NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

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

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

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

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

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

(for NQF staff use) **NQF Review #:** OT3-029-10 **NQF Project:** Patient Outcomes Measures: Child Health and Mental Health (Phase III)
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Standardized adverse event ratio for children and adults undergoing cardiac catheterization for congenital heart disease
De.2 **Brief description of measure***:* Ratio of observed to expected clinically important preventable and possibly preventable adverse events, risk-adjusted
1.1-2 **Type of Measure:** Outcome De.3 **If included in a composite or paired with another measure, please identify composite or paired measure**
De.4 **National Priority Partners Priority Area:** Safety De.5 **IOM Quality Domain**: Safety De.6 **Consumer Care Need:**

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Agreement will be signed and submitted prior to or at the time of measure submission A.4 **Measure Steward Agreement attached:** NQF Measure Stewards-634006372321361164.pdf	**A** **Y** ☐ **N** ☐

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	**B** Y☐ N☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement	**C** Y☐ N☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** No, testing will be completed within 24 months D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** Y☐ N☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** Y☐ N☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:**	
Staff Reviewer Name(s):	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Leading cause of morbidity/mortality 1a.2 1a.3 **Summary of Evidence of High Impact:** Congenital heart disease is a common birth defect, affecting 1 of 100 infants, which engenders major risk of morbidity and mortality. In the past decade, cardiac catheterization for congenital heart disease has evolved from a primarily diagnostic procedure to an interventional procedure with therapeutic goals, complementing surgical strategies and at times eliminating the need for surgery. 1a.4 **Citations for Evidence of High Impact:** Keane J, Lock J, Fyler D. Nadas' pediatric cardiology. Philadelphia, PA: Elsevier; 2006. Schneider DJ, Levi DS, Serwacki MJ, Moore SD, Moore JW. Overview of interventional pediatric cardiology in 2004. Minerva Pediatr. 2004; 56:1-28. Freedom RM, Lock J, Bricker JT. Pediatric cardiology and cardiovascular surgery: 1950-2000. Circulation. 2000; 102:IV58-68. Shim D, Lloyd TR, Crowley DC, Beekman RH, 3rd. Neonatal cardiac catheterization: a 10-year transition from diagnosis to therapy. Pediatr Cardiol. 1999; 20:131-133.	**1a** C☐ P☐ M☐ N☐
1b. Opportunity for Improvement	**1b** C☐

1b.1 Benefits (improvements in quality) envisioned by use of this measure: In cardiac catheterization for congenital heart disease, reported adverse event rates vary widely and lack uniformity in outcome definitions. Standardized reporting including a method to adjust for case mix complexity will allow meaningful comparisons of performance among institutions and physicians.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Adverse event rates associated with cardiac catheterization for congenital heart disease vary widely across institutions and physicians.

