NATIONAL QUALITY FORUM

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

DRAFT REPORT FOR COMMENTING

NATIONAL QUALITY FORUM

TO: NQF Members

FROM: NQF Staff

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

DA: August 9, 2010

This draft report is from NQF's 2009 Pediatric Cardiac Surgery Project. This project seeks to identify and endorse quality measures that specifically address the pediatric cardiac surgical population for public reporting and quality improvement. Performance measurement for healthcare quality reporting and improvement have to date focused largely on the adult population. This is NQF's first project focused on pediatric heart surgery.

In an effort to understand the full implications of this process for NQF and other relevant stakeholders, NQF convened a Steering Committee comprised of 13 experts in the field to evaluate submitted measures and to make recommendations across the spectrum of pediatric cardiac surgery. As part of the Steering Committee's work, the group evaluated measures regarding the topic areas of mortality, programmatic structure, and antibiotic use. The Steering Committee ultimately recommended 2 measures for full endorsement and 11 for time-limited endorsement.

The draft document, *National Voluntary Consensus Standards for Pediatric Cardiac Surgery: A Consensus Report*, is posted on the NQF website at http://www.qualityforum.org/projects/pediatric-cardiac-surgery.aspx#t=2&s=&p=5%7C along with the following additional information:

- measure submission forms,
- measure evaluation summary table, and
- meeting and call summaries for the Steering Committee.

Pursuant to section II.A of the Consensus Development Process v. 1.8, this draft document, along with the accompanying materials, is being provided to you at this time for purposes of review and comment only—not voting. You may post your comments and view the comments of others on the NQF website.

Public comments must be submitted no later than 6:00 pm ET, August 31, 2010.
NQF Member comments must be submitted no later than 6:00 pm ET, September 7, 2010.

NQF is now using a program that facilitates electronic submission of comments on this draft report. **All comments must be submitted using the online submission process.**

Supporting documents related to your comments may be submitted by e-mail to pediatriccardiacsurgery@qualityforum.org with "*Comment-Pediatric Cardiac Surgery*" in the subject line and your contact information in the body of the e-mail.

Thank you for your interest in NQF's work. We look forward to your review and comments.

NATIONAL QUALITY FORUM

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PEDIATRIC CARDIAC SURGERY

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EXECUTIVE SUMMARY

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

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

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

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

Measures Recommended for Endorsement

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

Measures Recommended for Time-Limited Endorsement

- PCS-001-09: Participation in a national database for pediatric and congenital heart surgery (STS)
- PCS-002-09: Multidisciplinary preoperative planning conference (STS)
- PCS-003-09: Multidisciplinary rounds involving multiple members of the healthcare team (STS)
- PCS-004-09: Regularly scheduled quality assurance and quality improvement cardiac care conference (STS)
- PCS-005-09: Availability of intraoperative transesophageal echocardiography (TEE) (STS)
- PCS-006-09: Availability of institutional pediatric ECLS (extracorporeal life support) (STS)
- PCS-007-09: Surgical volume for pediatric and congenital heart surgery (STS)
- PCS-008-09: Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS Mortality Levels (STS)
- PCS-010-09: Timing of antibiotic administration for pediatric and congenital cardiac surgery (STS)
- PCS-011-09: Selection of antibiotic administration for pediatric and congenital cardiac surgery patients (STS)
- PCS-012-09: Use of an expanded pre-procedural and post-procedural time-out (STS)

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR PEDIATRIC CARDIAC SURGERY

BACKGROUND

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

National efforts to promote accountability and improvement in healthcare through performance measurement and reporting have focused largely on the adult population, but there are growing interest and momentum to include pediatric measures in these efforts. In September 2006 the Centers for Medicare & Medicaid Services issued a compendium containing primarily adult, but some pediatric, quality measures in broad categories to support states' programmatic needs in the areas of quality-based purchasing or pay-for-performance, public reporting, quality improvement, service delivery, benchmarking, and program/plan monitoring. Among the measures in the compendium was a measure of pediatric cardiac surgery mortality developed by the Agency for Healthcare Research and Quality.[8]

In October 2009, the 12-member Pediatric Cardiac Surgery Steering Committee met in person to evaluate 21 measures in the topic areas of mortality, programmatic structure, and antibiotic use and to make recommendations across the spectrum of pediatric cardiac surgery performance measurement. During that meeting, the Committee recommended 20 measures for time-limited endorsement and one for endorsement with the condition that its risk-stratification methodology be harmonized with that of another submitted measure. After the meeting, eight of those measures (seven outcome, one structural) were withdrawn by the developer. The seven outcome measures were submitted without risk adjustment or rationale and analysis supporting no risk adjustment. The developers agreed the measures need risk adjustment and withdrew them from further consideration at this time.

