category (see item 8 below) where patient disposition is death prior to hospital discharge.	Number of deaths (DISP=20) among cases meeting the inclusion and exclusion rules for the denominator with a code of pediatric heart surgery with ICD-9-CM diagnosis of congenital heart disease in any field.
Denominator	Number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-	Total cases of congenital heart surgery among patients <18 years of age.	Discharges under age 18 with ICD-9-CM procedure codes for congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD-9-CM

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	institutional validated complexity stratification tool		diagnosis of congenital heart disease (2D) in any field.
Denominator Details	As demonstrated in the following publication (STS Attachment 1 (of 2) - O'Brien et al, JTCVS, Nov 2009), the five STS-EACTS Mortality Levels constitute an objective and empirically based tool for complexity stratification. In addition, it represents an improvement over existing consensus-based tools. Definition: The number of patients who undergo pediatric and congenital Cardiac Operation - Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1]. Definition: The number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool. The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the	Pediatric cases <18 years of age undergoing surgical repair of a congenital heart defect and able to be placed into a RACHS-1 risk category (see item 8 below).	Discharges under age 18 with ICD-9-CM procedure codes for congenital heart disease (1P) or non-specific heart surgery (2P) with ICD-9-CM diagnosis of congenital heart disease (2D) in any field. Congenital heart disease procedures (1P): 3500 CLOSED VALVOTOMY NOS 3501 CLOSED AORTIC VALVOTOMY 3502 CLOSED MITRAL VALVOTOMY 3503 CLOSED PULMON VALVOTOMY 3504 CLOSED TRICUSP VALVOTOMY 3510 OPEN VALVULOPLASTY NOS 3511 OPN AORTIC VALVULOPLASTY 3512 OPN MITRAL VALVULOPLASTY 3513 OPN PULMON VALVULOPLASTY 3514 OPN TRICUS VALVULOPLASTY 3520 REPLACE HEART VALVE NOS 3521 REPLACE AORT VALV-TISSUE

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
	following component procedures on a patient with pediatric and/or congenital cardiac disease: STS Denominator Codes: 10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330,		3522 REPLACE AORTIC VALVE NEC 3523 REPLACE MITR VALV-TISSUE 3524 REPLACE MITRAL VALVE NEC 3525 REPLACE PULM VALV-TISSUE 3526 REPLACE PULMON VALVE NEC 3527 REPLACE TRIC VALV-TISSUE 3528 REPLACE TRICUSP VALV NEC 3531 PAPILLARY MUSCLE OPS 3532 CHORDAE TENDINEAE OPS 3533 ANNULOPLASTY 3534 INFUNDIBULECTOMY 3535 TRABECUL CARNEAE CORD OP 3539 TISS ADJ TO VALV OPS NEC 3541 ENLARGE EXISTING SEP DEF 3542 CREATE SEPTAL DEFECT 3550 PROSTH REP HRT SEPTA NOS 3551

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
	2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 **Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions. Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease		PROS REP ATRIAL DEF-OPN 3552 PROS REPAIR ATRIA DEF-CL 3553 PROST REPAIR VENTRIC DEF 3554 PROS REP ENDOCAR CUSHION 3560 GRFT REPAIR HRT SEPT NOS 3561 GRAFT REPAIR ATRIAL DEF 3562 GRAFT REPAIR VENTRIC DEF 3563 GRFT REP ENDOCAR CUSHION 3570 HEART SEPTA REPAIR NOS 3571 ATRIA SEPTA DEF REP NEC 3572 VENTR SEPTA DEF REP NEC 3573 ENDOCAR CUSHION REP NEC 3581 TOT REPAIR TETRAL FALLOT 3582 TOTAL REPAIR OF TAPVC 3583 TOT REP TRUNCUS ARTERIOS 3584 TOT COR TRANSPOS GRT VES 3591 INTERAT VEN RETRN TRANSP

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
			3592 CONDUIT RT VENT-PUL ART 3593 CONDUIT LEFT VENTR-AORTA 3594 CONDUIT ARTIUM-PULM ART 3595 HEART REPAIR REVISION 3598 OTHER HEART SEPTA OPS 3599 OTHER OP ON HRT VALVES 3699 OTHER OPERATIONS ON VESSEL OF HEART 3733 EXCISION OR DESTRUCTION OF OTHER LESION OR TISSUE OF HEART 3736 EXCISION OR DESTRUCTION OF LEFT ATRIAL APPENDAGE (LAA) OCT08- 375 HEART TRANSPLANTATION (invalid as of OCT03) 3751 HEART TRANSPLANTATION OCT03- 3752 IMPLANT TOT REP HRT SYS OCT03- 390 SYSTEMIC-PULM ART SHUNT 3921 CAVAL-PULMON ART ANASTOM

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
			Non-specific cardiac procedures (2P): 3834 RESECTION OF ABDOMINAL AORTA WITH ANASTOMOSIS 3835 THOR VESSEL RESECT/ANAST 3844 RESECTION OF ABDOMINAL AORTA WITH REPLACEMENT 3845 RESECT THORAC VES W REPL 3864 OTHER EXCISION OF ABDOMINAL AORTA 3865 OTHER EXCISION OF THORACIC VESSEL 3884 OTHER SURGICAL OCCLUSION OF ABDOMINAL AORTA 3885 OCCLUDE THORACIC VES NEC 3949 OTHER REVISION OF VASCULAR PROCEDURE 3956 REPAIR OF BLOOD VESSEL WITH TISSUE PATCH GRAFT 3957 REPAIR OF BLOOD VESSEL WITH SYNTHETIC PATCH GRAFT 3958 REPAIR OF BLOOD VESSEL WITH

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
			UNSPECIFIED TYPE OF PATCH GRAFT 3959 REPAIR OF VESSEL NEC Congenital heart disease diagnoses (2D): 7450 COMMON TRUNCUS 74510 COMPL TRANSPOS GREAT VES 74511 DOUBLE OUTLET RT VENTRIC 74512 CORRECT TRANSPOS GRT VES 74519 TRANSPOS GREAT VESS NEC 7452 TETRALOGY OF FALLOT 7453 COMMON VENTRICLE 7454 VENTRICULAR SEPT DEFECT 7455 SECUNDUM ATRIAL SEPT DEF 74560 ENDOCARD CUSHION DEF NOS 74561 OSTIUM PRIMUM DEFECT 74569 ENDOCARD CUSHION DEF NEC 7457 COR BILOCULARE 7458 SEPTAL CLOSURE ANOM NEC

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
			7459 SEPTAL CLOSURE ANOM NOS 74600 PULMONARY VALVE ANOM NOS 74601 CONG PULMON VALV ATRESIA 74602 CONG PULMON VALVE STENOS 74609 PULMONARY VALVE ANOM NEC 7461 CONG TRICUSP ATRES/STEN 7462 EBSTEIN'S ANOMALY 7463 CONG AORTA VALV STENOSIS 7464 CONG AORTA VALV INSUFFIC 7465 CONGEN MITRAL STENOSIS 7466 CONG MITRAL INSUFFICIENC 7467 HYPOPLAS LEFT HEART SYND 74681 CONG SUBAORTIC STENOSIS 74682 COR TRIATRIATUM 74683 INFUNDIB PULMON STENOSIS 74684 OBSTRUCT HEART ANOM NEC 74685

	Measure# PCS-018-09	Measure# PCS-021-09	Measure #0339
			CORONARY ARTERY ANOMALY 74687 MALPOSITION OF HEART 74689 CONG HEART ANOMALY NEC 7469 CONG HEART ANOMALY NOS 7470 PATENT DUCTUS ARTERIOSUS 74710 COARCTATION OF AORTA 74711 INTERRUPT OF AORTIC ARCH 74720 CONG ANOM OF AORTA NOS 74721 ANOMALIES OF AORTIC ARCH 74722 AORTIC ATRESIA/STENOSIS 74729 CONG ANOM OF AORTA NEC 7473 PULMONARY ARTERY ANOM 74740 GREAT VEIN ANOMALY NOS 74741 TOT ANOM PULM VEN CONNEC 74742 PART ANOM PULM VEN CONN 74749 GREAT VEIN ANOMALY NEC
Exclusions	Any operation that is not a pediatric or congenital Cardiac Operation.	Patients >=18 years of age, those undergoing heart transplantation,	Exclude cases: • MDC 14 (pregnancy, childbirth and

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	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.	neonates or premature infants with patent ductus arteriosus repair as the only cardiac surgical procedure, transcatheter interventions, surgical cases unable to be assigned to a RACHS-1 risk category.	pueperium) • with transcatheter interventions (either 3AP, 3BP, 3CP, 3DP, 3EP with 3D, or 3FP) as single cardiac procedures, performed without bypass (5P) but with catheterization (6P) • with septal defects (4P) as single cardiac procedures without bypass (5P) • with diagnosis of ASD or VSD (5D) with PDA as the only cardiac procedure • heart transplant (7P) • premature infants (4D) with PDA closure (3D and 3EP) as only cardiac procedure; • age less than or equal to 30 days with PDA closure as only cardiac procedure • missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1 =missing) • transferring to another short-term hospital (DISP=2) • neonates with birth weight less than 500 grams (Birth Weight Category 1)
Exclusion Details		Neonates are defined as patients <=30 days of age at surgery; premature infants are defined as <37 weeks gestation. See item 8 for RACHS-1 risk categories.	Exclude cases: • MDC 14 (pregnancy, childbirth and pueperium) • with transcatheter interventions (either 3AP, 3BP, 3CP, 3DP, 3EP with 3D, or 3FP) as single cardiac procedures, performed without bypass (5P) but with catheterization (6P) • with septal defects (4P) as single cardiac

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			procedures without bypass (5P) • with diagnosis of ASD or VSD (5D) with PDA as the only cardiac procedure • heart transplant (7P) • premature infants (4D) with PDA closure (3D and 3EP) as only cardiac procedure; • age less than or equal to 30 days with PDA closure as only cardiac procedure • missing discharge disposition (DISP=missing), gender (SEX=missing), age (AGE=missing), quarter (DQTR=missing), year (YEAR=missing) or principal diagnosis (DX1 =missing) • transferring to another short-term hospital (DISP=2) • neonates with birth weight less than 500 grams (Birth Weight Category 1)
Methods & Risk Adjustment	Stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Uses a statistical risk modelRACHS-1 risk categories, age at surgery, prematurity, presence of major non-cardiac structural anomaly, combinations of cardiac procedures performed.	PQI: The predicted value for each case is computed using a logistic regression model and covariates for gender and age in years (in 5-year age groups). The reference population used in the model is the universe of discharges for states that participate in the HCUP State Inpatient Databases (SID) for the year 2007 (updated annually), a database consisting of 43 states and approximately 30 million adult discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., county, state, and region). The risk adjusted rate is computed using indirect standardization as the observed rate

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			divided by the expected rate, multiplied by the reference population rate The model includes additional covariates for RACHS-1 risk categories. Required data elements: CMS Diagnosis Related Group (DRG); CMS Major Diagnostic Category (MDC); age in days up to 364, then age years at admission; International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) principal and secondary diagnosis codes.
Risk Model Performance Statistics	C-statistics: STS-EACTS Congenital Heart Surgery Mortality Categories (2009) Model without patient covariates: C = 0.778 Model with patient covariates: C = 0.812	I -- Validation of Risk Adjustment Model Original derivation of RACHS-1: (1) Pediatric Cardiac Care Consortium (PCCC) database 1996; 4370 cases from 32 institutions. (2) Hospital discharge data from three states (Illinois 1994, Massachusetts 1995, California 1995); 3646 total cases. Subsequent validation: (3) 1996 hospital discharge data from six states (California, Illinois, Massachusetts, New York, Pennsylvania, Washington); 4318 total cases. (4) Retrospectively collected primary data from a newly created pediatric cardiac care program in Guatemala, 1997-2004; 1215 total cases. (5) Kids' Inpatient Database (KID) 2000; 12717 total cases. Other uses:	We performed a cross-sectional analysis of California hospital discharges from 2005–2007 for patients aged <18 years. [1] Agency for Healthcare Research and Quality pediatric-specific quality indicators were used to identify adverse events in 431524 discharges from 38 freestanding, academic, not-for-profit, tertiary care pediatric hospitals in the United States participating in the Pediatric Health Information System database in 2006. [2] References [1] Bardach NS, Chien AT, Dudley RA. Small numbers limit the use of the inpatient pediatric quality indicators for hospital comparison. Acad Pediatr. 2010 Jul-Aug;10(4):266-73. PMID: 20599180; doi:10.1016/j.acap.2010.04.025.

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		(6) Kids' Inpatient Database (KID) 2003; 11395 total cases. (7) Pediatric Health Information System (PHIS) 2002-2006; 45621 total cases. Risk Model C-Statistics: (1) Area under the ROC curve for the full RACHS-1 model 0.811; p value for Hosmer-Lemeshow test 0.34. (2) Area under the ROC curve 0.814; p value for Hosmer-Lemeshow test 0.21. (3) Area under the ROC curve 0.818; p value for Hosmer-Lemeshow test 0.83. (4) Area under the ROC curve 0.854. (5) Area under the ROC curve 0.828; p value for Hosmer-Lemeshow test 0.66. (6) Area under the ROC curve 0.809; p value for Hosmer-Lemeshow test 0.18. (7) Area under the ROC curve 0.822; p value for Hosmer-Lemeshow test 0.08.	[2] Kronman MP, Hall M, Slonim AD, Shah SS. Charges and lengths of stay attributable to adverse patient-care events using pediatric-specific quality indicators: a multicenter study of freestanding children´s hospitals. Pediatrics. 2008 Jun;121(6):e1653-9. PMID: 18519468; DOI: http://dx.doi.org/10.1542/peds.2007-2831.
Data Source	Paper Medical Record, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Clinical Database, Electronic Health/Medical Record, Other	Electronic administrative data/claims
Level	Community/Population, Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home)	Facility (e.g., hospital, nursing home)	Facility/Agency
Setting	Hospital	Hospital	Hospital

Competing Volume Measures

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
Title	Surgical Volume for Pediatric and Congenital Heart Surgery	Surgical Volume for Pediatric and Congenital Heart Surgery, Stratified by the Five STS-EACTS Mortality Levels	Pediatric Heart Surgery Volume (PDI 7)
Status	Recommended for Time-Limited Endorsement	Recommended for Time-Limited Endorsement	Under Endorsement-Maintenance Review
Steward	Society of Thoracic Surgeons	Society of Thoracic Surgeons	Agency for Healthcare Research and Quality
Description	Surgical Volume for Pediatric and Congenital Heart Surgery	Surgical volume for pediatric and congenital heart surgery stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool	Number of discharges with procedure for pediatric heart surgery
Numerator	Number of pediatric and congenital heart surgery operations	Number of pediatric and congenital cardiac surgery operations (types "CPB" and "No-CPB Cardiovascular") in each of the strata of complexity specified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Discharges under age 18 with ICD-9-CM procedure codes for either congenital heart disease (1P) in any field or non-specific heart surgery (2P) with ICD-9-CM diagnosis of congenital heart disease (2D) in any field.
Denominator	N/A	N/A	This measure does not have a denominator due to the fact it is a volume measure.
Exclusions	Measure Exclusions: Any operation that is not a pediatric or congenital Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1].	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	N/A

