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 .

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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 .

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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 impatient 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.	Thank you for your comment.

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4	Dr. Ellen Schwalenstocker, PhD, MBA	National Association of Children's Hospitals and Related Institutions	Comments on the general draft report	(continued) 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). 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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

Comment Submitter		Comment Submitter Organization	Comment Type/Measure Name	Comment	Final Response
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.

Comment Submitter		Comment Submitter Organization	Comment Type/Measure Name	Comment	Final Response
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.

Comment Submitter		Comment Submitter Organization	Comment Type/Measure Name	Comment	Final Response
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:

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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	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.

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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.

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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.