At that time, both developers were also given the opportunity to submit additional information to further support the reliability and validity of their measure submissions. The Steering Committee was subsequently asked to re-evaluate the 13 remaining measures.

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

STRATEGIC DIRECTIONS FOR NQF

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

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

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

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

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

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

NATIONAL PRIORITIES PARTNERSHIP

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

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

NQF'S CONSENSUS DEVELOPMENT PROCESS (CDP)

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

implementation, as well as on recommendations for priority areas for research and measure development.

Evaluating Potential Consensus Standards

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

The measures were evaluated using NQF's standard evaluation criteria.[10] The12-member, multi-stakeholder Committee provided evaluations of the four main criteria: importance to measure and report, scientific acceptability of the measure properties, usability, and feasibility, as well as the recommendation for endorsement. Measure developers responded to Steering Committee questions and clarified any issues or concerns.

RELATIONSHIP TO OTHER NQF-ENDORSED CONSENSUS STANDARDS

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

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

RECOMMENDATIONS FOR ENDORSEMENT

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

Competing Measures

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

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

Candidate Consensus Standards Recommended for Endorsement

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

The initial specifications for this operative mortality measure that were reviewed at the October 2009 Steering Committee meeting included three methods for stratifying or adjusting the population (Aristotle, RACHS-1, and STS-EACTS) allowing the user to select the method that would be used for each use. However, in an effort to standardize this measure and improve comparability, NQF

asked the measure developer to select one method of risk-stratification and resubmit the measure with support of this method. The measure reflected in this report was resubmitted by the developer as a measure of operative mortality within 30 days after surgery or prior to discharge for patients who undergo pediatric and congenital open heart surgery, stratifying for complexity using only the STS-EACTS mortality levels. The use of this measure relies on the STS registry database to calculate the mortality levels and determine complexity levels. The Steering Committee agreed that understanding of comparative mortality following congenital and pediatric cardiac surgery across institutions is immensely important. The Committee also emphasized the importance of capturing post-discharge mortality, especially for distant referrals, which needs to be assured for this measure to work. This measure was ultimately recommended for endorsement by the Committee based on the agreement that this is an important measure for the field.

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

This measure uses the RACHS-1 system of risk analysis to compute an observed-to-expected (O/E) standardized mortality ratio (SMR). A score of >1.0 indicates that the observed mortality is greater than the expected mortality. The risk analysis method (RACHS-1) incorporates five clinical characteristics: six predefined risk categories, age at surgery, prematurity, presence of a major non-cardiac structural anomaly, and combinations of cardiac procedures performed. The data required for this measure can be collected through manual chart abstraction or administrative data (ICD-9-CM codes) to determine the RACHS-1 score. During the initial evaluation of this measure at the October meeting, the Committee voted to recommend this measure for endorsement on the condition that the risk analysis method used in the SMR is harmonized with the three methods used in the initial submission for PCS-018-09. The Committee was reluctant to determine a best-in-class among these three methods (Aristotle, RACHS-1, and STS-EACTS) given that the field has yet to determine which method is best. The Committee expressed concerns about the use of administrative data to calculate this measure and noted references that have demonstrated the shortcomings of the use of administrative data in congenital heart disease. The concerns with administrative data also extended to any potential issues with the conversion from ICD-9-CM to ICD-10-CM/PCS codes; however, the measure developer confirmed that this mapping process has already begun and no major issues are

anticipated. This measure was ultimately recommended for endorsement without conditions following its second review..

Candidate Consensus Standards Recommended for Time-Limited Endorsement

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

Structural Measures

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

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

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

that might be incurred to implement a measure that requires a high level of administrative commitment. This measure was recommended for time-limited endorsement by the Committee.