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
		Cardiovascular") that cannot be classified into a level of complexity by the five STS-EACTS Mortality Levels.	
Methods & Risk Adjustment	N/A	N/A	N/A
Numerator Details	Cardiac operations are defined as operations that are of operation types "CPB" or "No CPB Cardiovascular" (CPB is cardiopulmonary bypass.) [1]. The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease: 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,	There are currently three validated systems of Complexity Stratification in use to categorize operations for pediatric and congenital heart disease on the basis of complexity. Each of these is used in some registry databases, and data is currently stratified using each of the three systems in the most recent outcome reports of the Society of Thoracic Surgery Congenital Heart Surgery database. The three systems are: 1. the RACHS-1 (Risk Adjustment in Congenital Heart Surgery) System with 5 functional levels; 2. The Aristotle Basic Complexity Score with 4 levels; and 3. STS-EACTS Mortality Levels (5 levels). As demonstrated in the following publication (STS Attachment 1 (of 2) - O'Brien et al, JTCVS, Nov 2009), the five STS-EACTS Mortality Levels constitute an objective and empirically based tool for complexity stratification. In addition, it represents an improvement over existing consensus-based tools. Numerator definition: The number of patients who undergo pediatric and	Discharges under age 18 with ICD-9-CM procedure codes for either congenital heart disease (1P) or non-specific heart surgery (2P) with ICD-9-CM diagnosis of congenital heart disease (2D) in any field. Congenital heart disease procedures (1P): 3500 CLOSED VALVOTOMY NOS 3501 CLOSED AORTIC VALVOTOMY 3502 CLOSED MITRAL VALVOTOMY 3503 CLOSED PULMON VALVOTOMY 3504 CLOSED TRICUSP VALVOTOMY 3510 OPEN VALVULOPLASTY NOS 3511 OPN AORTIC VALVULOPLASTY 3512 OPN MITRAL VALVULOPLASTY 3513 OPN PULMON VALVULOPLASTY 3514 OPN TRICUS VALVULOPLASTY 3520

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	670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 **Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions. Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart	congenital Cardiac Operation - Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1].Numerator definition: The number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool. The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease: 10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920,	REPLACE HEART VALVE NOS 3521 REPLACE AORT VALV-TISSUE 3522 REPLACE AORTIC VALVE NEC 3523 REPLACE MITR VALV-TISSUE 3524 REPLACE MITRAL VALVE NEC 3525 REPLACE PULM VALV-TISSUE 3526 REPLACE PULMON VALVE NEC 3527 REPLACE TRIC VALV-TISSUE 3528 REPLACE TRICUSP VALV NEC 3531 PAPILLARY MUSCLE OPS 3532 CHORDAE TENDINEAE OPS 3533 ANNULOPLASTY 3534 INFUNDIBULECTOMY 3535 TRABECUL CARNEAE CORD OP 3539 TISS ADJ TO VALV OPS NEC 3541 ENLARGE EXISTING SEP DEF 3542 CREATE SEPTAL DEFECT

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	surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease	930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 **Please find data definitions in STS Attachment 2 (of 2) - STS Procedure Code Definitions. Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease	3550 PROSTH REP HRT SEPTA NOS 3551 PROS REP ATRIAL DEF-OPN 3552 PROS REPAIR ATRIA DEF-CL 3553 PROST REPAIR VENTRIC DEF 3554 PROS REP ENDOCAR CUSHION 3560 GRFT REPAIR HRT SEPT NOS 3561 GRAFT REPAIR ATRIAL DEF 3562 GRAFT REPAIR VENTRIC DEF 3563 GRFT REP ENDOCAR CUSHION 3570 HEART SEPTA REPAIR NOS 3571 ATRIA SEPTA DEF REP NEC 3572 VENTR SEPTA DEF REP NEC 3573 ENDOCAR CUSHION REP NEC 3581 TOT REPAIR TETRAL FALLOT 3582 TOTAL REPAIR OF TAPVC 3583 TOT REP TRUNCUS ARTERIOS 3584

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			TOT COR TRANSPOS GRT VES 3591 INTERAT VEN RETRN TRANSP 3592 CONDUIT RT VENT-PUL ART 3593 CONDUIT LEFT VENTR-AORTA 3594 CONDUIT ARTIUM-PULM ART 3595 HEART REPAIR REVISION 3598 OTHER HEART SEPTA OPS 3599 OTHER OP ON HRT VALVES 3699 OTHER OPERATIONS ON VESSEL OF HEART 3733 EXCISION OR DESTRUCTION OF OTHER LESION OR TISSUE OF HEART 3736 EXCISION OR DESTRUCTION OF LEFT ATRIAL APPENDAGE (LAA) OCT08- 375 HEART TRANSPLANTATION (invalid as of OCT03) 3751 HEART TRANSPLANTATION OCT03- 3752 IMPLANT TOT REP HRT SYS OCT03- 390 SYSTEMIC-PULM ART SHUNT

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			3921 CAVAL-PULMON ART ANASTOM Non-specific cardiac procedures (2P): 3834 RESECTION OF ABDOMINAL AORTA WITH ANASTOMOSIS 3835 THOR VESSEL RESECT/ANAST 3844 RESECTION OF ABDOMINAL AORTA WITH REPLACEMENT 3845 RESECT THORAC VES W REPL 3864 OTHER EXCISION OF ABDOMINAL AORTA 3865 OTHER EXCISION OF THORACIC VESSEL 3884 OTHER SURGICAL OCCLUSION OF ABDOMINAL AORTA 3885 OCCLUDE THORACIC VES NEC 3949 OTHER REVISION OF VASCULAR PROCEDURE 3956 REPAIR OF BLOOD VESSEL WITH TISSUE PATCH GRAFT 3957 REPAIR OF BLOOD VESSEL WITH

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			SYNTHETIC PATCH GRAFT 3958 REPAIR OF BLOOD VESSEL WITH UNSPECIFIED TYPE OF PATCH GRAFT 3959 REPAIR OF VESSEL NEC Congenital heart disease diagnoses (2D): 7450 COMMON TRUNCUS 74510 COMPL TRANSPOS GREAT VES 74511 DOUBLE OUTLET RT VENTRIC 74512 CORRECT TRANSPOS GRT VES 74519 TRANSPOS GREAT VESS NEC 7452 TETRALOGY OF FALLOT 7453 COMMON VENTRICLE 7454 VENTRICULAR SEPT DEFECT 7455 SECUNDUM ATRIAL SEPT DEF 74560 ENDOCARD CUSHION DEF NOS 74561 OSTIUM PRIMUM DEFECT 74569 ENDOCARD CUSHION DEF NEC 7457

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			COR BILOCULARE 7458 SEPTAL CLOSURE ANOM NEC 7459 SEPTAL CLOSURE ANOM NOS 74600 PULMONARY VALVE ANOM NOS 74601 CONG PULMON VALV ATRESIA 74602 CONG PULMON VALVE STENOS 74609 PULMONARY VALVE ANOM NEC 7461 CONG TRICUSP ATRES/STEN 7462 EBSTEIN'S ANOMALY 7463 CONG AORTA VALV STENOSIS 7464 CONG AORTA VALV INSUFFIC 7465 CONGEN MITRAL STENOSIS 7466 CONG MITRAL INSUFFICIENC 7467 HYPOPLAS LEFT HEART SYND 74681 CONG SUBAORTIC STENOSIS 74682 COR TRIATRIATUM 74683 INFUNDIB PULMON STENOSIS

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			74684 OBSTRUCT HEART ANOM NEC 74685 CORONARY ARTERY ANOMALY 74687 MALPOSITION OF HEART 74689 CONG HEART ANOMALY NEC 7469 CONG HEART ANOMALY NOS 7470 PATENT DUCTUS ARTERIOSUS 74710 COARCTATION OF AORTA 74711 INTERRUPT OF AORTIC ARCH 74720 CONG ANOM OF AORTA NOS 74721 ANOMALIES OF AORTIC ARCH 74722 AORTIC ATRESIA/STENOSIS 74729 CONG ANOM OF AORTA NEC 7473 PULMONARY ARTERY ANOM 74740 GREAT VEIN ANOMALY NOS 74741 TOT ANOM PULM VEN CONNEC 74742 PART ANOM PULM VEN CONN 74749

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			GREAT VEIN ANOMALY NEC Exclude cases: • MDC 14 (pregnancy, childbirth and pueperium) • with transcatheter interventions (either 3AP, 3BP, 3CP, 3DP, 3EP with 3D, or 3FP) as single cardiac procedures, performed without bypass (5P) but with catheterization (6P); • with septal defects (4P) as single cardiac procedures without bypass (5P) Transcatheter interventions procedure codes: Closed heart valvotomy (3AP): 3500 CLOSED HEART VALVOTOMY, UNSPECIFIED VALUE 3501 CLOSED HEART VALVOTOMY, AORTIC VALUE 3502 CLOSED HEART VALVOTOMY, MITRAL VALUE 3503 CLOSED HEART VALVOTOMY, PULMONARY VALUE 3504 CLOSED HEART VALVOTOMY, TRICUSPID VALUE Atrial septal enlargement (3BP): 3541

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			ENLARGEMENT OF EXISTING ATRIAL SEPTAL DEFECT 3542 CREATION OF SEPTAL DEFECT IN HEART Atrial septal defect repair (3CP): 3551 REPAIR OF ATIAL SEPTAL DEFECT WITH PROSTHESIS, OPEN TECHNIQUE 3571 OTHER AND UNSPECIFIED REPAIR OF ATRIAL SEPTAL DEFECT Ventricular septal defect repair (3DP): 3553 REPAIR OF VENTRICULAR SEPTAL DEFECT WITH PROSTHESIS 3572 OTHER AND UNSPECIFIED REPAIR OF VENTRICULAR SEPTAL DEFECT Occlusion of thoracic vessel (3EP): 3885 OCCLUDE THORACIC VES NEC PDA closure diagnosis code (3D): 7470 PATENT DUCTUS ARTERIOSUS Other surgical occlusion (3FP): 3884 OTHER SURGICAL OCCLUSION OF

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			AORTA, ABDOMINAL 3885 OTHER SURGICAL OCCLUSION OF THORACIC VESSEL 3959 OTHER REPAIR OF VESSEL Extracorporeal circulation (5P): 3961 EXTRACORPOREAL CIRCULAT Catheterization (6P): 3721 RT HEART CARDIAC CATH 3722 LEFT HEART CARDIAC CATH 3723 RT/LEFT HEART CARD CATH 8842 CONTRAST AORTOGRAM 8843 CONTR PULMON ARTERIOGRAM 8844 ARTERIOGRAPHY OF OTHER INTRATHORACIC VESSELS 8850 ANGIOCARDIOGRAPHY, NOT OTHERWISE SPECIFIED 8851 ANGIOCARDIOGRAPHY OF VENAE CAVAE 8852 ANGIOCARDIOGRAPHY OF RIGHT

	Measure# PCS-007-09	Measure# PCS-008-09	Measure # 0340
			HEART STRUCTURES 8853 ANGIOCARDIOGRAPHY OF LEFT HEART STRUCTURES 8854 COMBINED RIGHT AND LEFT HEART ANGIOCARDIOGRAPHY 8855 CORONARY ARTERIOGRAPHY USING A SINGLE CATHETER 8856 CORONARY ARTERIOGRAPHY USING TWO CATHETERS 8857 OTHER AND UNSPECIFIED CORONARY ARTERIOGRAPHY 8858 NEGATIVE-CONTRAST CARDIAC ROENTGENOGRAPHY Atrial septal defect repair and enlargement (4P): 3541 ENLARGE EXISTING SEP DEF 3552 PROS REPAIR ATRIA DEF-CL
Denominator Details	N/A	N/A	N/A
Exclusion Details	N/A	N/A	N/A
Data Source	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Electronic administrative data/claims

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

Summary of Pediatric Cardiac Surgery Steering Committee Evaluation

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

Measure Evaluation Ratings: I: Y-9; N-0 **S:** H-8; M-1; L-0 **U:** H-6; M-2; L-0 **F:** H-8; M-1; L-0

This is measure of operative mortality within 30 days after surgery or prior to discharge for patients who undergo pediatric and congenital open heart surgery, stratifying for complexity using the STS-EACTS mortality levels.

- *Scientific acceptability:* In an effort to standardize this measure, NQF asked the measure developer to select one method of risk-stratification. The capture of post-discharge mortality, especially for distant referrals, needs to be assured for this measure to work. This measure requires use of the same set of STS codes as do the process measures discussed above; therefore the same concerns regarding the selection of STS codes apply. The STS-EACTS mortality score is based mostly on actual data that have been assessed by the STS and EACTS databases.

- *Feasibility:* There is the need to use the STS-EACTS database to generate the measure and to determine complexity levels.

PCS-021-09 Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) method *Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool*

Measure Evaluation Ratings: I: Y-9; N-0 **S:** H-7; M-1; L-1 **U:** H-5; M-2; L-1 **F:** H-6; M-2; L-1

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

- *Scientific acceptability:* The Steering Committee agreed that this measure demonstrates scientific acceptability. This measure uses the RACHS-1 system of risk analysis based on observed mortality (numerator) as related to expected mortality (denominator). The risk analysis takes into account all risk levels and condenses the program's performance on the basis of O/E. A score of 1.0 or higher indicates that the observed mortality is greater than the expected mortality, and, therefore, the program is underachieving. Concerns have been expressed in the literature about the use of administrative datasets, particularly in areas in which the coding choices are limited. Some Committee members expressed concerns about the conversion of the ICD-9-CM codes to ICD-10-CM; however, the measure developer confirmed that it has already begun the mapping process for this measure.

- *Feasibility:* The data required for this measure can be easily collected through manual chart

abstraction to determine the RACHS-1 score and from administrative data. Particularly with administrative data, the burden of gathering data to calculate the measure is low.

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

Measure Evaluation Ratings: I: Y-9; N-0 **S:** H-5; M-3; L-1 **U:** H-6; M-3; L-0 **F:** H-8; M-1; L-0

- *Usability:* It is not harmonized with NQF-endorsed measure #0340. Some thought that data derived from a clinical dataset is a more valid representation of number of procedures than the administrative data used in the existing NQF-endorsed measure. In response to a question of why both this measure and PCS-008 were needed, the developer responded that the totals by mortality level as counted in PCS-008-09 cannot be rolled up and would not equal the total volume calculated for this measure.

- *Feasibility:* This measure requires use of STS codes or a crosswalk from ICD-9-CM for those who do not use the STS database.

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

Measure Evaluation Ratings: I: Y-9; N-0 **S:** H-6; M-3; L-0 **U:** H-9; M-0; L-0 **F:** H-9; M-0; L-0

- *Usability:* The mortality Score is a stratified schema based on true data. This score was implemented by several authors based on actual data from the STS database. This measure is used in conjunction with the STS mortality measure stratified by risk level (PCS-018) This is not harmonized to previously NQF-endorsed measure #0339, as this uses a more robust identification of procedures.

- *Feasibility:* As with PCS-007-09, this measure requires the use of STS codes or a crosswalk from STS codes to ICD-9 codes.

Competing Measure Discussion

The Pediatric Cardiac Surgery Steering Committee was reluctant to determine a best-in-class mortality measures among the two methods (RACHS-1, and STS-EACTS) given that the field has yet to determine which method is best. The Committee noted above mentioned concerns regarding the use of administrative data to calculate the CHB measure noting references that have demonstrated the shortcomings of the use of administrative data in congenital heart disease. The CHB measure has been extensively tested and in active use. The analysis of the AHRQ measure on pediatric heart surgery mortality in the Surgery Project will allow a full comparison of the mortality and volume measures across the various data sources.

THE SOCIETY OF THORACIC SURGEONS

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September 7, 2010

Pediatric Cardiac Surgery Steering Committee
National Quality Forum
601 Thirteenth Street NW
Suite 500 North
Washington, DC 20005

Re: National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report-Draft Report for Commenting

Dear Steering Committee Members:

On behalf of The Society of Thoracic Surgeons (STS), a member of the National Quality Forum (NQF), we would like to take this opportunity to provide comments regarding the aforementioned document.

STS is a not-for-profit organization representing more than 6,000 cardiothoracic surgeons, researchers, and allied health professionals worldwide who are dedicated to ensuring the best surgical care for patients with diseases of the chest. Founded in 1964, the mission of STS is to enhance the ability of cardiothoracic surgeons to provide the highest quality care through education, research and advocacy. STS supports data-driven approaches to the improvement of the quality of cardiothoracic surgical care.