1b.3 Citations for data on performance gap:
Bergersen L, Gauvreau K, Lock JE, Jenkins KJ. A risk-adjusted method for comparing adverse outcomes among practitioners in pediatric and congenital cardiac catheterization. Congenital Heart Disease 2008; 3:230-240.
Bergersen L, Marshall A, Gauvreau K, Beekman R, Hirsch R, Foerster S, Balzer D, Vincent J, Hellenbrand W, Holzer R, Cheatham J, Moore J, Lock J, Jenkins K. Adverse event rates in congenital cardiac catheterization – a multi-center experience. Catheter Cardiovasc Interv. 2009 Sep 24. [Epub ahead of print].
Agnoletti G, Bonnet C, Boudjemline Y, Bihan CL, Bonnet D, Sidi D, Bonhoeffer P. Complications of paediatric interventional catheterization: an analysis of risk factors. Cardiology in the Young 2005; 15:402-408.
Rhodes JF, Asnes JD, Blaufox AD, Sommer RJ. Impact of low body weight on frequency of pediatric cardiac catheterization complications. American Journal of Cardiology 2000; 86:1275-1278, A9.
Tavli V, Kayhan B, Okur FF, Kirman M, Tekdogan M. Complications of pediatric cardiac catheterization: 18-month study. Turkish Journal of Pediatrics 2000; 42:294-297.
Zeevi B, Berant M, Fogelman R, Galit B, Blieden L. Acute complications in the current era of therapeutic cardiac catheterization for congenital heart disease. Cardiology in the Young 1999; 9:266-272.
Vitiello R, McCrindle BW, Nykanen D, Freedom RM, Benson LN. Complications associated with pediatric cardiac catheterization. Journal of the American College of Cardiology 1998; 32:1433-40.
Love BA, Rosenberg HC, Nykannen D, Li MD. The safety of pediatric cardiac catheterization in an adult hospital setting. Canadian Journal of Cardiology 1992; 8:347-350.
Cassidy SC, Schmidt KG, Van Hare GF, Stanger P, Teitel DF. Complications of pediatric cardiac catheterization: a 3-year study. Journal of the American College of Cardiology 1992; 19:1285-1293.
Fellows KE, Radtke W, Keane JF, Lock JE. Acute complications of catheter therapy for congenital heart disease. American Journal of Cardiology 1987; 60:679-683.
Cohn HE, Freed MD, Hellenbrand WF, Fyler DC. Complications and mortality associated with cardiac catheterization in infants under one year: a prospective study. Pediatric Cardiology 1985; 6:123-131.
Kennedy JW. Complications associated with cardiac catheterization and angiography. Catheter Cardiovascular Diagnosis. 1982; 8:5-11.

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

1b.5 Citations for data on Disparities:
N/A

P☐ M☐ N☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Congenital heart disease is a common birth defect, affecting 1 of 100 infants, which engenders major risk of morbidity and mortality. In the past decade, cardiac catheterization for congenital heart disease has evolved from a primarily diagnostic procedure to an interventional procedure with therapeutic goals, complementing surgical strategies and at times eliminating the need for surgery. Currently, there is increasing interest in the evaluation of health care delivery systems and the identification and implementation of quality improvement strategies. Similarly, there is an expanding quest for knowledge relevant to the comparison of institutional and practitioner outcomes. In cardiac catheterization for congenital heart disease, however, reported adverse event rates vary widely and lack uniformity in outcome definitions. Standardized reporting including a method to adjust for case mix complexity will allow meaningful

1c
C☐ P☐ M☐ N☐

comparisons of performance among institutions and physicians. **1c.2-3. Type of Evidence:** Other N/A **1c.4 Summary of Evidence** (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:** N/A **1c.5 Rating of strength/quality of evidence (***also provide narrative description of the rating and by whom***):** N/A **1c.6 Method for rating evidence:** N/A **1c.7 Summary of Controversy/Contradictory Evidence:** N/A **1c.8 Citations for Evidence (***other than guidelines***):** N/A **1c.9 Quote the Specific guideline recommendation (***including guideline number and/or page number***):** N/A **1c.10 Clinical Practice Guideline Citation:** N/A **1c.11 National Guideline Clearinghouse or other URL:** N/A **1c.12 Rating of strength of recommendation (***also provide narrative description of the rating and by whom***):** N/A **1c.13 Method for rating strength of recommendation** (*If different from* USPSTF system*, also describe rating and how it relates to USPSTF)***:** N/A **1c.14 Rationale for using this guideline over others:** N/A	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, **met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome***):** Diagnostic and interventional cardiac catheterization cases performed in a pediatric cardiac catheterization lab resulting in a clinically important preventable or possibly preventable adverse event. **2a.2 Numerator Time Window (***The time period in which cases are eligible for inclusion in the*	**2a-specs** **C☐** **P☐** **M☐** **N☐**

numerator)**:**
Not pre-specified, but a minimum of one year is recommended

2a.3 Numerator Details (*All information required to collect/calculate the numerator, including all codes, logic, and definitions***):**
Clinically important events are defined as follows: Moderate adverse event (transient change in condition may be life-threatening if not treated, condition returns to baseline, required monitoring, required intervention such as reversal agent, additional medication, transfer to the intensive care unit for monitoring, or moderate transcatheter intervention to correct condition); major adverse event (change in condition, life-threatening if not treated, change in condition may be permanent, may have required an intensive care unit admission or emergent re-admit to hospital, may have required invasive monitoring, required interventions such as electrical cardioversion or unanticipated intubation or required major invasive procedures or transcatheter interventions to correct condition); or catastrophic adverse event (any death or emergent surgery or heart lung bypass support to prevent death with failure to wean from bypass support).