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

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

PCS-003-09 Multidisciplinary rounds involving multiple members of the healthcare team *Occurrence of multidisciplinary rounds for pediatric and congenital cardiac surgery patients involving multiple members of the healthcare team, with recommended participation including but not limited to cardiology, cardiac surgery, critical care, primary caregiver, family, nurses, pharmacist, and respiratory therapist. Involvement of the family is encouraged.* (STS)

The intent of this measure is to determine whether a program holds multidisciplinary rounds with a multidisciplinary healthcare team. Clear and detailed rounds help with planning of the therapeutic interventions. The literature supporting the importance of this measure shows there is strong evidence that multidisciplinary rounds lead to improved clinical outcomes. As such, there was general consensus among the Committee that this activity is important to measure and report. The Committee agreed this measure is of particular importance in advancing the partnership between families and healthcare providers. In particular, given the nature of children with cardiac-related issues, it is usually their families and/or caregivers who need to be fully engaged in the care plan to ensure effective communication among all entities involved. Despite agreement on the measure's importance, the Committee had similar concerns with this measure's specifications as with the previous measure PCS-002-09. Although the measure specifies that rounds should take place daily, there is no definition or description of a "round" and its components. The Committee agreed that the specifications must be defined such that the requirements are clear to the user as whether they have or have not been met. Related to the measure's feasibility, the Committee agreed this type of activity can be easily tracked through progress notes in the patients' charts. Despite the Committee's concerns with the specifications, they believed the measure is important for the field and voted to recommend this measure for time-limited endorsement.

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

The intent of this measure is to determine whether a facility or pediatric/congenital heart surgery program implements regularly scheduled quality assurance and quality improvement cardiac care conferences. The purpose of the conference is to discuss opportunities for improvement. While there is no direct evidence linking this activity to patient outcomes, there is indirect evidence from other fields that shows that such conferences improve quality. Based on the conditions for recommendation put forth by the Committee in October 2009, the developers changed the specifications to reflect these meetings should occur quarterly. Steering Committee agreed that this measure addresses an important aspect of healthcare, but similar to the two previous measures (PCS-002-09, PCS-003-09), the specifications do not clearly identify the components of a quality assurance and quality improvement care conference and the criteria for selecting the patients to be discussed during the

conference. More precise measure specifications are needed to ensure that the measure is comparable across sites. Despite the Committee's concerns with the specifications, they did vote to recommend it for time-limited endorsement.

PCS-005-09 Availability of intraoperative transesophageal echocardiography (TEE) *Availability of intraoperative transesophageal echocardiography (TEE) for pediatric and congenital heart operations* (STS)

The purpose of this measure is to determine whether a facility or program has a TEE available for use. The Committee agreed that TEE is a well-known and well-documented imaging technique that has been shown to positively affect the outcome of operations for congenital heart disease. However, the accessibility of this tool by facilities and its range of appropriate use are unclear. The Committee's discussion of this measure revolved around the many publications that support the use of TEE. Because this is not a patient-level measure, it will be used to determine the availability of TEE, not necessarily whether it is being used for patients who need it. Some Committee members stated that the measure will be more useful if it calculated a percentage of patients for which TEE is used appropriately, and recommended that a future version should specify the measure in this way. The Committee agreed that this measure would be easy to report. Although not required because this is a structure measure, patient-level data should be available from clinical sources to determine the presence of this tool. While the use of TEE or extracorporeal life support (ECLS) in individual patients can be captured, that does not always imply consistent availability. These concerns were ultimately outweighed by the Committee's belief that this was an important measure for the field, and it was recommended for time-limited endorsement.

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

Similar to the previous measure, PCS-005-09, the intent of this measure is to determine the availability of an ECLS program at a facility. During its discussion, the Steering Committee cited multiple manuscripts that have documented the importance of ECLS, which can rehabilitate hearts, save lives, and in the end serve as a bridge to transplantation. Clear evidence exists that ties improved outcomes to ECLS therapy in cardiac surgery patients with an estimated 50 to 60 percent chance of survival. Some Committee members expressed concern about the overlap of ECLS and

extracorporeal membrane oxygenation (ECMO) programs: Does one program produce better outcomes than the other for cardiac patients? Similar to the concerns of the previous measures, the Committee was pointed out that the specifications of this measure do not clearly delineate the criteria for answering "Yes" and what having a "program" actually means (e.g., having any ECLS capability at all, existing program components). The Committee discussed the issue of capturing the measure data. Data on ECLS use for individual patients can be retrieved by the STS database and EHRs. However, the measure does not require patient-level data because it is a structure measure focused only on the availability of the program. The Committee believed that this was an important measure for the field and voted to recommend it for time-limited endorsement.