STS would like to comment specifically about two measures recommended for NQF endorsement:

1. **PCS-018-09**: Operative Mortality Stratified by the Five STS-EACTS Mortality Levels [Society of Thoracic Surgeons (STS)]

2. **PCS-021-09**: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1 Method) [Children's Hospital Boston (CHB)]

This document contains three parts:

1. General discussion about the use of administrative data versus clinical data for the evaluation of quality of care for patients undergoing pediatric cardiac surgery
2. Comparison between **PCS-018-09** and **PCS-021-09**
3. Critique of **PCS-021-09** organized according to the four criteria proposed by NQF for evaluation of measures

I. Administrative Data versus Clinical Data for the Evaluation of Quality of Care for Patients Undergoing Pediatric Cardiac Surgery

STS advocates the use of clinical databases rather than administrative databases for the evaluation of the quality of care for patients undergoing treatment for pediatric cardiac disease. 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 (ICD) by administrative databases is likely to be poor [1, 2, 3]:

Among 373 infants with congenital cardiac defects at the Children's Hospital of Wisconsin, investigators reported that only 52% of the cardiac diagnoses in the medical records had a corresponding ICD code in the hospital discharge database [1].

The Hennepin County Medical Center discharge database in Minnesota identified all infants born during 2001 with an ICD-9 code for congenital cardiac disease. Physician review of these 66 medical records confirmed the accuracy of only 41% of the codes contained in the administrative database from the ICD [2].

The Metropolitan Atlanta Congenital Defect Program of the Centers for Disease Control and Prevention's Birth Defect Branch carried out surveillance of infants and fetuses with cardiac defects delivered to mothers residing in Atlanta during the years 1988 through 2003 [3]. These records were reviewed and classified using both administrative coding from the ICD and the clinical nomenclature used in the STS Congenital Heart Surgery Database. It was concluded that analyses based on the codes available in the ICD are likely to "have substantial misclassification" of congenital cardiac disease.

The following are potential reasons for the poor diagnostic accuracy of administrative databases and codes from the ICD:

- accidental miscoding
- coding performed by medical records clerks who have never seen the actual patient
- contradictory or poorly described information in the medical record
- lack of diagnostic specificity for congenital cardiac disease in ICD codes
- inadequately trained medical coders

Based on the above discussion, STS supports the endorsement of NQF National Voluntary Consensus Standards for Pediatric and Congenital Cardiac Surgery based on data from clinical databases rather than administrative databases.

II. Comparison of Pediatric Cardiac Surgery Outcome Measures Submitted to NQF:

A. PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1 Method) [Children's Hospital Boston (CHB)]

Published in 2002, RACHS-1 is a consensus-based method for risk adjustment for congenital heart surgery. At its inception, a panel of 11 experts ordered procedures by likelihood of short-term mortality, evaluated the results, and made adjustments based on data observed from two large databases: Pediatric Cardiac Care Consortium (1996, 32 institutions) and hospital discharge data purchased from three states (Illinois 1994, Massachusetts 1995, California 1996). After establishing initial assignments to categories by a consensus process, the panel decided that for some operations, age at surgery or specific cardiac diagnoses were potentially important additional risk factors. The procedures were then assigned to risk categories. Then the panel reviewed the information from the "reference data sets," and revised the categorizations of some procedures because the actual mortality rate differed considerably from the initial subjective judgment about risk for death. Case selection was largely dependent upon ICD-9 and CPT-4 codes.

In 2002, in the Journal of Thoracic and Cardiovascular Surgery (JTCVS), Jenkins et al. published an evaluation of center-specific differences in mortality using the RACHS-1 method. By using 1996 hospital discharge data from six states, centers performing at least 100 operations for congenital heart disease, in patients age <18 years, were identified. Using the RACHS-1 method, procedures were grouped into six risk categories, and institutions were ranked in order of increasing mortality rate. Among 109 centers performing 7,177 operations for congenital heart disease, 22 performed at least 100 cases (72.3% of total operations). Unadjusted mortality rates ranged from 2.5% to 11.4%. A total of 4,318 of the 7,177 cases could be placed into one of the six risk categories. Few deaths occurred in risk category 1, and few institutions performed procedures in risk categories 5 and 6, making institutional comparisons in these categories uninformative. Considering mortality rates in categories 2 through 4, institutions displayed either relatively consistent ranks, a threshold increase in mortality as higher-risk procedures were performed, or a threshold decrease in mortality. Used in many settings as an expression of performance, Standardized Mortality Ratios (SMRs) were calculated with the intent of describing which institutions performed better or worse than expected on the basis of their case mix.

RACHS-1 levels have been widely used as a tool to express relative risk of in-hospital mortality for various procedures. In addition to procedure information, the complete RACHS-1 model incorporates certain patient factors (i.e. age, prematurity, major non-cardiac structural anomaly) into the risk adjustment process.

The proposed measure utilizes assignment of cases to RACHS-1 levels and other patient and procedural variables (i.e. age, prematurity, presence of non-cardiac anomalies, combination procedures) to determine an institution's SMR, which is defined as its actual or observed in-hospital mortality rate divided by its expected in-hospital mortality rate. The expected rate is calculated based on the patient case mix at the institution relative to the case mix in the reference data set as a whole.

Advantages:

1. Having been used in many published evaluations of outcomes, the RACHS-1 system of procedure categorization is widely recognized.
2. The development of RACHS-1 was based upon expert panel opinion.

3. When SMR is calculated using logistic regression based on coefficients that appropriately pertain to the correct reference data set and if all centers are participants in the same reference data set, then institutions may be "ranked" according to SMR (lowest to highest).

Disadvantages:

1. RACHS-1 is based largely upon expert opinion, rather than objective evidence.
2. The measure steward has made reference to the possible release of "RACHS-2 levels" in 2010, which presumably will supplant and thus render obsolete the current system.
3. The development of RACHS-1 was based on administrative data, now more than 10 years old. The measure description describes the use of at least four independent, disparate reference data sets, the majority of which depend entirely upon administrative data. Many important and frequently performed procedures do not have ICD-9 codes (e.g., Norwood Stage 1), and thus, they must be inferred from aggregate codes in administrative data sets. Coding of patient factors such as non-cardiac anomalies may be quite variable between data sets, and these factors lack rigorous, consistent definitions.
4. Many pediatric cardiac surgical procedures cannot be classified by RACHS-1. Specifically, only 85.8% of procedures in the STS Congenital Heart Surgery Database can be classified by RACHS-1 [4]. In the previously mentioned study by Jenkins et al. on center-specific differences in mortality, only 4,318 of 7,177 congenital cardiac surgical operations (60%) could be placed in one of the six RACHS-1 categories.
5. The mainstay of the proposed measure is an SMR, which is determined by the calculation of observed to expected (O-E) mortality ratio for a given center. This process is dependent upon the availability, accuracy, and applicability of a reference data set, and the solution to a multivariate equation with specific coefficients for each of the "risk variables." The reference data set used to develop RACHS-1 was based mainly on administrative data, now more than 10 years old. It is unknown whether there is a new "contemporary universal reference data set." **No such unique reference data set is described or identified in the measure description. As such, the mechanism by which expected mortality will be calculated for a given center is unknown.** This problem leads to many unanswered questions:
    a. Will index institutions need to be among the centers from which the reference data are derived?
    b. Can an institution base their measurement and reporting on a reference data set which does not include their own data?
    c. Will one of several sets of coefficients for the logistic regression need to be provided to each institution?
    d. Will this set of coefficients depend on the participation of that particular center in one of several consortia or databases from which a reference data set is derived?
    e. Will each institution need to enlist the services of a biostatistician to analyze their own outcome data, apply the institution-specific logistic regression model, and calculate their observed and expected mortalities and SMR?
    f. Can the SMR of an institution that utilizes one reference data set (which determines the coefficients used to calculate their expected mortality) be compared to the SMR of another institution that utilizes a different reference data set?
6. SMR incompletely illustrates outcome and does not appropriately address questions regarding a center's performance within the individual strata of complexity or risk. From SMR, it is not possible to determine whether an institution is dealing at all with cases in a specific stratum of risk or complexity. For example, two centers may have the same

calculated SMR but one of those centers may be dealing with many complex "high risk" cases, while the other center deals only with cases of lesser complexity and thus lower risk.

B. PCS-018-09: Operative Mortality Stratified by the Five STS-EACTS Mortality Levels [The Society of Thoracic Surgeons (STS)]

Historically, STS has recognized the limitations of using raw, unadjusted mortality rates as a measure of outcome, quality, and performance. Given the enormous diversity of congenital heart operations, it is understandable that the initial approach to the characterization of case mix (i.e., description of relative complexity and relative risk of mortality) was largely based on expert opinion. For nearly a decade, the STS Congenital Heart Surgery Database reported outcomes of cases stratified by RACHS-1 and the Aristotle Complexity Score, two popular and widely used tools adapted to this purpose. The importance of strict definitions (e.g., procedural terms, patient factors, mortality, and time intervals) was emphasized in the methodology. Ultimately, the goal was to transition from subjectively derived estimates of risk or complexity to an empirically-based tool for analyzing mortality associated with congenital heart surgery.

In 2009, the STS-EACTS Congenital Heart Surgery Mortality Categories (STS-EACTS Categories) were published [5]. Mortality risk was estimated for 148 types of pediatric and congenital cardiac surgical operations using data from 77,294 operations entered into the STS Congenital Heart Surgery Database (43,934 patients) and the European Association for Cardiothoracic Surgery (EACTS) Congenital Heart Surgery Database (33,360 operations) between 2002 and 2007. Procedure-specific mortality rate estimates were calculated using a Bayesian model that adjusted for small denominators. Procedures were then sorted by increasing mortality risk and grouped into five categories (STS–EACTS Congenital Heart Surgery Mortality Categories [2009]) that were chosen to be optimal with respect to minimizing within-category variation and maximizing between-category variation. Model performance was subsequently assessed using an independent validation sample (n = 27,700; 2007-2008 data) and compared with two existing methods: RACHS-1 Categories and the Aristotle Basic Complexity Score.

Estimated mortality rates ranged across procedure types from 0.3% (atrial septal defect repair with patch) to 29.8% (truncus + interrupted aortic arch repair). The STS–EACTS Categories demonstrated good discrimination for predicting mortality in the validation sample (C-index= 0.773).

In the subset of procedures for which STS–EACTS Category, RACHS-1 Category, and Aristotle Basic Complexity Score are defined, discrimination was highest for the STS–EACTS Categories (C-index = 0.778), followed by RACHS-1 Categories (C-index = 0.745), and Aristotle Basic Complexity scores (C-index = 0.687).

Table 1 shows the results of comparing the STS–EACTS Categories (2009) to the RACHS-1 Categories and the Aristotle Basic Complexity Score using an independent validation sample of 27,700 operations performed in 2007 and 2008.

Table 1: Method of Modeling Procedures	Model without patient covariates	Model with patient covariates	Percent of operations that can be classified
STS-EACTS Congenital Heart Surgery Mortality Categories (2009)	**C = 0.778**	**C = 0.812**	**99%**
RACHS-1 Categories	**C = 0.745**	**C = 0.802**	**86%**
Aristotle Basic Complexity Score	**C = 0.687**	**C = 0.795**	**94%**

The STS–EACTS Categories are now incorporated into the outcomes reports of the STS Congenital Heart Surgery Database. In addition, the five STS-EACTS Categories are the basis for stratification of mortality outcomes in the measure submitted to NQF.

Advantages:

1. The STS–EACTS Categories are based on objective data from a clinical data set that is internally validated and checked by site verification on an ongoing basis.
2. The accuracy and discrimination of the STS–EACTS Categories were validated using 2007-2008 data.
3. The majority (99%) of pediatric and congenital cardiac surgical operations that are coded by centers participating in the STS Congenital Heart Surgery Database can be assigned to one of the five STS-EACTS Categories. In comparison, 94% can be categorized using the Aristotle Basic Complexity Score, and 86% can be assigned to a RACHS-1 Category.
4. Comparison (by C-statistic) to Aristotle Basic Complexity Score and RACHS-1 Categories, both with and without patient factors, reveals best performance by STS–EACTS Categories.
5. Using the STS–EACTS Categories eliminates the uncertainties of coding that are associated with the use of administrative data, both for center reporting and for development of a reference data set.
6. The proposed measure is maximally informative, allowing the stakeholder to draw inferences concerning mortality outcomes associated with procedures of low, intermediate, and high levels of complexity.
7. Calculation and reporting of mortality outcomes by STS-EACTS Categories does not require each institution to solve any multivariable equations and does not require biostatistician-level skill. For centers participating in the STS Congenital Heart Surgery Database, the calculation and reporting is already completed at six month intervals.
8. Measurement and reporting is not dependent upon a reference data set and is therefore not susceptible to error or misinterpretation that could result from use of incorrect or inappropriate reference data.

Disadvantages: As a consequence of having been developed over the past three years, this empirically derived system of mortality levels may be less familiar to some stakeholders than Aristotle or RACHS-1.

STS recommends that ONLY the STS–EACTS Congenital Heart Surgery Mortality Categories (2009) are used for complexity stratification of mortality. Main rationale for this recommendation is two-fold:

1. The C-statistic for the STS-EACTS Congenital Heart Surgery Mortality Categories (2009) is better than for the RACHS-1 Categories and the Aristotle Basic Complexity Score.
2. 86% of pediatric and congenital cardiac operations can be assessed by the RACHS-1 Categories, 94% by the Aristotle Basic Complexity Score, and 99% by the STS-EACTS Congenital Heart Surgery Mortality Categories (2009).

III. Critique of PCS-021-09, Organized According to the Four Criteria Proposed by NQF for Measure Evaluation

This critique is organized according to the four NQF evaluation criteria:
(1) I=Importance to Measure and Report;
(2) S=Scientific Acceptability of Measure Properties;
(3) U=Usability;
(4) F=Feasibility

(1) Importance to Measure and Report

Measuring mortality in a way that includes a demonstration of case complexity is generally accepted as being of great importance. For quality improvement, this is essential and fundamental. For public reporting, the issues are different and even more complex. Despite explanations and disclaimers, the concept of what does and does not reach a level of statistical significance is difficult to convey in the public reporting of surgical outcomes. This becomes even more difficult and complex when reporting mortality outcomes by assigning a specific institution with a calculated numerical value such as the SMR. Use of a derived value such as an SMR leads to misunderstandings that result from the erroneous assumption that the process of "standardizing" enables the interested party to draw inferences concerning the significance of an institution's SMR as being higher or lower than that of another institution (see below). An impression of "good performance" is generally inferred from a low SMR (i.e., SMR<1), while at the same time, it conveys no information about whether or not an institution is managing cases in the higher strata of risk or complexity, and to what extent these high complexity cases account for the observed mortality rate. While the individual factors that contribute to the complexity of this problem are numerous, one that is of overriding importance is the accuracy, reliability, and applicability of the "reference data set" from which the "expected mortality" (the denominator in SMR) is derived. ***Unless there is a single, universally applicable reference data set, then reporting of individual institution SMRs based upon a variety of disparate, non-harmonious data sets is likely to misinform those to whom it is reported.***

(2) Scientific Acceptability of Measure Properties

The elements of an SMR are the observed mortality (numerator), the expected mortality (denominator), and the calculated ratio. In the case of this measure, both the numerator and denominator are derived, or calculated values.

The numerator used in the calculation of SMR is the observed mortality, which is calculated using data from the participant. Observed mortality is defined as the number of pediatric cases of congenital heart surgery resulting in in-hospital death that can be placed into a RACHS-1 risk category divided by the total number of pediatric cases of congenital heart surgery that can be placed into a RACHS-1 risk category. ***The use of the RACHS-1 risk categories limits the cases in both the numerator and denominator to those that can be classified according to RACHS-1. It has been determined that currently, 86% of the cardiac procedure types coded by participants in the STS Congenital Heart Surgery Database can be assigned to a RACHS-1 risk category. Thus, one in seven cases would be excluded from the SMR calculation*** [4, 5].