Preventable or possibly preventable events are defined as follows: Events in which a definite breach of standard technique was identified, necessary precautions were not taken, event was preventable by modification of technique or care; or events in which a definite breach of standard technique was not identified but may have occurred, necessary precautions may not have been taken, the event may have been preventable by modification of technique or care.

Types of cardiac catheterization procedures eligible for this measure are listed below:
Any diagnostic catheterization within 72 hours of surgery
Any interventional catheterization within 72 hours of surgery
Atrial septostomy / BAS
Atrial septostomy / dilation and stent
Atrial septostomy / static balloon dilation
Balloon angioplasty / aorta
Balloon angioplasty / lobar segment LPA RPA
Balloon angioplasty / native RVOT
Balloon angioplasty / proximal LPA or RPA
Balloon angioplasty / RV to PA conduit
Balloon angioplasty / RVOT s/p surgery (no conduit)
Balloon angioplasty / systemic artery (not aorta)
Balloon angioplasty / systemic shunt
Balloon angioplasty / systemic vein
Balloon angioplasty or stent / pulmonary vein(s)
Coil / coronary fistula
Coil occlusion / device / systemic arterial collaterals
Coil occlusion / LSVC
Coil occlusion / PDA
Coil occlusion / systemic shunt
Coil occlusion / veno-veno collaterals
Device closure / ASD
Device closure / baffle leak
Device closure / fenestration
Device closure / PDA
Device closure / perivalvar leak
Device closure / PFO
Device closure / venous collateral
Device closure / VSD
Diagnostic catheterization with EPS
Hemodynamic catheterization
Interventional techniques / atherectomy catheter
Interventional techniques / atretic valve perforation
Interventional techniques/ recanulization of jailed vessel in stent
Interventional techniques / recanulization of occluded peripheral vessels

Interventional techniques / snare foreign body
Interventional techniques / trans-septal puncture
Invasive procedure / central line placement
Invasive procedure / elective chest tube pericardiocentesis
Invasive procedure / pericardiocentesis
Other intended hemodynamic alteration / oxygen-nitric trial or ionotropes
Other procedures: bronchoscopy, drains, echo, TEE
RV biopsy diagnostic
RV biopsy elective post transplant
Stent placement / aorta
Stent placement / intracardiac / atria
Stent placement / intracardiac / ventricular
Stent placement / lobar segment LPA or RPA
Stent placement / native RVOT
Stent placement / proximal LPA or RPA
Stent placement / RV to PA conduit
Stent placement / RVOT s/p surgery (no conduit)
Stent placement / systemic artery (not aorta)
Stent placement / systemic shunt
Stent placement / systemic vein
Stent redilation / aorta
Stent redilation / intracardiac / atria
Stent redilation / intracardiac / ventricular
Stent redilation / lobar segment LPA or RPA
Stent redilation / proximal LPA or RPA
Stent redilation / pulmonary vein
Stent redilation / RV to PA conduit
Stent redilation / systemic artery not aorta
Stent redilation / systemic vein
Ultrasound / IVUS
Valvuloplasty / aorta
Valvuloplasty / mitral
Valvuloplasty / pulmonary
Valvuloplasty / tricuspid

ASD = atrial septal defect, BAS = balloon atrial septostomy, EPS = electrophysiology study, IVUS = intravascular ultrasound, LPA = left pulmonary artery, LSVC = left superior vena cava, PA = pulmonary artery, PDA = patent ductus arteriosus, PFO = patent foramen ovale, RPA = right pulmonary artery, RV = right ventricle, RVOT = right ventricular outflow tract, TEE = transesophageal echocardiogram, VSD = ventricular septal defect.