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

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

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

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

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

The intent of this measure is to determine whether a facility with a congenital/pediatric heart surgery program implements pre- and post-procedural timeouts for surgical cases. This is an emerging area of research with evidence that shows that "time-outs" are related to improved outcomes. While data are not yet amassed to determine whether this measurement will yield improved outcomes, the Committee's expert opinion was that this activity is important to measure and report, as a time-out is a critical component of knowledge sharing for the healthcare team. This is also supported by the implementation of this activity as policy by most centers around the country. The Steering Committee sought to clarify that this is specified as an "all-or-none" (i.e., all four elements must be in place for the institution to answer "Yes") or not to ensure consistency and usability of the results. While the Committee was in agreement of this measure's importance, some members questioned the feasibility of measuring the presence of time-outs in a program. They argued that such information is not

routinely documented, and it is unclear from the measure specifications if time-outs must occur for every patient. These concerns were outweighed by the measure's importance and the Committee voted to recommend the measure for endorsement.

Process Measures

Both of the submitted process measures are untested and therefore reliability or validity data are not available. Consequently, the evaluation of scientific acceptability is limited to review of the measure specifications. Although evidence was provided to show that the reliability and validity of the current STS database have been verified, the measure developer acknowledged that the measures have not yet been added to the database. Therefore, these measures are only eligible for time-limited endorsement.

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

This measure is intended to determine the rate at which congenital and pediatric heart surgery patients are receiving prophylactic antibiotics within the appropriate time-frame (one hour prior to surgical incision). The Steering Committee agreed that this measure is clinically relevant and has a clear linkage to improved outcomes; there is evidence to support that timely administration of antibiotics prevents infections. There is also evidence that adherence to timing improves outcomes in pediatric cardiac surgery, although on a limited basis. The Committee, did however, express some concerns with the specifications of the measure related to coding and exclusions. For example, knowing the number of patients who are excluded from a measure because of inadequate documentation of such things as incision and/or antibiotic start times is itself important and should be captured in some way rather than excluding the case from the measure. There was also concern that the codes, particularly for congenital surgery, were too inclusive and could inadvertently count patients with acquired heart disease requiring surgery rather than strictly counting congenital heart surgeries.

A significant amount of Committee discussion of this measure, at both the October 2009 meeting and subsequent discussions, centered on this measure as it relates to the following measure (PCS-011-09,

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

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

This measure is intended to measure both the selection of the appropriate prophylactic antibiotic as well as the appropriate weight-based dose administration. The Steering Committee agreed that this is a relevant measure with high impact as surgical site infection in cardiac patients is a major complication. The Committee was concerned, however, that the list of the appropriate antibiotics specified in this measure may be subject to debate. There are many acceptable antibiotics that can be used, and they change often. The variations in the type of antibiotics used nationwide may make this a difficult measure to meet requirements. The Committee acknowledged that experience with measures in other fields indicates that options for quickly changing the approved drug list in the specifications must be in place. Other Committee members were concerned that body weight is not the only factor that determines the appropriate dosages of antibiotics in high-risk patients. Clinicians also take into account renal/liver dysfunction and anticipated drug clearance, and these are not accounted for in the measure. The measure also does not clearly identify who is responsible for selecting the dose. In terms of feasibility, the Committee agreed that the required information can be feasibly obtained from electronic medical records. The Steering Committee ultimately recommended time-limited endorsement of the measure individually.