The measure specifies consideration of "total cases of congenital heart surgery among patients <18 years of age" rather than limiting the analysis to index cases, as is done in other proposed

measures. By using this criterion for the numerator and the denominator, the methodology introduces the potential for significant underestimation of mortality in both the institutional calculation and the reference data set. Mortality calculation based on the number of operative cases as opposed to the number of surgical admissions (i.e., the number of index cases) can be very misleading. This phenomenon is explained and exemplified in the following example: Consider a center that performs Norwood Stage 1 operations on ten patients in a year, with one of those patients returning to the operating room during the same admission for additional atrial septectomy, one returning for conversion from a modified Blalock-Taussig shunt to a Right-Ventricle to Pulmonary Artery Conduit, two of the ten patients being re-explored for bleeding, and seven of the ten patients being treated with delayed sternal closure operations. One patient dies prior to discharge. Twenty-one operations (total cases) were performed. But ten index operations were performed on ten patients. If mortality is calculated based upon total cases, the mortality rate would be $^1/_{21}$ or 4.8%. Based upon index cases, the mortality rate is $^1/_{10}$ or 10%, which of course reflects the true outcome for the group of ten patients. ***The description of PCS-021-09 (Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery [RACHS-1 Method]) does not specify calculation based on index cases in either the institutional calculation of observed mortality or in the mortality determination for the reference data set. By using all cases (total cases) rather than index cases, the methodology of PCS-021-09 introduces the potential for significant underestimation of mortality in both the institutional calculation (numerator) and the reference data set (denominator).***

The denominator used in the calculation of SMR is the expected mortality rate, which is calculated specifically for each group or participant. In this calculation, a multivariable logistic regression model, with the outcome "in-hospital death," is fitted. Five clinical characteristics are incorporated as covariates:

1. RACHS-1 risk categories 2, 3, 4, 5, and 6 as binary covariates, with category 1 as the reference group;
2. Age ≤30 days and age 31 days to 1 year, with age ≥ 1 year as the reference group;
3. Prematurity;
4. Presence of a major non-cardiac structural anomaly; and
5. Presence of combinations of cardiac surgical procedures

This logistic model is used to calculate the predicted probability of death for each individual case in the data set. The average predicted probability of death for all cases is computed by summing the predicted probabilities for each case and dividing by the total number of cases that can be placed into a RACHS-1 risk category; this average predicted probability of death for all cases represents the expected mortality rate for the group, adjusting for case mix.

The SMR is then calculated as the observed mortality rate divided by the expected mortality rate. ***A very important problem is that the measure proponents include in their measure description three distinctly different sets of coefficients for the risk adjustment model. Each pertains to a given "reference data set."*** Each set of coefficients was used by the measure stewards in validation exercises in which they considered outcome data from institutions that participated in different consortia or databases.

In the "original model validation set" the coefficients for RACHS-1 levels 2 and 6 are 1.7477 and 4.0022, with odds ratios of 5.74 and 54.7, respectively. For a second reference data set, the Kids' Inpatient Database 2006, the corresponding coefficients are 0.0202 and 1.8726, with odds ratios

of 1.02 and 6.51. For the Pediatric Health Information System 2002-2006, a third reference data set, the corresponding coefficients are 0.4081 and 2.2412, with odds ratios of 1.50 and 9.40. Thus, for one reference data set the odds ratio for mortality in RACHS-1 level 6 is 9.53 times the odds ratio for mortality in RACHS-1 level 2. For another reference data set, it is 6.38 times greater. For the third reference data set it is 6.27 times higher. The odds ratio for mortality associated with the presence of a Major Non-cardiac Structural Anomaly is 2.20, 1.29, or 1.70, depending upon the reference data set. The odds ratio for this variable in the second reference data set is outside of the 95% confidence intervals for that odds ratio in the first reference data set, and vice versa.

On page 25 of the Measure Submission Form, in the table entitled: Mortality Rates by Risk Category (RACHS-1) Single Procedures, the measure steward presents calculated mortality rates with 95% confidence intervals in each of six RACHS-1 risk categories in five different reference data sets (four American, one European). For Risk Category 3, the mortality in the KID 2003 data set is well outside the 95% confidence intervals of the PHIS 2002-2006 data set for the same risk category. The same is true in Risk Categories 5 and 6. In fact in Risk Category 6, the mortality in the KID 2003 database is outside the 95% confidence intervals of all of the other American data sets. In Risk Category 2, the mortality in the PCCC 2002-2004 data set is well outside the 95% confidence intervals of the KID 2003 data set in the same risk category. ***Since the detailed description of the measure does not actually specify what will constitute the reference data set (which will be the basis for calculation of expected mortality, the denominator in SMR), it is assumed that it may be chosen by the reporting institution, presumably from the universe of consortia, registries, or administrative data sets in which it is included. Obviously, the calculated value of SMR can vary tremendously, based upon the choice of reference data set.***

Another important measure property that affects scientific acceptability is ascertainment (i.e., to find out or learn with certainty). In the words of the measure stewards, page 3 section 11, "Data elements may be obtained from an administrative database (e.g., Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient Database (KID), Pediatric Health Information System (PHIS)); from a clinical database (e.g., Pediatric Cardiac Care Consortium (PCCC), Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database); from hospital-specific electronic medical records; or from paper medical records." ***Of all of the potential sources of data, the STS Congenital Heart Surgery Database is the only data source for which there is a formalized process of data verification. Data from other sources are not verified.***

As discussed above, ***the diagnostic and procedural information in the various administrative data sets has been shown to be less reliable, accurate, and predictable than that in the clinical registry database of STS***. Strickland and associates at the National Center on Birth Defects and Developmental Disabilities of the Centers for Disease Control and Prevention described their findings in comparing coding of congenital cardiac anomalies and procedures by ICD-9-CM and by the clinical nomenclature used in the STS Congenital Heart Surgery Database [3]. Their investigation revealed that the sensitivity of ICD diagnosis codes was 83% for tetralogy of Fallot, 100% for transposition of the great arteries, and 95% for hypoplastic left heart syndrome. The false positive fraction was 2% for tetralogy of Fallot, 49% for transposition, and 11% for HLHS. They concluded that "analyses based on International Classification of Diseases diagnosis codes may have substantial misclassification of congenital heart disease. Isolating the major defect is difficult, and certain codes do not differentiate between variants that are clinically and developmentally different."

As a corollary, the use of ICD-9 (and ICD-10) codes to assign cases to RACHS-1 procedural risk levels is fraught with uncertainty because of the incomplete nature and vagaries of codes.

For example, there is no ICD-9 code for the Norwood stage 1 operation. Accordingly, determination from hospital charge records (the "front sheet") or from codes in administrative databases is reliant upon the probability that a patient coded in the following fashion actually underwent a Norwood procedure:

Stage 1 Repair Risk Category 6
Require:
Proc 35.41 Enlargement of existing ASD
or 35.42 Creation of septal defect in heart
Proc 39.0 Systemic to pulmonary artery shunt
or 35.92 Creation of conduit between RV and PA
Proc 38.35 *or* 38.45 Resection of thoracic vessel
or 38.34 *or* 38.44 Resection of abdominal aorta
or 38.64 *or* 38.65 Other excision of vessel/aorta
or 38.84 *or* 38.85 Other surg occlusion of vessel/aorta
or 39.56, 39.57, 39.58 Repair of blood vessel
or 39.59
or 36.99 Other operation on vessel of heart
Cannot have:
Proc 35.94 Creation of conduit between atrium-PA
Proc 35.95 Revision corrective procedure on heart
Proc 39.21 Caval-pulmonary artery anastomosis
Allow:
Dx 745.5 Ostium secundum atrial septal defect
Dx 746.3 Congenital stenosis of aortic valve
Dx 746.5 Congenital mitral stenosis
Dx 747.0 Patent ductus arteriosus
Dx 747.10 Coarctation of aorta
Dx 747.22 Atresia and stenosis of aorta
Dx 747.89 Other anomalies of great veins
Proc 37.33 Excision of other lesion/tissue of heart
Cannot have: Any other cardiac dx

The Norwood procedure is one of the most frequently performed congenital heart operations, and is one for which operative mortality is substantial. To rely upon probabilistic matching to ascertain whether a given patient actually underwent a Norwood procedure introduces a substantial degree of uncertainty that undermines the usefulness of the measure for both quality improvement and public reporting purposes.

Another similar example is the Ross operation. This procedure consists of replacement of the aortic valve with the patient's own pulmonary valve (autograft) and replacement of the pulmonary valve with a prosthesis or homograft. Under the heading, "Define individual cardiac procedures assigned to a risk category," the specifications for the Ross procedure in Measure PCS-021-09 appear as listed below:

Ross Procedure Risk Category 3
Require:
Proc 35.21 *or* 35.22 Aortic valve replacement
Proc 35.25 *or* 35.26 Pulmonary valve replacement
Allow:
Proc 35.01 Aortic valvotomy

Proc 35.11 Aortic valvuloplasty
Proc 35.03 Pulmonary valvotomy
Proc 35.13 Pulmonary valvuloplasty
Proc 35.33 Annuloplasty
Proc 35.99 Other operation on valves of heart
Proc 39.56, 39.57, 39.58 Repair of blood vessel
or 39.59
Proc 36.99 Other operation on vessel of heart
Proc 37.33 Excision of other lesion/tissue of heart
PDA surgery
ASD2 repair

This complex method of coding the Ross procedure introduces considerable potential for error, since any combination of aortic and pulmonary valve replacement would meet these criteria, whether or not it involved pulmonary autograft replacement of the aortic valve, which is the sine qua non for the Ross procedure.

These examples of the Norwood and Ross procedures are merely two of many examples of the imprecision that can result from coding of congenital cardiac surgical procedures based upon administrative data.

(3) Usability

Given the requirement that each institution must apply a logistic model to calculate the predicted probability of death for each individual case in the data set, it seems clear that each reporting institution will be obligated to devote to this measure the efforts of a biostatistician or comparable member of the work force.

In addition, ***SMR can only be calculated once the coefficients specific to a given reference data set are determined, verified, and provided to the institution. The measure description for PCS-021-09 does not specify how it identifies what reference data set is to be used for a given institution, or how the appropriate coefficients for the logistic model will be determined and made available to each institution. Thus, the method by which this measure would be usable at the level of the measuring and reporting institution is unclear.*** The examples of validation exercises described by the measure steward involve at least four reference data sets. For some institutions, one data set pertains; for a few institutions, more than one data set pertain. If the measure can ultimately be used by all centers and institutions, then there will inevitably be some institutions for which none of the aforementioned reference data sets are applicable and some for which it would be necessary to choose among reference data sets or to calculate more than one SMR.

In section 23 of the measure description, the measure steward states that, "quality improvement efforts can be enhanced and stimulated by a clear understanding of how an entity (e.g., an institution) is performing in comparison to other entities." ***In terms of usability by stakeholders to make such determinations of relative performance, the measure is severely hampered by:***

1. ***Its failure to include reporting of any directly measured outcomes data (e.g., observed mortality, stratified by level of complexity); and***
2. ***The fact that comparison of SMR between institutions "affiliated" with different reference data sets and thus applying different risk variable coefficients in the logistic***

model, can be expected to mislead and misinform, which is certainly not the desired outcome.

(4) Feasibility

The measure description template includes the following instruction: "Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure." The measure steward states that "because this measure can be applied in administrative databases, it can be subject to the coding inaccuracies sometimes associated with these databases."

Indeed, a growing prevalence of data supports the use of clinical databases rather than administrative databases for the evaluation of quality of care for patients undergoing treatment for congenital cardiac disease. As described previously, evidence from three recent studies suggested that the validity of ICD coding of lesions seen in the congenitally malformed heart as used in administrative databases is likely to be poor [1, 2, 3].

Unintended consequences

Notwithstanding the best of intentions, public reporting of a methodologically flawed numerical index (i.e., SMR based upon a variety of disparate reference data sets) has the potential to misinform rather than educate and enlighten stakeholders and consumers. In addition, it would be worse to do so utilizing a measure that is based partially or entirely on data from administrative sources which utilize coding nomenclature that fails to address the diversity and granularity of congenital cardiac anomalies and the surgical procedures used to treat them. STS's position should not be taken as an across-the-board condemnation of the use of administrative data; we acknowledge that administrative data are a rich and essential tool that are best suited for numerous applications and across many domains. Rather, our position reflects the current state of nomenclature and coding of congenital cardiac diseases and their treatments.

Thank you for this opportunity to submit comments. Please do not hesitate to contact Jane Han, STS Manager of Quality Initiatives, at jhan@sts.org or (312) 202-5856, with any questions you may have. We appreciate your time.

Sincerely,

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Children's Hospital Boston Responses-RACHS-1
Measure Developers-Dr. Kathy Jenkins and Dr. Kim Gauvreau
Measure Steward: Nina Rauscher
Date: Monday September 20, 2010

I. Administrative Data versus Clinical Data for the Evaluation of Quality of Care for Patients Undergoing Pediatric Cardiac Surgery

STS advocates the use of clinical databases rather than administrative databases for the evaluation of the quality of care for patients undergoing treatment for pediatric cardiac disease. 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 (ICD) by administrative databases is likely to be poor [1, 2, 3]:

Among 373 infants with congenital cardiac defects at the Children's Hospital of Wisconsin, investigators reported that only 52% of the cardiac diagnoses in the medical records had a corresponding ICD code in the hospital discharge database [1].

The Hennepin County Medical Center discharge database in Minnesota identified all infants born during 2001 with an ICD-9 code for congenital cardiac disease. Physician review of these 66 medical records confirmed the accuracy of only 41% of the codes contained in the administrative database from the ICD [2].

The Metropolitan Atlanta Congenital Defect Program of the Centers for Disease Control and Prevention's Birth Defect Branch carried out surveillance of infants and fetuses with cardiac defects delivered to mothers residing in Atlanta during the years 1988 through 2003 [3]. These records were reviewed and classified using both administrative coding from the ICD and the clinical nomenclature used in the STS Congenital Heart Surgery Database. It was concluded that analyses based on the codes available in the ICD are likely to "have substantial misclassification" of congenital cardiac disease.

The following are potential reasons for the poor diagnostic accuracy of administrative databases and codes from the ICD:

- accidental miscoding
- coding performed by medical records clerks who have never seen the actual patient
- contradictory or poorly described information in the medical record
- lack of diagnostic specificity for congenital cardiac disease in ICD codes
- inadequately trained medical coders

Based on the above discussion, STS supports the endorsement of NQF National Voluntary Consensus Standards for Pediatric and Congenital Cardiac Surgery based on data from clinical databases rather than administrative databases.

CHB Response

(1) This criticism is not supported by the data provided in our submission. Administrative data is widely used for quality benchmarking, and is an excellent source of comprehensive, population-based information about inpatient care. Furthermore, most of the comments regarding coding "accuracy" do not pertain to RACHS-1, which only requires that codes be accurate enough to place the procedure in the appropriate risk category. Similar to the previously NQF-endorsed measure for inpatient mortality following congenital heart surgery (ID #0340), we have provided reliability testing for RACHS-1 risk categories demonstrating excellent agreement between the information obtained from an administrative database (Pediatric Health Information System) and a clinical database where risk categories were assigned manually by chart review.

In addition, although the RACHS-1 methodology can be applied in administrative databases, it is a flexible methodology that can also be applied in clinical databases.

II. Comparison of Pediatric Cardiac Surgery Outcome Measures Submitted to NQF:

A. PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1 Method) [Children's Hospital Boston (CHB)]

Published in 2002, RACHS-1 is a consensus-based method for risk adjustment for congenital heart surgery. At its inception, a panel of 11 experts ordered procedures by likelihood of short-term mortality, evaluated the results, and made adjustments based on data observed from two large databases: Pediatric Cardiac Care Consortium (1996, 32 institutions) and hospital discharge data purchased from three states (Illinois 1994, Massachusetts 1995, California 1996). After establishing initial assignments to categories by a consensus process, the panel decided that for some operations, age at surgery or specific cardiac diagnoses were potentially important additional risk factors. The procedures were then assigned to risk categories. Then the panel reviewed the information from the "reference data sets," and revised the categorizations of some procedures because the actual mortality rate differed considerably from the initial subjective judgment about risk for death. Case selection was largely dependent upon ICD-9 and CPT-4 codes.