2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured***):**
Diagnostic and interventional cardiac catheterization procedures performed in a pediatric cardiac catheterization lab.

2a.5 Target population gender: Female, Male
2a.6 Target population age range: All ages, but the majority of cases will be < 18 years of age

2a.7 Denominator Time Window (*The time period in which cases are eligible for inclusion in the denominator***):**
Not pre-specified, but a minimum of one year is recommended.

2a.8 Denominator Details (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions***):**
Types of cardiac catheterization procedures eligible for this measure are listed in Item 2a.3.

2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population***):** Primary electrophysiology cases, ablation cases, pericardiocentesis only, thoracentesis only.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
Primary electrophysiology cases, ablation cases, pericardiocentesis only, thoracentesis only.

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

2a.12-13 Risk Adjustment Type: Case-mix adjustment

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
Variables are procedure type risk group and indicator of hemodynamic vulnerability. Details are provided in attachment Item 2a.15.

2a.15-17 Detailed risk model available Web page URL or attachment: Attachment Item 2a.15 Risk Adjustment-634007193146101876.doc

2a.18-19 Type of Score: Ratio
2a.20 Interpretation of Score:
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
The measure is a standardized adverse event ratio for children and adults undergoing cardiac catheterization for congenital heart disease.

It is defined as the ratio of observed to expected rates of clinically important preventable and possibly preventable adverse events (AE) occurring during or following cardiac catheterization for congenital heart disease. This technique allows computation of an overall risk-adjusted measure of performance for groups of patients.

To begin, the observed AE rate is calculated for each group. This is defined as the number of diagnostic and interventional cardiac catheterization cases performed in a pediatric cardiac catheterization lab resulting in a clinically important preventable or possibly preventable adverse event divided by the total number of hemodynamic and interventional cardiac catheterization cases performed in a pediatric cardiac catheterization lab.

Next, the expected AE rate is calculated for each group. To do this, a multivariable logistic regression model with outcome any clinically important preventable or possibly preventable AE is fitted. Two clinical characteristics are incorporated as covariates: procedure type risk groups 2 and 3 as binary covariates, with group 1 as the reference category; and presence of any indicator of hemodynamic vulnerability. This logistic model is used to calculate the predicted probability of an AE for each individual case in the data set. The average predicted probability of AE for all cases, calculated by summing the predicted probabilities for each case and dividing by the total number of cases, represents the expected AE rate for the group, adjusting for case mix.

The standardized adverse event ratio (SAER) is then calculated as the observed AE rate divided by the expected AE rate.

If the observed AE rate for a group is higher than expected, meaning that the group performs worse than would be expected given its case mix, the SAER is greater than 1. If the observed AE rate for a group is lower than would be expected, indicating better than anticipated performance, the SAER is less than 1.

Reference:
Bergersen L, Gauvreau K, Lock JE, Jenkins KJ. A risk-adjusted method for comparing adverse outcomes among practitioners in pediatric and congenital cardiac catheterization. Congenital Heart Disease 2008; 3:230-240.