Candidate Consensus Standards Withdrawn from Consideration

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

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

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NATIONAL QUALITY FORUM

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

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

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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
PCS-001-09*	Participation in a national database for pediatric and congenital heart surgery	Participation in at least one multi-center, standardized data collection, and feedback program that provides benchmarking of the physician's data relative to national and regional programs and uses process and outcome measures.	STS	Whether or not there is participation in at least one multi-center, data collection, and feedback program for pediatric and congenital heart surgery.	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".″	Electronic Health/Medical Record, Electronic Clinical Database, Name: The Society of Thoracic Surgeons Congenital Heart Surgery Database, Electronic Clinical Registry, Electronic Claims, Paper Medical Records	Group of clinicians, Facility, Integrated delivery system, Health plan, Community/Population
PCS-002-09*	Multidisciplinary preoperative	Occurrence of a pre-operative	STS	Whether or not there is a pre-	N/A	Any operation that is not a pediatric or congenital cardiac	Electronic Health/Medical Record,, Electronic Claims, Paper Medical Record, Other:	Group of clinicians, Facility,

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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		involving multiple members of the healthcare team, with recommended participation including but not limited to cardiology, cardiac surgery, critical care, primary caregiver, family, nurses, pharmacist and respiratory therapist. Involvement of the family is encouraged.		critical care professionals for pediatric and congenital cardiac surgery patients.				
PCS-004-09*	Regularly scheduled quality assurance and quality improvement cardiac care conference	Occurrence of a regularly scheduled quality assurance and quality improvement cardiac care conference to discuss	STS	Whether or not the facility holds a regularly scheduled quality assurance and quality improvement cardiac care	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".″ (CPB is cardiopulmonary bypass.))	Electronic Health/Medical Record, Electronic Claims, Paper Medical Record, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection & analysis	Group of clinicians, Facility, Integrated delivery system, Health plan, Community/Population

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		care provided to patients who undergo pediatric and congenital cardiac surgery operations and to discuss opportunities for improvement. This conference should be held at least every three months (quarterly).		conference to discuss care provided to patients who undergo pediatric and congenital cardiac surgery operations and to discuss opportunities for improvement. This conference should be held at least every three months (quarterly).				
PCS-005-09*	Availability of intraoperative transesophageal echocardiography (TEE)	Availability of intraoperative transesophageal echocardiography (TEE) for pediatric and congenital heart operations.	STS	Whether or not intraoperative transesophageal echocardiography (TEE) is available for pediatric and congenital cardiac surgery operations.	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".″ (CPB is cardiopulmonary bypass.).	Electronic Health/Medical Record, Electronic Claims, Paper Medical Record, Hospital Records, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection & analysis	Group of clinicians, Facility, Integrated delivery system, Health plan, Community/Population
PCS-006-09*	Availability of	Availability of an	STS	Whether or not the	N/A	Any operation that is not a pediatric or	Electronic Health/Medical Record, Electronic Claims,	Facility, Integrated

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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		complexity stratification tool.		the five STS-EACTS mortality levels, a multi-institutional validated complexity stratification tool.				
PCS-010-09*	Timing of antibiotic administration for pediatric and congenital cardiac surgery patients	Percentage of patients undergoing pediatric and congenital cardiac surgery who received prophylactic antibiotics within one hour of surgical incision (two hours if receiving Vancomycin).)	STS	Number of pediatric and congenital cardiac surgery patients who received prophylactic antibiotics within one hour of surgical incision (two hours if Vancomycin). In the event that surgery is delayed, as long as the patient is re-dosed (if clinically appropriate) the patient should be included in the	All patients undergoing pediatric and congenital cardiac surgery operations.	Patients who: • had principal or admission diagnosis of preoperative infectious disease • were receiving antibiotics at time of admission • have medical records that do not include antibiotic start date/time or incision date/time • were receiving antibiotics more than 24 hours prior to surgery • have physician documentation of infection prior to surgical procedure. Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined	Electronic Health/Medical Record, Electronic Claims, Paper Medical Record, Electronic Pharmacy Data, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection & analysis	Individual clinician, Group of clinicians, Facility, Integrated facility, integrated delivery system, Health plan

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
				numerator.		as operations that are of operation types of "CPB" or "No CPB cardiovascular".″ (CPB is cardiopulmonary bypass.))		
PCS-011-09*	Selection of antibiotic administration for pediatric and congenital cardiac surgery patients	Percentage of patients undergoing pediatric and congenital cardiac surgery who received body weight appropriate prophylactic antibiotics recommended for the operation.	STS	Number of pediatric and congenital cardiac surgery patients who received body weight appropriate prophylactic antibiotics recommended for the operation.	Number of pediatric and congenital cardiac surgery operations.	Patients who: • had principal or admission diagnosis of preoperative infectious disease • were receiving antibiotics at time of admission • have medical records that do not include antibiotic start date/time or incision date/time • were receiving antibiotics more than 24 hours prior to surgery • have physician documentation of infection prior to surgical procedure. Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".″ (CPB is cardiopulmonary	Electronic Health/Medical Record, Electronic Claims, Paper Medical Record, Electronic Pharmacy Data, Paper Medical Records, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection & analysis	Individual clinician, Group of clinicians, facility,