In 2002, in the Journal of Thoracic and Cardiovascular Surgery (JTCVS), Jenkins et al. published an evaluation of center-specific differences in mortality using the RACHS-1 method. By using 1996 hospital discharge data from six states, centers performing at least 100 operations for congenital heart disease, in patients age <18 years, were identified. Using the RACHS-1 method, procedures were grouped into six risk categories, and institutions were ranked in order of increasing mortality rate. Among 109 centers performing 7,177 operations for congenital heart disease, 22 performed at least 100 cases (72.3% of total operations). Unadjusted mortality rates ranged from 2.5% to 11.4%. A total of 4,318 of the 7,177 cases could be placed into one of the six risk categories. Few deaths occurred in risk category 1, and few institutions performed procedures in risk categories 5 and 6, making institutional comparisons in these categories uninformative. Considering mortality rates in categories 2 through 4, institutions displayed either relatively consistent ranks, a threshold increase in mortality as higher-risk procedures were performed, or a threshold decrease in mortality. Used in many settings as an expression of

performance, Standardized Mortality Ratios (SMRs) were calculated with the intent of describing which institutions performed better or worse than expected on the basis of their case mix.

RACHS-1 levels have been widely used as a tool to express relative risk of in-hospital mortality for various procedures. In addition to procedure information, the complete RACHS-1 model incorporates certain patient factors (i.e. age, prematurity, major non-cardiac structural anomaly) into the risk adjustment process.

The proposed measure utilizes assignment of cases to RACHS-l levels and other patient and procedural variables (i.e. age, prematurity, presence of non-cardiac anomalies, combination procedures) to determine an institution's SMR, which is defined as its actual or observed in-hospital mortality rate divided by its expected in-hospital mortality rate. The expected rate is calculated based on the patient case mix at the institution relative to the case mix in the reference data set as a whole.

Advantages:

1. Having been used in many published evaluations of outcomes, the RACHS-1 system of procedure categorization is widely recognized.
2. The development of RACHS-1 was based upon expert panel opinion.
3. When SMR is calculated using logistic regression based on coefficients that appropriately pertain to the correct reference data set and if all centers are participants in the same reference data set, then institutions may be "ranked" according to SMR (lowest to highest).

Disadvantages:

1. RACHS-1 is based largely upon expert opinion, rather than objective evidence.

CHB Response

(2) We have provided considerable objective evidence about the validity of RACHS-1. As outlined in our submission, the RACHS-1 surgical risk categories were based on a combination of expert opinion and empirical evidence derived from two databases, one administrative and one clinical. Decisions about the additional clinical factors included in the RACHS-1 methodology were entirely empirical. However derived, RACHS-1 has subsequently shown excellent discrimination for predicting in-hospital mortality.

2. The measure steward has made reference to the possible release of "RACHS-2 levels" in 2010, which presumably will supplant and thus render obsolete the current system.

CHB Response

(3) The NQF process requires that the steward for each measure revise the measure on a regular basis, at least every 3 years. "RACHS-2" methodology is a planned revision.

3. The development of RACHS-1 was based on administrative data, now more than 10 years old. The measure description describes the use of at least four independent, disparate reference data sets, the majority of which depend entirely upon administrative data. Many important and frequently performed procedures do not have ICD-9 codes (e.g., Norwood

Stage 1), and thus, they must be inferred from aggregate codes in administrative data sets. Coding of patient factors such as non-cardiac anomalies may be quite variable between data sets, and these factors lack rigorous, consistent definitions.

CHB Response

(4) As mentioned previously, administrative data has been widely used for quality benchmarking. Although there are some limitations to the ICD-9-CM codes for congenital heart operations, our method accounts for this by excluding vague codes, and by using combinations of codes, including diagnosis codes. Similar to the previously NQF-endorsed measure for inpatient mortality following congenital heart surgery, RACHS-1 shows excellent discrimination. In addition, the RACHS-1 methodology is not limited to use in ICD-9 coded databases; algorithms have been developed to apply the methodology in a variety of coding frameworks. As an example, documentation for an algorithm used with Pediatric Cardiac Care Consortium codes was included as part of our submission.

4. Many pediatric cardiac surgical procedures cannot be classified by RACHS-1. Specifically, only 85.8% of procedures in the STS Congenital Heart Surgery Database can be classified by RACHS-1 [4]. In the previously mentioned study by Jenkins et al. on center-specific differences in mortality, only 4,318 of 7,177 congenital cardiac surgical operations (60%) could be placed in one of the six RACHS-1 categories.

CHB Response

(5) We have intentionally excluded some procedures for which accurate risk adjustment for mortality is not possible, such as rare procedures, complex reoperations is older patients, and procedures where factors other than surgical risk are major drivers of risk of death, such as newborns and premature infants undergoing PDA ligation. In addition, the RACHS-1 methodology was developed for congenital heart surgical procedures only; it does not include all pediatric cardiac procedures. For example, ICD and pacemaker surgeries are not included. Many of the procedures in the STS Congenital Heart Surgery Database which cannot be assigned to a RACHS-1 risk category are actually ineligible.

In the study examining center-specific differences in mortality, it is incorrect that only 60% of procedures could be placed into a risk category. We stated that in the database used for this evaluation, there were 7177 cases of congenital heart surgery performed at 109 centers. However, we analyzed and presented only those cases from the 22 institutions performing at least 100 congenital heart surgeries per year. The 4318 cases analyzed are from these 22 institutions only, not all 109. Therefore 7177 is an incorrect denominator.

5. The mainstay of the proposed measure is an SMR, which is determined by the calculation of observed to expected (O-E) mortality ratio for a given center. This process is dependent upon the availability, accuracy, and applicability of a reference data set, and the solution to a multivariate equation with specific coefficients for each of the "risk variables." The reference data set used to develop RACHS-1 was based mainly on administrative data, now more than 10 years old. It is unknown whether there is a new "contemporary universal reference data set." **No such unique reference data set is described or identified in the measure description. As such, the mechanism by which expected mortality will be calculated for a given center is unknown**.

CHB Response

(6) We do not propose that the original data sets used for derivation of the RACHS-1 methodology should serve as the reference group against which institutions compare themselves. In our applications, we have chosen reference groups appropriate to the situation. We acknowledge that we have not selected any one unique reference data set to be used in all instances. We consider the flexibility of the RACHS-1 methodology to be an advantage, not a disadvantage.

This problem leads to many unanswered questions:

a. Will index institutions need to be among the centers from which the reference data are derived?
b. Can an institution base their measurement and reporting on a reference data set which does not include their own data?
c. Will one of several sets of coefficients for the logistic regression need to be provided to each institution?
d. Will this set of coefficients depend on the participation of that particular center in one of several consortia or databases from which a reference data set is derived?
e. Will each institution need to enlist the services of a biostatistician to analyze their own outcome data, apply the institution-specific logistic regression model, and calculate their observed and expected mortalities and SMR?

6. Can the SMR of an institution that utilizes one reference data set (which determines the coefficients used to calculate their expected mortality) be compared to the SMR of another institution that utilizes a different reference data set?

CHB Response

(7) These questions highlight the benefits of the RACHS-1 methodology. Institutions that participate in databases, such as those sponsored by STS, the Pediatric Cardiac Care Consortium, the Children's Hospital Corporation of America, NACHRI, or AHRQ, can use RACHS-1 for comparisons within that database. Institutions that do not participate in a database can use the coefficients provided to track their own performance over time. The calculations are straightforward and should be able to be performed by most trained analysts, similar to other risk-adjusted data used by most institutions to track finances, staffing, etc. Specific comparisons of standardized mortality ratios derived from different data sources should be made with caution.

7. SMR incompletely illustrates outcome and does not appropriately address questions regarding a center's performance within the individual strata of complexity or risk. From SMR, it is not possible to determine whether an institution is dealing at all with cases in a specific stratum of risk or complexity. For example, two centers may have the same calculated SMR but one of those centers may be dealing with many complex "high risk" cases, while the other center deals only with cases of lesser complexity and thus lower risk.

CHB Response

(8) This is true, but comparisons are simplified by use of a single number instead of five separate mortality rates. We are also able to adjust for additional clinical factors which have a significant impact on mortality, such as age at surgery. Last, the accuracy of the assessment using the SMR is greater; since there are more cases in the total caseload than in any individual risk category, confidence limits are narrower.

B. PCS-018-09: Operative Mortality Stratified by the Five STS-EACTS Mortality Levels [The Society of Thoracic Surgeons (STS)]

Historically, STS has recognized the limitations of using raw, unadjusted mortality rates as a measure of outcome, quality, and performance. Given the enormous diversity of congenital heart operations, it is understandable that the initial approach to the characterization of case mix (i.e., description of relative complexity and relative risk of mortality) was largely based on expert opinion. For nearly a decade, the STS Congenital Heart Surgery Database reported outcomes of cases stratified by RACHS-1 and the Aristotle Complexity Score, two popular and widely used tools adapted to this purpose. The importance of strict definitions (e.g., procedural terms, patient factors, mortality, and time intervals) was emphasized in the methodology. Ultimately, the goal was to transition from subjectively derived estimates of risk or complexity to an empirically-based tool for analyzing mortality associated with congenital heart surgery.

In 2009, the STS-EACTS Congenital Heart Surgery Mortality Categories (STS-EACTS Categories) were published [5]. Mortality risk was estimated for 148 types of pediatric and congenital cardiac surgical operations using data from 77,294 operations entered into the STS Congenital Heart Surgery Database (43,934 patients) and the European Association for Cardiothoracic Surgery (EACTS) Congenital Heart Surgery Database (33,360 operations) between 2002 and 2007. Procedure-specific mortality rate estimates were calculated using a Bayesian model that adjusted for small denominators. Procedures were then sorted by increasing mortality risk and grouped into five categories (STS–EACTS Congenital Heart Surgery Mortality Categories [2009]) that were chosen to be optimal with respect to minimizing within-category variation and maximizing between-category variation. Model performance was subsequently assessed using an independent validation sample (n = 27,700; 2007-2008 data) and compared with two existing methods: RACHS-1 Categories and the Aristotle Basic Complexity Score.

Estimated mortality rates ranged across procedure types from 0.3% (atrial septal defect repair with patch) to 29.8% (truncus + interrupted aortic arch repair). The STS–EACTS Categories demonstrated good discrimination for predicting mortality in the validation sample (C-index= 0.773).

In the subset of procedures for which STS–EACTS Category, RACHS-1 Category, and Aristotle Basic Complexity Score are defined, discrimination was highest for the STS–EACTS Categories (C-index = 0.778), followed by RACHS-1 Categories (C-index = 0.745), and Aristotle Basic Complexity scores (C-index = 0.687).

Table 1 shows the results of comparing the STS–EACTS Categories (2009) to the RACHS-1 Categories and the Aristotle Basic Complexity Score using an independent validation sample of 27,700 operations performed in 2007 and 2008.

Table 1: Method of Modeling Procedures	Model without patient covariates	Model with patient covariates	Percent of operations that can be classified
STS-EACTS Congenital Heart Surgery Mortality Categories (2009)	**C = 0.778**	**C = 0.812**	**99%**
RACHS-1 Categories	**C = 0.745**	**C = 0.802**	**86%**
Aristotle Basic Complexity Score	**C = 0.687**	**C = 0.795**	**94%**

The STS–EACTS Categories are now incorporated into the outcomes reports of the STS Congenital Heart Surgery Database. In addition, the five STS-EACTS Categories are the basis for stratification of mortality outcomes in the measure submitted to NQF.

Advantages:

1. The STS–EACTS Categories are based on objective data from a clinical data set that is internally validated and checked by site verification on an ongoing basis.
2. The accuracy and discrimination of the STS–EACTS Categories were validated using 2007-2008 data.
3. The majority (99%) of pediatric and congenital cardiac surgical operations that are coded by centers participating in the STS Congenital Heart Surgery Database can be assigned to one of the five STS-EACTS Categories. In comparison, 94% can be categorized using the Aristotle Basic Complexity Score, and 86% can be assigned to a RACHS-1 Category.

CHB Response

The issue of fewer procedures being eligible for RACHS-1 risk adjustment was addressed in item (5) above.

4. Comparison (by C-statistic) to Aristotle Basic Complexity Score and RACHS-1 Categories, both with and without patient factors, reveals best performance by STS–EACTS Categories.

CHB Response

(9) The c statistic was demonstrated to be higher for the STS-EACTS risk categories than for the RACHS-1 risk categories in the STS database, as would be expected since the STS-EACTS categories were derived exclusively from the STS-EACTS data. However, the RACHS-1 risk categories performed nearly as well, and have also been shown to perform well in other data sources. This has not been demonstrated with the STS-EACTS categories. Furthermore, the RACHS-1 methodology also incorporates age, prematurity, major non-cardiac structural anomaly, and combinations of procedures. We are not proposing that the categories be used alone. As noted in the table above, the c statistic for the full RACHS-1 model is higher than the c statistic for the STS-EACTS categories, even within the STS database. The resultant SMR is thus the best (most discriminatory) measure of performance that is currently available.

5. Using the STS–EACTS Categories eliminates the uncertainties of coding that are associated with the use of administrative data, both for center reporting and for development of a reference data set.

CHB Response

The issue of administrative data was addressed in item (1) above.

6. The proposed measure is maximally informative, allowing the stakeholder to draw inferences concerning mortality outcomes associated with procedures of low, intermediate, and high levels of complexity.
7. Calculation and reporting of mortality outcomes by STS-EACTS Categories does not require each institution to solve any multivariable equations and does not require biostatistician-level skill. For centers participating in the STS Congenital Heart Surgery Database, the calculation and reporting is already completed at six month intervals.
8. Measurement and reporting is not dependent upon a reference data set and is therefore not susceptible to error or misinterpretation that could result from use of incorrect or inappropriate reference data.

Disadvantages: As a consequence of having been developed over the past three years, this empirically derived system of mortality levels may be less familiar to some stakeholders than Aristotle or RACHS-1.

STS recommends that ONLY the STS–EACTS Congenital Heart Surgery Mortality Categories (2009) are used for complexity stratification of mortality. Main rationale for this recommendation is two-fold:

1. The C-statistic for the STS-EACTS Congenital Heart Surgery Mortality Categories (2009) is better than for the RACHS-1 Categories and the Aristotle Basic Complexity Score.

CHB Response

We are not proposing that the RACHS-1 risk categories be used alone. This was addressed in item (9) above.

2. 86% of pediatric and congenital cardiac operations can be assessed by the RACHS-1 Categories, 94% by the Aristotle Basic Complexity Score, and 99% by the STS-EACTS Congenital Heart Surgery Mortality Categories (2009).

CHB Response

The issue of fewer procedures being eligible for RACHS-1 risk adjustment was addressed in item (5) above.

III. Critique of PCS-021-09, Organized According to the Four Criteria Proposed by NQF for Measure Evaluation

This critique is organized according to the four NQF evaluation criteria:

(1) I=Importance to Measure and Report;
(2) S=Scientific Acceptability of Measure Properties;
(3) U=Usability;
(4) F=Feasibility

(1) Importance to Measure and Report

Measuring mortality in a way that includes a demonstration of case complexity is generally accepted as being of great importance. For quality improvement, this is essential and fundamental. For public reporting, the issues are different and even more complex. Despite explanations and disclaimers, the concept of what does and does not reach a level of statistical significance is difficult to convey in the public reporting of surgical outcomes. This becomes even more difficult and complex when reporting mortality outcomes by assigning a specific institution with a calculated numerical value such as the SMR. Use of a derived value such as an SMR leads to misunderstandings that result from the erroneous assumption that the process of "standardizing" enables the interested party to draw inferences concerning the significance of an institution's SMR as being higher or lower than that of another institution (see below). An impression of "good performance" is generally inferred from a low SMR (i.e., SMR<1), while at the same time, it conveys no information about whether or not an institution is managing cases in the higher strata of risk or complexity, and to what extent these high complexity cases account for the observed mortality rate. While the individual factors that contribute to the complexity of this problem are numerous, one that is of overriding importance is the accuracy, reliability, and applicability of the "reference data set" from which the "expected mortality" (the denominator in SMR) is derived. ***Unless there is a single, universally applicable reference data set, then reporting of individual institution SMRs based upon a variety of disparate, non-harmonious data sets is likely to misinform those to whom it is reported***.