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
						bypass.))		
PCS-012-09*	Use of an expanded pre-procedural and post-procedural "time-out"	Use of an expanded pre-procedural and post-procedural "time-out" that includes the following elements: 1. The conventional pre-procedural "time-out", which includes identification of patient, operative site, procedure and history of any allergies. 2. A pre-procedural briefing wherein the surgeon shares with all members of the operating room team the essential elements of the operative	STS	Whether or not the facility implements an expanded pre-procedural and post-procedural "time-out" for all patients undergoing pediatric and congenital heart surgery operations. Pre-procedural and post-procedural time-out includes the following elements: 1. The conventional pre-procedural "time-out", which includes identification of patient, operative site, procedure and history	N/A	Any operation that is not a pediatric or congenital cardiac operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB cardiovascular".″ (CPB is cardiopulmonary bypass.)	Electronic Health/Medical Record, Clinical Database, Electronic Claims, Paper Medical Record, Electronic Pharmacy Data, Other: Upon receiving NQF endorsement will be added to the STS congenital heart surgery database for collection & analysis	Individual clinicians, Group of clinicians, Facility

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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		improvement. This debriefing should take place prior to the patient leaving the operating room or its equivalent, and may be followed by a more in-depth dialogue involving team members at a later time. (The actual debriefing in the operating room is intentionally and importantly brief,; in recognition of the fact that periods of transition may be times of instability or vulnerability for the patient). 4. A briefing		all members of the operating room team the essential elements of the operative plan, identifying both the successful components and the opportunities for improvement. This debriefing should take place prior to the patient leaving the operating room or its equivalent, and may be followed by a more in-depth dialogue involving team members at a later time. (The actual debriefing in the operating room is				

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

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

Measure Number	Measure Title	Measure Description	Measure Steward	Numerator	Denominator	Exclusions	Data Source	Level of Analysis
		using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method.					Congenital Heart Surgery Database)*; from hospital-specific electronic medical records; or from paper medical records. * The STS database does not currently include all variables, but there are plans to add them.	

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APPENDIX B: PEDIATRIC CARDIAC SURGERY STEERING COMMITTEE AND NQF STAFF

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APPENDIX C: COMPETING MEASURES

	Measure Review # PCS-018-09	Measure Review # PCS-021-09	Measure ID # 0339
Title	Operative Mortality Stratified by the Five STS-EACTS Mortality Levels	Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1).	Pediatric heart surgery mortalityHeart Surgery Mortality (PDI 6) (risk adjusted)
Status	Under Review 9/18/2009	Under Review 9/18/2009	Endorsed 5/15/2008
Steward	Society of Thoracic Surgeons	Children's Hospital Boston	Agency for Healthcare Research and Quality
Description	Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Ratio of observed to expected rate of in-hospital mortality following surgical repair of congenital heart defect among patients <18 years of age, risk-adjusted using the Risk Adjustment for Congenital Heart Surgery (RACHS-1) method.	Number of in-hospital deaths in patients undergoing surgery for congenital heart disease per 1,0001000 patients.
Numerator	Number of patients who undergo pediatric and congenital open heart surgery and die during either of the following two time intervals: 1. Prior to hospital discharge 2. Within 30 days of the date of surgery.	Cases of congenital heart surgery among patients <18 years of age resulting in in-hospital death.	Number of deaths, age under 18 years, with a code of pediatric heart surgery in any procedure field with an *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) code of congenital heart disease in any field.
Denominator	Number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool	Total cases of congenital heart surgery among patients <18 years of age.	All discharges age under 18 years with ICD-9-CM procedure codes for congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD--9-CM diagnosis of congenital heart disease (2D) in any field.
Exclusions	Any operation that is not a pediatric or congenital cardiac operation.Cardiac Operation. Cardiac operations are defined as operations that are of operation types of “CPB” or “No CPB Cardiovascular”.” (CPB is cardiopulmonary bypass.) [1] Any operation that is a pediatric or congenital open heart surgery (operation types of “CPB” or “"No CPB Cardiovascular”)") that cannot be classified into a level of complexity by the five STS-EACTS Mortality Levels.	Patients ≥18 years of age, those undergoing heart transplantation, neonates or premature infants with patent ductus arteriosus repair as the only cardiac surgical procedure, transcatheter interventions, surgical cases unable to be assigned to a RACHS-1 risk category.	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass; heart transplant; premature infants with PDA closure as only cardiac procedure; age less than 30 days with PDA closure as only cardiac procedure; missing discharge disposition; transferring to another short-term hospital and newborns less than 500 grams.
Methods & Risk-Adjustment	N/A	RACHS-1 risk categories, age at surgery, prematurity, presence of major non-cardiac structural anomaly, combinations of cardiac procedures performed.	The predicted value for each case is computed using a hierarchical model (logistic regression with hospital random effect) and covariates for gender, birthweight (500g groups), age in days (29-60, 61-90, 91+), age in years (in 5-year age groups), modified CMS DRG and AHRQ CCS co-morbidities. The reference population used