CHB Response
As noted in item (6) above, we consider the flexibility of the RACHS-1 method to be an advantage.

(2) Scientific Acceptability of Measure Properties

The elements of an SMR are the observed mortality (numerator), the expected mortality (denominator), and the calculated ratio. In the case of this measure, both the numerator and denominator are derived, or calculated values.

The numerator used in the calculation of SMR is the observed mortality, which is calculated using data from the participant. Observed mortality is defined as the number of pediatric cases of congenital heart surgery resulting in in-hospital death that can be placed into a RACHS-1 risk

category divided by the total number of pediatric cases of congenital heart surgery that can be placed into a RACHS-1 risk category. ***The use of the RACHS-1 risk categories limits the cases in both the numerator and denominator to those that can be classified according to RACHS-1. It has been determined that currently, 86% of the cardiac procedure types coded by participants in the STS Congenital Heart Surgery Database can be assigned to a RACHS-1 risk category. Thus, one in seven cases would be excluded from the SMR calculation*** [4, 5].

CHB Response
The issue of fewer procedures being eligible for RACHS-1 risk adjustment was addressed in item (5) above.

The measure specifies consideration of "total cases of congenital heart surgery among patients <18 years of age" rather than limiting the analysis to index cases, as is done in other proposed measures. By using this criterion for the numerator and the denominator, the methodology introduces the potential for significant underestimation of mortality in both the institutional calculation and the reference data set. Mortality calculation based on the number of operative cases as opposed to the number of surgical admissions (i.e., the number of index cases) can be very misleading. This phenomenon is explained and exemplified in the following example: Consider a center that performs Norwood Stage 1 operations on ten patients in a year, with one of those patients returning to the operating room during the same admission for additional atrial septectomy, one returning for conversion from a modified Blalock-Taussig shunt to a Right-Ventricle to Pulmonary Artery Conduit, two of the ten patients being re-explored for bleeding, and seven of the ten patients being treated with delayed sternal closure operations. One patient dies prior to discharge. Twenty-one operations (total cases) were performed. But ten index operations were performed on ten patients. If mortality is calculated based upon total cases, the mortality rate would be $^{1}/_{21}$ or 4.8%. Based upon index cases, the mortality rate is $^{1}/_{10}$ or 10%, which of course reflects the true outcome for the group of ten patients. ***The description of PCS-021-09 (Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery [RACHS-1 Method]) does not specify calculation based on index cases in either the institutional calculation of observed mortality or in the mortality determination for the reference data set. By using all cases (total cases) rather than index cases, the methodology of PCS-021-09 introduces the potential for significant underestimation of mortality in both the institutional calculation (numerator) and the reference data set (denominator).***

CHB Response
(10) The interpretation above is incorrect. Mortality is calculated at the admission (patient) level; individual surgeries for the same patient are not counted separately. Patients with more than one surgery are placed into the category corresponding to the single highest risk procedure, and are noted to have combinations of cardiac surgical procedures in the risk adjustment model.

The denominator used in the calculation of SMR is the expected mortality rate, which is calculated specifically for each group or participant. In this calculation, a multivariable logistic regression model, with the outcome "in-hospital death," is fitted. Five clinical characteristics are incorporated as covariates:

1. RACHS-1 risk categories 2, 3, 4, 5, and 6 as binary covariates, with category 1 as the reference group;
2. Age ≤30 days and age 31 days to 1 year, with age ≥ 1 year as the reference group;
3. Prematurity;
4. Presence of a major non-cardiac structural anomaly; and
5. Presence of combinations of cardiac surgical procedures

This logistic model is used to calculate the predicted probability of death for each individual case in the data set. The average predicted probability of death for all cases is computed by summing the predicted probabilities for each case and dividing by the total number of cases that can be placed into a RACHS-1 risk category; this average predicted probability of death for all cases represents the expected mortality rate for the group, adjusting for case mix.

The SMR is then calculated as the observed mortality rate divided by the expected mortality rate. ***A very important problem is that the measure proponents include in their measure description three distinctly different sets of coefficients for the risk adjustment model. Each pertains to a given "reference data set."*** Each set of coefficients was used by the measure stewards in validation exercises in which they considered outcome data from institutions that participated in different consortia or databases.

In the "original model validation set" the coefficients for RACHS-1 levels 2 and 6 are 1.7477 and 4.0022, with odds ratios of 5.74 and 54.7, respectively. For a second reference data set, the Kids' Inpatient Database 2006, the corresponding coefficients are 0.0202 and 1.8726, with odds ratios of 1.02 and 6.51. For the Pediatric Health Information System 2002-2006, a third reference data set, the corresponding coefficients are 0.4081 and 2.2412, with odds ratios of 1.50 and 9.40. Thus, for one reference data set the odds ratio for mortality in RACHS-1 level 6 is 9.53 times the odds ratio for mortality in RACHS-1 level 2. For another reference data set, it is 6.38 times greater. For the third reference data set it is 6.27 times higher. The odds ratio for mortality associated with the presence of a Major Non-cardiac Structural Anomaly is 2.20, 1.29, or 1.70, depending upon the reference data set. The odds ratio for this variable in the second reference data set is outside of the 95% confidence intervals for that odds ratio in the first reference data set, and vice versa.

On page 25 of the Measure Submission Form, in the table entitled: Mortality Rates by Risk Category (RACHS-1) Single Procedures, the measure steward presents calculated mortality rates with 95% confidence intervals in each of six RACHS-1 risk categories in five different reference data sets (four American, one European). For Risk Category 3, the mortality in the KID 2003 data set is well outside the 95% confidence intervals of the PHIS 2002-2006 data set for the same risk category. The same is true in Risk Categories 5 and 6. In fact in Risk Category 6, the mortality in the KID 2003 database is outside the 95% confidence intervals of all of the other American data sets. In Risk Category 2, the mortality in the PCCC 2002-2004 data set is well outside the 95% confidence intervals of the KID 2003 data set in the same risk category. ***Since the detailed description of the measure does not actually specify what will constitute the reference data set (which will be the basis for calculation of expected mortality, the denominator in SMR), it is assumed that it may be chosen by the reporting institution, presumably from the universe***

of consortia, registries, or administrative data sets in which it is included. Obviously, the calculated value of SMR can vary tremendously, based upon the choice of reference data set.

CHB Response
(11) We agree that comparisons are most accurate when made using similar methods for data collection and coding. RACHS-1 can be used with a variety of data sources, but comparisons across data sources should be made with caution.

Another important measure property that affects scientific acceptability is ascertainment (i.e., to find out or learn with certainty). In the words of the measure stewards, page 3 section 11, "Data elements may be obtained from an administrative database (e.g., Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient Database (KID), Pediatric Health Information System (PHIS)); from a clinical database (e.g., Pediatric Cardiac Care Consortium (PCCC), Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database); from hospital-specific electronic medical records; or from paper medical records." ***Of all of the potential sources of data, the STS Congenital Heart Surgery Database is the only data source for which there is a formalized process of data verification. Data from other sources are not verified***.

As discussed above, ***the diagnostic and procedural information in the various administrative data sets has been shown to be less reliable, accurate, and predictable than that in the clinical registry database of STS***. Strickland and associates at the National Center on Birth Defects and Developmental Disabilities of the Centers for Disease Control and Prevention described their findings in comparing coding of congenital cardiac anomalies and procedures by ICD-9-CM and by the clinical nomenclature used in the STS Congenital Heart Surgery Database [3]. Their investigation revealed that the sensitivity of ICD diagnosis codes was 83% for tetralogy of Fallot, 100% for transposition of the great arteries, and 95% for hypoplastic left heart syndrome. The false positive fraction was 2% for tetralogy of Fallot, 49% for transposition, and 11% for HLHS. They concluded that "analyses based on International Classification of Diseases diagnosis codes may have substantial misclassification of congenital heart disease. Isolating the major defect is difficult, and certain codes do not differentiate between variants that are clinically and developmentally different."

As a corollary, the use of ICD-9 (and ICD-10) codes to assign cases to RACHS-1 procedural risk levels is fraught with uncertainty because of the incomplete nature and vagaries of codes. For example, there is no ICD-9 code for the Norwood stage 1 operation. Accordingly, determination from hospital charge records (the "front sheet") or from codes in administrative databases is reliant upon the probability that a patient coded in the following fashion actually underwent a Norwood procedure:

Stage 1 Repair Risk Category 6
Require:
Proc 35.41 Enlargement of existing ASD
or 35.42 Creation of septal defect in heart
Proc 39.0 Systemic to pulmonary artery shunt
or 35.92 Creation of conduit between RV and PA
Proc 38.35 *or* 38.45 Resection of thoracic vessel
or 38.34 *or* 38.44 Resection of abdominal aorta

or 38.64 *or* 38.65 Other excision of vessel/aorta
or 38.84 *or* 38.85 Other surg occlusion of vessel/aorta
or 39.56, 39.57, 39.58 Repair of blood vessel
or 39.59
or 36.99 Other operation on vessel of heart
Cannot have:
Proc 35.94 Creation of conduit between atrium-PA
Proc 35.95 Revision corrective procedure on heart
Proc 39.21 Caval-pulmonary artery anastomosis
Allow:
Dx 745.5 Ostium secundum atrial septal defect
Dx 746.3 Congenital stenosis of aortic valve
Dx 746.5 Congenital mitral stenosis
Dx 747.0 Patent ductus arteriosus
Dx 747.10 Coarctation of aorta
Dx 747.22 Atresia and stenosis of aorta
Dx 747.89 Other anomalies of great veins
Proc 37.33 Excision of other lesion/tissue of heart
Cannot have: Any other cardiac dx

The Norwood procedure is one of the most frequently performed congenital heart operations, and is one for which operative mortality is substantial. To rely upon probabilistic matching to ascertain whether a given patient actually underwent a Norwood procedure introduces a substantial degree of uncertainty that undermines the usefulness of the measure for both quality improvement and public reporting purposes.

Another similar example is the Ross operation. This procedure consists of replacement of the aortic valve with the patient's own pulmonary valve (autograft) and replacement of the pulmonary valve with a prosthesis or homograft. Under the heading, "Define individual cardiac procedures assigned to a risk category," the specifications for the Ross procedure in Measure PCS-021-09 appear as listed below:

Ross Procedure Risk Category 3
Require:
Proc 35.21 *or* 35.22 Aortic valve replacement
Proc 35.25 *or* 35.26 Pulmonary valve replacement
Allow:
Proc 35.01 Aortic valvotomy
Proc 35.11 Aortic valvuloplasty
Proc 35.03 Pulmonary valvotomy
Proc 35.13 Pulmonary valvuloplasty
Proc 35.33 Annuloplasty
Proc 35.99 Other operation on valves of heart
Proc 39.56, 39.57, 39.58 Repair of blood vessel
or 39.59
Proc 36.99 Other operation on vessel of heart
Proc 37.33 Excision of other lesion/tissue of heart

PDA surgery
ASD2 repair

This complex method of coding the Ross procedure introduces considerable potential for error, since any combination of aortic and pulmonary valve replacement would meet these criteria, whether or not it involved pulmonary autograft replacement of the aortic valve, which is the sine qua non for the Ross procedure.

These examples of the Norwood and Ross procedures are merely two of many examples of the imprecision that can result from coding of congenital cardiac surgical procedures based upon administrative data.

CHB Response

The issue of administrative data was addressed in item (1) above.

(3) Usability

Given the requirement that each institution must apply a logistic model to calculate the predicted probability of death for each individual case in the data set, it seems clear that each reporting institution will be obligated to devote to this measure the efforts of a biostatistician or comparable member of the work force.

CHB Response

The issue of ease of application was addressed in item (7) above.

In addition, ***SMR can only be calculated once the coefficients specific to a given reference data set are determined, verified, and provided to the institution. The measure description for PCS-021-09 does not specify how it identifies what reference data set is to be used for a given institution, or how the appropriate coefficients for the logistic model will be determined and made available to each institution. Thus, the method by which this measure would be usable at the level of the measuring and reporting institution is unclear.*** The examples of validation exercises described by the measure steward involve at least four reference data sets. For some institutions, one data set pertains; for a few institutions, more than one data set pertain. If the measure can ultimately be used by all centers and institutions, then there will inevitably be some institutions for which none of the aforementioned reference data sets are applicable and some for which it would be necessary to choose among reference data sets or to calculate more than one SMR.

In section 23 of the measure description, the measure steward states that, "quality improvement efforts can be enhanced and stimulated by a clear understanding of how an entity (e.g., an institution) is performing in comparison to other entities." ***In terms of usability by stakeholders to make such determinations of relative performance, the measure is severely hampered by:***

1. ***Its failure to include reporting of any directly measured outcomes data (e.g., observed mortality, stratified by level of complexity); and***

2. ***The fact that comparison of SMR between institutions "affiliated" with different reference data sets and thus applying different risk variable coefficients in the logistic model, can be expected to mislead and misinform, which is certainly not the desired outcome.***

CHB Response

(12) Observed mortality (mortality rate) is in fact the numerator of the SMR. As noted in item (6) above, we consider the flexibility of the RACHS-1 method to be an advantage.

(4) Feasibility

The measure description template includes the following instruction: "Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure." The measure steward states that "because this measure can be applied in administrative databases, it can be subject to the coding inaccuracies sometimes associated with these databases."

Indeed, a growing prevalence of data supports the use of clinical databases rather than administrative databases for the evaluation of quality of care for patients undergoing treatment for congenital cardiac disease. As described previously, evidence from three recent studies suggested that the validity of ICD coding of lesions seen in the congenitally malformed heart as used in administrative databases is likely to be poor [1, 2, 3].

CHB Response

The issue of administrative data was addressed in item (1) above.

Unintended consequences

Notwithstanding the best of intentions, public reporting of a methodologically flawed numerical index (i.e., SMR based upon a variety of disparate reference data sets) has the potential to misinform rather than educate and enlighten stakeholders and consumers. In addition, it would be worse to do so utilizing a measure that is based partially or entirely on data from administrative sources which utilize coding nomenclature that fails to address the diversity and granularity of congenital cardiac anomalies and the surgical procedures used to treat them. STS's position should not be taken as an across-the-board condemnation of the use of administrative data; we acknowledge that administrative data are a rich and essential tool that are best suited for numerous applications and across many domains. Rather, our position reflects the current state of nomenclature and coding of congenital cardiac diseases and their treatments.

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NATIONAL QUALITY FORUM

Comments on Draft Report: National Voluntary Consensus Standards for Pediatric Cardiac Surgery

The Steering Committee reviewed the submitted comments and proposed responses on a conference call on September 13, 2010.