	Measure Review # PCS-018-09	Measure Review # PCS-021-09	Measure ID # 0339
			in the regression is the universe of discharges for states that participate in the HCUP State Inpatient Data (SID) for the years 2002-2004 (combined), a database consisting of 37 states and approximately 20 million pediatric discharges. The expected rate is computed as the sum of the predicted value for each case divided by the number of cases for the unit of analysis of interest (i.e., hospital, state, and region). The risk-adjusted rate is computed using indirect standardization as the observed rate divided by the expected rate, multiplied by the reference population rate.
Numerator Details	N/A	Number of cases of congenital heart surgery among patients <18 years of age able to be placed into a RACHS-1 risk category (see item 8 below) where patient disposition is death prior to hospital discharge.	N/A
Denominator Details	As demonstrated in the following publication (STS Attachment 1 (of 2)—O'Brien) - O'Brien et al.,, JTCVS, Nov 2009), the five STS-EACTS Mortality Levels constitute an objective and empirically based tool for complexity stratification. In addition, it represents an improvement over existing consensus-based tools. Definition: The number of patients who undergo pediatric and congenital cardiac operation—Cardiac Operation Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1] Definition: The number of index cardiac operations in each level of complexity stratification using the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Pediatric cases <18 years of age undergoing surgical repair of a congenital heart defect and able to be placed into a RACHS-1 risk category (see item 8 below).	N/A

	Measure Review # PCS-018-09	Measure Review # PCS-021-09	Measure ID # 0339
	The following are STS procedure codes for pediatric and congenital cardiac operations per the STS Congenital Heart Surgery Database Version 3.0 Data Specifications. Analysis should include any index operation performed with any of the following component procedures on a patient with pediatric and/or congenital cardiac disease: 10, 20, 30, 40, 2110, 50, 60, 70, 80, 85, 100, 110, 120, 130, 140, 150, 170, 180, 190, 2300, 2250, 2230, 210, 220, 230, 240, 2290, 250, 2220, 260, 270, 2120, 280, 2200, 290, 300, 310, 330, 340, 350, 360, 370, 380, 390, 400, 420, 430, 440, 450, 460, 2280, 465, 470, 480, 490, 500, 510, 520, 530, 540, 550, 570, 590, 2270, 600, 630, 640, 650, 610, 620, 1774, 1772, 580, 660, 2240, 2310, 2320, 670, 680, 690, 700, 715, 720, 730, 735, 740, 750, 760, 770, 780, 2100, 790, 800, 810, 820, 830, 2260, 840, 850, 860, 870, 880, 2160, 2170, 2180, 2140, 2150, 890, 900, 910, 920, 930, 940, 950, 960, 970, 980, 1000, 1010, 1025, 1030, 2340, 1035, 1050, 1060, 1070, 1080, 1090, 1110, 1120, 1123, 1125, 1130, 1140, 1145, 1150, 1160, 2190, 2210, 1180, 1200, 1210, 1220, 1230, 1240, 1250, 1260, 1275, 1280, 1285, 1290, 1291, 1300, 1310, 1320, 1330, 1340, 1360, 1365, 1370, 1380, 1390, 1410, 1450, 1460, 2350, 1470, 1480, 1490, 1500, 1590, 1600, 1610, 1630, 2095, 1640, 1650, 1660, 1670, 1680, 1690, 1700, 2330, 2130, 1720, 1730, 1740, 1760, 1780, 1790, 1802, 1804, 1830, 1860 Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease.		

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	Measure Review # PCS-018-09	Measure Review # PCS-021-09	Measure ID # 0339
	Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease.		
Exclusion Details	N/A	Neonates are defined as patients ≤<=30 days of age at surgery; premature infants are defined as <37 weeks gestation. See item 8 below for RACHS-1 risk categories.	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium);); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass; heart transplant; premature infants with PDA closure as only cardiac procedure; age less than 30 days with PDA closure as only cardiac procedure; missing discharge disposition; transferring to another short-term hospital and newborns less than 500 grams.
Data Source	Paper Medical Record, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Clinical Database, Electronic Health/Medical Record, Other	Electronic Claims
Level	Community/Population, Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home)	Can be measured at all levels	Facility (e.g., hospital, nursing home)
Setting	Hospital	Hospital	Hospital

	Measure Review # PCS-007-09	Measure Review # PCS-008-09	Measure ID # 0340
Title	Surgical volumeVolume for pediatricPediatric and congenital heart surgeryCongenital Heart Surgery	Surgical volumeVolume for pediatricPediatric and congenital heart surgery, stratifiedCongenital Heart Surgery, Stratified by the fiveFive STS-EACTS Mortality Levels	Pediatric heart surgery volumeHeart Surgery Volume (PDI 7)
Status	Under Review 9/18/2009	Under Review 9/21/2009	Endorsed 5/15/2008
Steward	Society of Thoracic Surgeons	Society of Thoracic Surgeons	Agency for Healthcare Research and Quality
Description	Surgical volumeVolume for pediatricPediatric and congenital heart surgery.Congenital Heart Surgery	Surgical volume for pediatric and congenital heart surgery stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool.	Raw volume compared to annual thresholds (100 procedures).)
Numerator	Number of pediatric and congenital heart	Number of pediatric and congenital cardiac surgery	Discharges, age under 18 years, with an *International Classification*

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	surgery operations.	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.	*of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) code for either congenital heart disease (1P) in any field or non-specific heart surgery (2P) in any field with ICD-9-CM diagnosis of congenital heart disease (2D) in any field.
Denominator	N/A	N/A	N/A
Exclusions	Measure Exclusions: Any operation that is not a pediatric or congenital cardiac pperation.Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular". (CPB is cardiopulmonary bypass.) [1]	Any operation that is not a pediatric or congenital cardiac operation.Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular"." (CPB is cardiopulmonary bypass.) [1] 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.	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium);); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass.
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,	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) - O'Brien et al.,, JTCVS, Nov 2009), the five STS-EACTS Mortality	N/A

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

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		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 Pediatric heart surgery is heart surgery on patients <18 years of age to treat congenital or acquired cardiac disease. Congenital heart surgery is heart surgery on patients of any age to treat congenital cardiac disease. Our measures apply to both pediatric heart surgery and congenital heart surgery, thus applying to the following operations: 1. heart surgery on patients less than 18 years of age to treat congenital or acquired cardiac disease 2. heart surgery on patients of any age to treat congenital cardiac disease.	
Denominator Details	N/A	N/A	N/A
Exclusion Details	N/A	N/A	Exclude patients with MDC 14 (Pregnancy, Childbirth, Puerperium);); patients with transcatheter interventions as single cardiac procedures, performed without bypass but with catheterization; patients with septal defects as single cardiac procedures without bypass.
Data Source	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Paper Medical Record, Electronic Claims, Electronic Clinical Registry, Electronic Clinical Database, Electronic Health/Medical Record	Electronic Claims
Level	Community/Population, Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home), Integrated delivery system	Health Plan, Group of clinicians (facility, dept/unit, group), Facility (e.g., hospital, nursing home), Integrated delivery system	Facility (e.g., hospital, nursing home)

NATIONAL QUALITY FORUM

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Setting	Hospital	Hospital	Hospital