	Comment Submitter	Comment Submitter Organization	Comment Type/Measure Name	Comment	Final Response
1	Ms. Jane Han, MSW	The Society of Thoracic Surgeons	Comments on the general draft report	STS advocates the use of clinical databases rather than administrative databases for the evaluation of the quality of care for patients undergoing treatment for pediatric cardiac disease. 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 (ICD) by administrative databases is likely to be poor [1, 2, 3]: Among 373 infants with congenital cardiac defects at the Childrens Hospital of Wisconsin, investigators reported that only 52% of the cardiac diagnoses in the medical records had a corresponding ICD code in the hospital discharge database [1]. The Hennepin County Medical Center discharge database in Minnesota identified all infants born during 2001 with an ICD-9 code for congenital cardiac disease. Physician review of these 66 medical records confirmed the accuracy of only 41% of the codes contained in the administrative database from the ICD [2]. The Metropolitan Atlanta Congenital Defect Program of the Centers for Disease Control and Preventions Birth Defect Branch carried out surveillance of infants and fetuses with cardiac defects delivered to mothers residing in Atlanta during the years 1988 through 2003 [3]. These records were reviewed and classified using both administrative coding from the ICD and the clinical nomenclature used in the STS Congenital Heart Surgery Database. It was concluded that continued...	Children's Hospital Boston developers also responded to this comment in a response letter. To view the letter, please click here .
2	Ms. Jane Han, MSW	The Society of Thoracic Surgeons	Comments on the general draft report	(continued) analyses based on the codes available in the ICD are likely to have substantial misclassification of congenital cardiac disease. The following are potential reasons for the poor diagnostic accuracy of administrative databases and codes from the ICD: accidental miscoding coding performed by medical records clerks who have never seen the actual patient contradictory or poorly described information in the medical record lack of diagnostic specificity for congenital cardiac disease in ICD codes inadequately trained medical coders STS supports the endorsement of measures for Pediatric and Congenital Cardiac Surgery based on data from clinical rather than administrative databases. 1. 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. 2. Frohnert BK, Lussky RC, Alms MA, et al. Validity of hospital discharge data for identifying infants with cardiac defects. J Perinatol 2005;25:737-42. 3. Strickland MJ, Riehle-Colarusso TJ, Jacobs JP, et al. 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. Cardiology in the Young, Vol 18, Issue Suppl. 2, pp 92100, Dec 9, 2008.	Children's Hospital Boston developers also responded to this comment in a response letter. To view the letter, please click here .
3	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	Comments on the general draft report	On behalf of the nation's children's hospitals, which are committed to excellence in providing care to infants, children, adolescents and their families, the National Association of Children's Hospitals and Related Institutions (NACHRI) is pleased to offer the following comments on the National Voluntary Consensus Standards for Pediatric Cardiac Surgery. NACHRI applauds the National Quality Forum for undertaking this important project and the thoughtful consideration of the measures submitted by the Steering Committee. In addition, we applaud the measure submitters, including The Society of Thoracic Surgeons and The Children's Hospital, Boston for bringing forward measures to move this important work forward. According to The Children's Heart Foundation, congenital heart defects are the most common birth defects in children and the most common cause of all infant deaths in the United States. Moreover, and as stated in the report, the cost of inpatient surgery to repair congenital heart disease is high.NACHRI believes the measures put forth in the report are an important first step in building a robust and balanced set of measures related to the quality and safety of health care for children. The Subcommittee of the AHRQ National Advisory Committee noted in their report on recommendations for an initial core set of measures for Medicaid and CHIP several gaps in measures, including measures of specialty and inpatient services. We also agree with the recommendations of the Steering Committee regarding time limited endorsement of a majority of the measures. Although the measures are an important first step, the Steering Committee noted important areas to address in developing more precise measure specifications and in testing the measures. Time limited endorsement should help to accomplish these objectives. We also look forward to the development of more robust and tested measures related to outcomes, such as the measure topics reviewed but not recommended for endorsement at this time (e.g., surgical complications, such as mediastinitis).	Thank you for your comment.
4	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	Comments on the general draft report	(continued) In general, we recommend that the potential collection mechanism for the proposed measures be clarified. For example, for measure 006, the evaluation summary states "there was also discussion surrounding the measure being available in other registries," but no conclusion or recommendation offered. Are these measures able to be embedded in other data bases or will they require participation in the STS database? In the measure submissions, it is frequently stated that "upon receiving NQF endorsement, this measure will be added to the STS Congenital Heart Surgery Database for data collection and analysis." Will the measures be considered proprietary? We offer specific comments under applicable measures. Our comments are based upon a careful review of the report and measure submission forms, but not the systematic input of cardiology and cardiac surgery experts. Therefore, our comments relate more to the measure methodology rather than to the clinical evidence behind the measures.	Based on the specifications provided for these measues, they can be implemented using clinical data from any source, and do not require participation in The Society of Thoracic Surgeons (STS) database. However, because they are specified using STS codes, they would require the use of the STS data collection tool to identify patients for each measure and strata(for applicable measures). These measures are not considered proprietary.
5	Dr. Mark S. Antman, DDS, MBA on behalf of Nancy H. Nielsen, MD, PhD	American Medical Association	Comments on the general draft report	The American Medical Association (AMA) appreciates the opportunity to comment on the National Quality Forums (NQF) National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report. The AMA believes performance measures for this population undergoing cardiac surgery are needed and we appreciate NQFs efforts to review and endorse such measures. While the AMA supports many of these measures, we have concerns regarding the level of measurement for one of the measures.	Thank you for your comment.
6	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	Comments on the general draft report	These benchmark areas should be the minimum of what is evaluated within a pediatric cardiac surgery center. These areas ensure an all-encompassing center prepared to treat the complex pediatric cardiac surgical patient.	Thank you for your comment.
7	Dr. Rita Munley Gallagher, PhD, RN	American Nurses Association	Comments on the general draft report	The American Nurses Association (ANA) wishes to advise you of a recent action by the ANA Board of Directors to adopt a position statement regarding the Registered Nurses Roles and Responsibilities in Providing Expert Counseling on and Care at the End of Life which has a huge potential role in the pediatric cardiac population. Unfortunately, parents are sometimes given the choice of either not treating their infant at all or consenting to the provision of every extraordinary measure available. The healthcare system has not yet come to appreciate the value of presenting the issues (pro and con); allowing parents to make the necessary decision(s); and, then honoring those decisions. The statement is designed to guide the nurse in vigilant advocacy for patients throughout the lifespan as they consider end-of-life choices.	Thank you for your comment.

8	Dr. Rita Munley Gallagher, PhD, RN	American Nurses Association	Comments on the general draft report	The American Nurses Association (ANA) believes the measurement of resource utilization and outcomes is critically important. Children with cardiac defects frequently do not thrive and experience developmental delays--requiring a great deal of acute care and community-based support to assure appropriate cardiorespiratory support, adequate nutrition, prevention of further complications, and appropriate growth and development through various home interventions and therapies--until such time as the cardiac repairs or treatment can be provided. The provision of care to these children (who are sick and in need of extensive acute and community-based services prior to surgery) is very expensive and difficult to maintain over the long term. Anecdotal experience indicates that these children who undergo cardiac surgery generally go on to live full, productive lives and are age-appropriate in their growth and development. In other words, pediatric cardiac surgery overall has excellent outcomes. The document speaks to the number of children who undergo cardiac surgery that are covered by Medicaid or SCHIP. However, there are also families who do not have this kind of public insurance and are often at far greater risk financially because private insurances often do not cover as adequately leaving the family to cover the cost of huge deductible and/or other associated costs.	Thank you for your comment.
9	Jan Bull	Nursing Alliance for Quality Care	Comments on the general draft report	Dear Colleagues: On behalf of the Nursing Alliance for Quality Care, we thank you for the opportunity to comment on the newly released NQF Report on Pedicatric Cardiac Surgery. NAQC is supportive of the consensus report and has specific comments related to the multidisciplinary measures as noted specifically below.	Thank you for your comment.
10	Mrs. Amy E. Basken on behalf of Bill Foley CEO Children's Heart Foundation	Adult Congenital Heart Association, Children's Heart Foundation	Comments on the general draft report	To the members of the National Quality Forum: On behalf of the 1.8 million patients and families dealing with congenital heart disease, we applaud your efforts to develop surgical standards to improve outcomes and identify research priorities through the National Quality Forums project to endorse performance measures for pediatric cardiac surgery. The NQF efforts will help ensure that children undergoing heart surgery are not needlessly endangered by sub-standard surgical practices. As organizations committed to improving health and well-being for congenital heart patients, we recognize that as surgical outcomes improve, life expectancy is extended. The majority of individuals living with even the most critical congenital heart defects are now adults. All individuals with congenital heart disease, regardless of age, require the same congenital-heart specific standardized, specialized surgical care. We urge you to extend these measures to apply to all adult surgical centers as well as pediatric heart units undertaking congenital heart surgery. As consumers of the congenital heart surgery being addressed today, we commend the work being done, and look forward to collaborating to provide a brighter future for those living with congenital heart disease. Sincerely, Jodi Lemacks National Program Director Mended Little Hearts	Thank you for your comment.
11	Mr. Lee Tilson	Patient Safety Activist	Comments on the general draft report	On the day before public comments are closed (today is August 30 and public comments are supposed to close tomorrow, August 31) , I can see only four comments by one individual, David Venner. His comments are thoughtful. Perhaps there are more comments that I cannot access. My inability to access more comments may well result from my lack of familiarity with this forum. If so, I am confident that someone will advise me. May I suggest a longer time period for public comments and solicitation of patient advocates? The new perspectives they bring will open up new solutions to old problems. This is especially true for well informed advocates such as Mary Ellen Mannix, Helen Haskell, and Lisa Salberg of the Hypertrophic Cardiomyopathy Association. The benefits of a limited comment period may be outweighed by the limited comments generated. Thanks, Lee Tilson	Thank you for your comment.
12	Dr. David F. Vener, MD	Texas Children's Hospital/Baylor CoM	PCS-001-09: Participation in a National Database for Pediatric and Congenital Heart Surgery	Anesthesia for patients with structural and acquired congenital cardiac disease is most often provided by physicians and members of the anesthesia care team with special expertise in this high-risk population. Because these patients have been found to have much higher rates of complications than non-cardiac patients, the Congenital Cardiac Anesthesia Society has joined with the Society of Thoracic Surgeons Congenital Surgery Database to include anesthesia-specific data points and complications in the most recent version (3.0). These data points include airway management, medication and monitoring modalities in addition to anesthesia-related complications. It would be prudent to include mentioning incorporating anesthesia into this NQF Consensus Standard on Participation in a National Database. The anesthesia portion of the STS database allows for capture of cardiac patients having non-cardiac surgery, which remains one of the highest risk groups for pediatric anesthesiologists. This includes procedures in the cardiac catheterization lab, the general OR and in remote locations such as radiology suites. Anesthesia is typically the common denominator in the care of these patients and crosses over into all areas of the hospital.	During Committee discussion of this issue, it was determined that it is unclear how many programs are collecting the anesthesia data via The Society of Thoracic Surgeons (STS) database. It is not in the Committee's perview to determine when this data should be added to the measure. The STS developers clarified that the anesthesia module is an optional module that began collection in January 2010, so it may be premature to begin developing standards around this data. At this time it is anticipated that 5-10 sites are participating in anesthesia collection. Because this module is in its early stages, in time with more data and participation, the addition of this to the measure specifications may be reconsidered.
13	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-001-09: Participation in a National Database for Pediatric and Congenital Heart Surgery	The discussion of the variability of this measure is based on the level of participation in the STS Congenital Heart Surgery Database. It is our understanding that this measure does not specifically require participation in the STS Congenital Heart Surgery Database. Once other databases are considered, is the degree of variation in participating in registries for congenital heart disease known?	Previous Committee discussion determined that participation in a database is not limited to The Society of Thoracic Surgeions (STS) database, although ~75% of pediatric cardiac facilities do participate in the STS database. There are other ongoing efforts, such as The Pedatric Cardiac Care Consortium (PCCC) and other organizations that offer similar tools to the STS cardiac module. Virtual Pediatric Intensive Care Unite (VPICU) Performance System (VPS) database is also is being used, but does not use the dataset as the STS database.
14	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	PCS-001-09: Participation in a National Database for Pediatric and Congenital Heart Surgery	Participation in a national data base allows for benchmarking of congenital heart programs. This recommendation is essential ,and the information gained from participation in a national database should be used to evaluate outcomes and make recommendations on national trends in congenital heart surgeries. National data base participation allows for identification of national trends in congenital heart surgery; potentially leading to multi centered research that could further the practice of congenital heart surgery. One must also consider the identification of those programs with poor results, high mortality and morbidity and what the recommendation should be for those programs. Should there be congenital heart program if the outcomes are better at another institution? Is it fiscally responsible to allow a program to continue in the practice if the morbidity is higher than at other programs?	The Committee pointed out that the purpose of this measure is not to determine which programs should be practicing and which should not, but to assist in the systematic collection of data such that benchmarking and analysis can be done. Determining which programs should be practiced is beyond the scope of this Committee. The project should be outlined by policy makers and other related parties.
15	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-002-09: Multidisciplinary conference to plan pediatric and congenital heart surgery cases cases	We agree that this is an important measure topic, but also agree with the evaluation summary with regard to the need for more precise specifications on what constitutes a meeting and if there are specific components of a meeting that would be needed to pass. It is important that this measure be able to inform quality improvement and not simply be a a check the box measure. In addition, it may be worthwhile to explore moving beyond a structure measure to a process measure by measuring whether or not a multidisciplinary conference is held for each case. Collecting the measure on each case might provide additional evidence to support the practice. However, perhaps there are data to suggest that, once a multidisciplinary conference is established, all cases are subjected to a conference.	The Committe discussed this issue as well as which participants from the healthcare team should be present at the conference.- They determined that the details of the conference should be left to the institution.
16	Dr. David F. Vener, MD	Texas Children's Hospital/Baylor CoM	PCS-002-09: Multidisciplinary conference to plan pediatric and congenital heart surgery cases cases	A representative from the anesthesia care team should be present at the Multidisciplinary Conference to ensure that all relevant information concerning upcoming patients is discussed which might impact anesthesia management, including specific airway, intravenous and arterial access as well as any genetic, metabolic or medical conditions which might be impacted by anesthesia such as mitochondrial disorders.	The Committee pointed out that the measure specifies that a member from the anesthesia team be present at the conference.

17	Jan Bull	Nursing Alliance for Quality Care	PCS-002-09: Multidisciplinary conference to plan pediatric and congenital heart surgery cases cases	NAQC recommends that the definition of who is included in the preoperative planning conference be expanded to include the same team members as defined for measure PCS-003-09 with recommended participation including but not limited to cardiology, cardiac surgery, critical care, primary caregiver, family, nurses,pharmacist, and respiratory therapist. Involvement of the family is encouraged. By including the same team members (including family members) we believe the integrity of care coordination and communication would be enhanced across the entire spectrum of the patients episode of care. Although evidence is emerging in this area, the expert opinion of the NAQC Board firmly believes that it is in the best interests of patients and /or their designees, health care practitioners, and providers to include a broader composition of stakeholders in preoperative planning.	The Committee recognizes that family is an important part of the healthcare team and should be included in discussions of the patient to make informed decisions about the patient's care. However, the Committee disagrees and suggests family involvement in interdisciplinary rounds. The Committee also noted that while useful, it may be challenging to mandate pharmacists, primary care, and respiratory therapists be present for every meeting.
18	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-003-09: Multidisciplinary rounds involving multiple members of the healthcare team	Similar to our comments on Measure 002, we agree that this is an important measure topic but also agree with the evaluation summary with regard to the need for more precise specification on how rounds are defined along with specific components of what should take place. It is important for this measure to be able to inform quality improvement and not simply be a check the box measure. We strongly agree that involvement of family should be an important aspect of this measure. Additionally, we wonder if this measure might be more useful as a process measure not simply whether the program has multidisciplinary rounds in place -- although we recognize that that would be more difficult to collect.	The Committee addressed this issue in its discussion of this measure and affirmed the decision to intentionally specify for multidisciplinary rounds to allow for institutional differences. The Comittee also acknowledged that this measure would also be useful as a process measure, but pointed out that implementation would be difficult and require frequent audits of the process. The Committee ultimately agreed that measuring this concept as a structural measure is sufficient.
19	Jan Bull	Nursing Alliance for Quality Care	PCS-003-09: Multidisciplinary rounds involving multiple members of the healthcare team	NAQC supports this measure based on emerging evidence as well as strong expert opinion among the NAQC Board that systematic interprofessional rounds, including meaningful involvement of patients and their families, leads to measurable improvements in outcomes. In specific we NAQC recommends the following: Contemporary terminology refers to teams that include professionals of various disciplines and licensure types as interprofessional. Therefore, we recommend use of the term interdisciplinary. NAQC specifically supports the inclusion of patients, their family members and/or their designees as part of interdisciplinary team rounds. NAQC recently reviewed the literature for evidence to support this model of care and found promising evidence for its effect on outcomes (http://www.gwumc.edu/healthsci/departments/nursing/naqc/documents/NAQC_2010_Family_Centered_Rounds.pdf) In the currently proposed measure, it is not clear why the numerator is limited to cardiology, cardiac surgery, and critical care professionals.... Since family-centered interprofessional rounds have been studied among more diverse populations of patients, NAQC recommends the numerator be expanded to include all pediatric patients and potentially all inpatients. We suggest future research include operational issues such as frequency and timing of family-centered rounds, patient status, and how to communicate with patients and families.	The Committee pointed out that the family was already included in the specifications as members of the healthcare team that should be present during rounds.The inclusion of other pediatric patients is beyond the scope of this project.
20	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-004-09: Regularly Scheduled Quality Assurance and Quality Improvement Cardiac Care Conference	Similar to our comments on Measures 001 and 002, we agree with the evaluation summary with regard to the need for more precise specification of what the necessary components of a quality assurance and quality improvement care conference are.	The Committee discussed this issue and agrees that the measure clearly indicates the purpose of the conference is to discuss "opportunities for improvement." During this conference, adverse outcomes and complications of the case would also be discussed, similar to a Morbidity and Mortality (M&M) conference. While open to changes in wording in the measure, the developer wanted to ensure that the intent of the measure is not changed.
21	Dr. David F. Vener, MD	Texas Children's Hospital/Baylor CoM	PCS-005-09: Availability of intraoperative transesophageal echocardiography (TEE)	A large number of congenital cardiac surgical patients are not candidates for Transesophageal Echocardiography due to either patient size limitations or structural limitations with esophageal or stomach disease or surgery. For example, it is not uncommon to have cardiac patients who have undergone a Nissen-type Fundoplication which may restrict the ability to safely pass a TEE probe through the EG junction. Additionally, there are a subset of patients in whom passage of the TEE probe causes unacceptable changes in either respiratory mechanics or cardiovascular compromise. It would be useful to mention in the consensus standard for TEE that epicardial echocardiography should be readily available for those patients in whom TEE is contraindicated.	The Society of Thoracic Surgeons (STS) measure developers agree that the epicardial echocardiography should also be available as needed and have agreed to add this text to the title and description of the measure.
22	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-005-09: Availability of intraoperative transesophageal echocardiography (TEE)	As a structural measure, the usefulness of this measure is unclear to us as approximately 98 percent of centers use TEE, although some centers employ it selectively. It may be more helpful to measure the use of TEE on a per case basis to better understand the relationship between this structure and outcomes, although one would need to be mindful of unintended consequences if there are situations, as some of the comments suggest, in which TEE should not be used.	The Committee also addressed this in the discussion of the measure and agrees that this measure would also be useful as a process measure. The Developers agree that it would also be useful, but contend that identifying denominator patients for this measure within a process measure would add significant complexity to the measure.Given the lack of endorsed measures in this area at this time, the Committee agreed that measuring this concept as a structural measure is sufficient at this time and recommend that converting this measure to a process measure in future iterations should be considered.
23	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	PCS-005-09: Availability of intraoperative transesophageal echocardiography (TEE)	NAPNAP belives that this measure will positively influence the outcomes in the pediatric congenital heart patient.	Thank you for your comment.
24	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	PCS-006-09: Availability of Institutional Pediatric ECLS (Extracorporeal Life Support) Program	NAPNAP belives that this measure will positively influence the outcomes in the pediatric congenital heart patient	Thank you for your comment.
25	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-007-09: Surgical Volume for Pediatric and Congenital Heart Surgery	We suggest studying the relationship of this measure to other measures will make an important contribution to understanding the validity of volume as a proxy for quality. The measure submission form states 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. Further testing the validity of the measure is critical.	The Committee acknowledges the link between volume and patient outcomes is unclear and suggests that this measure be used along side the mortality measure PCS-018-09, also stratified by the five European Association for Cardio-Thoracic Surgery (EACTS) risk categories for a more complete assessment of quality.
26	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	PCS-007-09: Surgical Volume for Pediatric and Congenital Heart Surgery	NAPNAP belives that this measure will positively influence the outcomes in the pediatric congenital heart patient	Thank you for your comment.
27	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-008-09: Surgical Volume for Pediatric and Congenital Heart Surgery, Stratified by the Five STS-EACTS Mortality Levels	The discussion on scientific validity states this being risk-stratified basically requires the use of STS codes, again suggesting the need for clarity on how the measure will or can be collected. We believe stratifying the measure by complexity will add to its validity, but as with measure 007, testing the relationship of this measure to outcomes measures will be a major contribution in understanding the validity of volume as a proxy for quality.	See response for comment # 4

28	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-010-09: Timing of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	We agree with the comment in the evaluation summary that knowing the number of patients excluded from some measure because of inadequate documentation of things like incision and/or antibiotic start times would itself be important and should not be exclusion.	See response for comment # 32
29	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	PCS-010-09: Timing of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	NAPNAP agrees with the recommendations for the use and timing of antibiotics in children undergoing congenital heart surgery. Decreasing the risk of health care associated infections is a National Patient Safety Goal per The Joint Commission, and should be aggressively implemented. The recommendations did not make a recommendation about the length of the use of antibiotics which can differ in different institutions; at the least it should include the recommendation to use them only as long as needed and for an identified infection or time limited prophylaxis.	The Society of Thoracic Surgeons (STS) measure developers agree this is an important comment as it identifies an important issue for this population, but note there is limited guidance on the length of use and timing of antibiotics in the literature.
30	Bernard Rosof, MD, MACP	Physician Consortium for Performance Improvement	PCS-010-09: Timing of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	**(LATE COMMENT)** The appropriate timing of antibiotic administration for pediatric and congenital cardiac surgery patients is clinically important. However, we are concerned that this measure lacks sufficient specificity with respect to instances when surgery is delayed. Given that this measure counts redosed patients with delayed surgery in the numerator, we believe clinicians could benefit from additional instruction regarding the timing of antibiotic administration in these instances. For instance, one might question how long of a delay is acceptable. Additionally, one might question what is the appropriate course of action regarding redosing when the rescheduled time is unknown. Answering these questions and others could aid clinicians in appropriately determining which patients should be counted in the numerator for this measure. We recommend that additional specificity is provided regarding instances when a patient's surgery is delayed for proposed measure PCS-010-09.This comment was submitted via a letter outside of the online comment tool following the comment deadline. To view the detailed comment letter, please click here.	The guidelines for redosing are dependent on renal function, type of antibiotic, and other patient dependent factors. The Committee agrees this should be left to the institution due to patient variability and lack of consistent evidence on appropriate redosing.
31	Dr. David F. Vener, MD	Texas Children's Hospital/Baylor CoM	PCS-010-09: Timing of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	Antibiotic prophylaxis in these patients is routinely provided by the anesthesiology team, since intravenous access is frequently not available unitl after the patient is in the Operating Room. Confirmation of antibiotic administration (both choice of antibiotic as well as dosing) is best carried out during the immediate time out period prior to incision. Are there any consensus guidelines about redosing of antibiotics in procedures lasting longer than 4 - 6 hours?	The Developers and Committee pointed out that the intent of this measure is for timing and administration of the initial does of antibiotics. The measure does not address redosing. The guidelines for redosing are dependent on renal function, type of antibiotic, and other patient dependent factors. The Committee agrees this should be left to the institution due to patient variability and lack of consistent evidence on appropriate redosing.
32	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-011-09: Selection of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	We are concerned about the exclusion of patients for whom medical records do not include an antibiotic start date/time or incision date/time from this measure denominator.	The Committee agreed that the issue of inadequate documentation (or missing data) should be addressed in the measure, but not as exclusions. They suggested that cases with inadequate documentation be counted in the denominator and identified as exclusions from the numerator due to inadequate documentation. In response to these concerns, the Measure Developer agreed to change the title and description to reflect that the intent is to measure those patients "with documentation" of antibiotic administration.
33	Ms. Denise Graham on behalf of Shannon Oriola	Association for Professionals in Infection Control and Epidemiology	PCS-011-09: Selection of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	The SCIP antibiotic selection criteria may not always be applied to the pediatric population. The science was taken from and applied to the adult population. The NQF review process states: 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. Expert consensus opinion lacks scientific rigor to demand uniformity in all situations where inclusion criteria is met. In addition, if a newer antibiotic were approved for surgical prophylaxis the measure may not be nimble to change antibiotics on the approved drug list.	The Society of Thoracic Surgery (STS) measure developers agree this it will be a challenge to maintain the list of approved antibiotics. However, through the NQF maintenance and ad hoc review processes, measure updates can be made as needed if the antibiotic list requires updates.
34	Bernard Rosof, MD, MACP	Physician Consortium for Performance Improvement	PCS-011-09: Selection of Antibiotic Administration for Pediatric and Congenital Cardiac Surgery Patients	**(LATE COMMENT)** We are concerned that though this measure relies on the "body weight appropriate" dosage of prophylactic antibiotics, no algorithm or guidance is provided regarding how a clinician would calculate such dosage. We recommend that the measure developer provide some algorithm or guidance with proposed measure PCS-011-09 so that users can determine body weight appropriate dosage. In reviewing this measure it appears that it does not simply relate to the "selection of antibiotic administration" as is implied by the measure title. Rather it also concerns the issue of appropriate dosage, as noted. We recommend that the measure title and numerator for proposed measure PCS-011-09 be revised so that the intent of the measure is more clearly specified.This comment was submitted via a letter outside of the online comment tool following the comment deadline. To view the detailed comment letter, please click here.	The Society of Thoracic Surgery (STS) measure developers agreed to change the title and description to make it more reflective of the intent of the measure. The Committee agreed that the measure as specified is sufficient and dosing should be left to the institution due to variations in patient characteristics.
35	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	PCS-012-09: Use of an expanded pre-procedural and post-procedural "time-out"	NAPNAP belives that this measures will positively influence the outcomes in the pediatric congenital heart patient.	Thank you for your comment.

36	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-012-09: Use of an expanded pre-procedural and post-procedural "time-out"	We agree that this is an important concept. Similar to measure 002, it is not clear why this is proposed as a structure measure as to whether the program is in place in general and not a measure that is employed for each case. It would seem that the measure would be much more useful as a process measure, although it may be burdensome to collect. It may be worthwhile to further describe the conventional pre-procedure time-out, including the use of checklist.	The Committee also addressed this in the discussion of the measure, and agrees that this measure would also be useful as a process measure. However, given the lack of endorsed measures in this area at this time, they agreed that measuring this concept as a structural measure is sufficient at this time and recommend that converting this measure to a process measure in future iterations should be considered.
37	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-018-09: Number of patients who undergo Operative Mortality Stratified by the Five STS-EACTS Mortality Levels	We appreciate the information provided with this measure. As a point of clarification, is there a baseline to which each level of mortality is compared (e.g., observed/expected)? This and Measure 021 are critically important measures. We look forward to the development of a more robust set of outcomes measures beyond mortality.	The mortality scores are stratified by complexity and do not provide a ratio of observed to expected as would be displayed in a standard mortality ratio (SMR), but represent actual or observed mortality for each strata.
38	Ms. Jennifer Knorr	National Association of Pediatric Nurse Practitioners	PCS-018-09: Number of patients who undergo Operative Mortality Stratified by the Five STS-EACTS Mortality Levels	NAPNAP believes that it is crucial all pediatric congenital heart surgery programs are using the same method to define operative mortality and standardizing mortality ratio. As public reporting in pediatric outcomes continues to become more predominant these outcome measures give a common language in reporting and allows the consumer (parents/patients) the ability to make informed comparisons. NAPNAP also believes that in order to achieve excellent results in this field, each program requires a surgical volume high enough to allow for the establishment and maintenance of excellent outcomes. These outcome measures will help identify those programs with enough volume to either prove or disprove their ability to provide excellent outcomes in patients.	Thank you for your comment.
39	Dr. Rita Munley Gallagher, PhD, RN	American Nurses Association	PCS-018-09: Number of patients who undergo Operative Mortality Stratified by the Five STS-EACTS Mortality Levels	The American Nurses Association (ANA)wishes to specifically express concerns regarding the possibility of misinterpretation of the data resulting from PCS-018-09 which is intended to measure Operative Mortality stratified by the five STSEACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	A detailed description of this measure and its purpose has been presented in The Society of Thoracic Surgeons (STS) comment letter. To view this letter, click here:
40	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted.	This and Measure 018 are critically important measures. We look forward to the development of a more robust set of outcomes measures beyond mortality.	Thank you for your comment.
41	Ms. Jane Han, MSW	The Society of Thoracic Surgeons	PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted.	STS has provided detailed comments to NQF regarding this measure under separate cover. To view the STS letter and please click here.	Thank you for your comment.
42	Dr. Mark S. Antman, DDS, MBA on behalf of Nancy H. Nielsen, MD, PhD	American Medical Association	PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted.	While this measure addresses important areas of care, we cannot support it as an accountability measure at the clinician level to be used for public reporting. There are other factors beyond the care directly provided by clinicians (including the efforts of other health care professionals) that could affect the care of those patients who would be impacted by this measure. We believe that performance measures are only appropriate at the clinician level when it has been consistently shown that the outcome is directly dependent on the clinician, and not when such results are dependent on other healthcare professionals or other factors exogenous to the care a clinician provides; such is the case with mortality. Accordingly, this type of measure is best represented at higher levels of data collection or aggregation. Reporting of this outcome at high levels of collection or aggregation does not take away from their value to individual clinicians and others who are part of the team of care. We recommend that NQF, in consultation with the measure developer, replace Can be measured at all levels with non-clinician levels for the Level of Measurement/Analysis for proposed measure PCS-021-09.	Children's Hospital Boston developers agree that this measure should not be publicly reported at physician level, but rather at the institutional level. The measure submission form has been updated to reflect the level of analysis is appropriate at the facility level only.
43	Dr. Rita Munley Gallagher, PhD, RN	American Nurses Association	PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted.	The American Nurses Association (ANA)also has concerns related to PCS-021-09 which calculates the ratio of observed to Expected rate of inhospital mortality following surgical repair of congenital heart defect among patients 18 years of age, risk-adjusted using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method. The RACHS-1 is an attempt to measure risk that is predominately subjectively derived. The Journal of Thoracic and Cardiovascular Surgery suggested that this system does not predict risks as well as the newer STS-EACVS method. ANA concurs with the statements made by the Steering Committee regarding the shortcomings of this approach as reported in the literature. The best method to predict potential operative mortality has not yet been determined.	In response to this comment and other similar concerns raised in The Society of Thoracic Surgeons (STS) comment letter, the Children's Hospital Boston developers/stewards prepared and submitted a response letter. To view the letter, please click here.
44	Jane Han, MSW on behalf of Jeffrey P. Jacobs, MD; Marshall L. Jacobs, MD; Fred H. Edwards, MD; David M. Shahian, MD	Society of Thoracic Surgeons	PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted.	STS submitted a letter outside of the comment tool. This letter included a detailed comparison of PCS-018-09 to PCS021-09 with numerous points. To view the letter, please click here.	In response to this letter Children's Hospital Boston developers/stewards provided a detailed response to the issues raised in The Society of Thoracic Surgeons (STS) comment letter. To review there letter, please click here.
45	Bernard Rosof, MD, MACP	Physician Consortium for Performance Improvement	PCS-021-09: Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) Adjusted.	**(LATE COMMENT)** While this measure addresses important areas of care, we cannot support it as an accountability measure at the clinician level to be used for public reporting. There are other factors beyond the care directly provided by clinicians (including the efforts of other health care professionals) that could affect the care of those patients who would be impacted by this measure. We believe that performance measures are only appropriate at the clinician level when it has been consistently shown that the outcome is directly dependent on the clinician, and not when such results are dependent on other healthcare professionals or other factors exogenous to the care a clinician provides; such is the case with mortality. Accordingly, this type of measure is best represented at "higher" levels of data collection or aggregation. Reporting of this outcome at high levels of collection or aggregation does not take away from their value to individual clinicians and others who are part of the team of care. We recommend that NQF, in consultation with the measure developer, replace "Can be measured at all levels" with non-"clinician" levels for the Level of Measurement/Analysis for proposed measure PCS-021-09. This comment was submitted via a letter outside of the online comment tool following the comment deadline. To view the detailed comment letter, please click here.	Children's Hospital Boston developers agreed with this comment and changed the level of analysis on the submission form to reflect that the facility level is the only appropriate level of analysis for this measure.
46	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	Comments on measures not recommended	The topics suggested by the standards that were not recommended appear promising for further measure development.	Thank you for your comment.