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

In addition to standardized adverse event ratios, 95% confidence intervals are calculated. If the entire confidence interval lies above 1.0, the observed AE rate is higher than expected and performance is worse than the average performance of the reference group. If the entire confidence interval lies below 1.0, the observed AE rate is lower than expected and performance is better than the average performance of the reference group.	
2a.23 **Sampling (Survey) Methodology** *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*: Not pre-specified, although it is recommended that the sample size be large enough such that there is at least one clinically important preventable or possibly preventable adverse event in each procedure type risk group.	
2a.24 **Data Source (***Check the source(s) for which the measure is specified and tested)* Paper medical record/flow-sheet, Electronic clinical data, Registry data 2a.25 **Data source/data collection instrument (***Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):** Multi-center registry for congenital cardiac catheterization procedures. 2a.26-28 **Data source/data collection instrument reference web page URL or attachment:** Attachment Adverse Event Rates in Congenital Cardiac Catheterization - A Multi-Center Experience 2009.pdf 2a.29-31 **Data dictionary/code table web page URL or attachment:** Attachment Item 2a.29 Data Dictionary.doc 2a.32-35 **Level of Measurement/Analysis** (*Check the level(s) for which the measure is specified and tested)* Facility/Agency 2a.36-37 **Care Settings (***Check the setting(s) for which the measure is specified and tested)* Hospital 2a.38-41 **Clinical Services** (*Healthcare services being measured, check all that apply*) Clinicians: Physicians (MD/DO)	
TESTING/ANALYSIS	
2b. Reliability testing 2b.1 **Data/sample** *(description of data/sample and size)***:** Formal testing of reliability/repeatability has not yet been performed. 2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)***:** N/A 2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)***:** N/A	**2b** **C**☐ **P**☐ **M**☐ **N**☐
2c. Validity testing 2c.1 **Data/sample** *(description of data/sample and size)***:** Preliminary Validation of Risk Adjustment Model (additional validation has not yet been performed) (1) Single institutional database (Children's Hospital Boston); 1727 cases performed by 7 practitioners over the 18-month period January 2004 through June 2005. (2) Multi-institutional database collected by the Congenital Cardiac Catheterization Outcomes Project (C3PO); 6737 cases from 6 institutions over the 23-month period February 2007 through December 2008. 2c.2 **Analytic Method** *(type of validity & rationale, method for testing)***:** Discrimination of the risk adjustment method has been quantified using the area under the receiver-	**2c** **C**☐ **P**☐ **M**☐ **N**☐

operator characteristic (ROC) curve (c statistic); calibration was assessed using the Hosmer-Lemeshow test.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
(1) Area under the ROC curve 0.741; p value for Hosmer-Lemeshow test 0.53.
(2) Area under the ROC curve 0.676; p value for Hosmer-Lemeshow test 0.70.

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
Formal testing of measure exclusions has not been performed. See Analytic Method below (2d.4).

2d.2 **Citations for Evidence:**
Bergersen L, Gauvreau K, Lock JE, Jenkins KJ. A risk-adjusted method for comparing adverse outcomes among practitioners in pediatric and congenital cardiac catheterization. Congenital Heart Disease 2008; 3:230-240.

2d.3 **Data/sample** *(description of data/sample and size)*: N/A

2d.4 **Analytic Method** *(type analysis & rationale)*:
The risk adjustment method applied – and in particular the procedure type risk groups and procedure exclusions – was developed with the clinical expertise of a panel of interventional cardiologists from 6 pediatric institutions. Measure exclusions were approved by panel members.

2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
N/A

2d
C☐ P☐ M☐ N☐ NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: N/A

2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
Formal testing of the need for risk adjustment has not been performed.
The risk adjustment procedure used was described in Items 2a.12 through 2a.15. The risk adjustment method applied was developed with the clinical expertise of a panel of interventional cardiologists from 6 pediatric institutions. Each of 11 participating cardiologists approved the final procedure type risk groups.

2e.3 **Testing Results** *(risk model performance metrics)*:
N/A

2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** N/A

2e
C☐ P☐ M☐ N☐ NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: Single institutional database (Children's Hospital Boston); 1727 cases performed by 7 practitioners over the 18-month period January 2004 through June 2005.

2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance** *(type of analysis & rationale)*:
A multivariable model (described in attachment Item 2a.15) can be used to generate expected rates of clinically important preventable and possibly preventable adverse events (AE) based on case mix (described in Item 2a.21) for groups of patients within a single data set. These expected rates, which are based on average performance within the data set, can be used to calculate standardized AE ratios for each group. 95% confidence intervals for the standardized AE ratios can also be calculated. If the confidence interval for a ratio fails to contain the value 1, this suggests that group performance is either significantly better or significantly worse than average.

2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in*

2f
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performance):
The table below shows standardized AE ratios for 7 interventional cardiologists contributing to the data sample over an 18-month period. The groups of patients being compared are those treated by each practitioner.

Operator	Observed Adverse Event Rate	Expected Rate for Case Mix	SAER	95% Confidence Interval
A	6.6%	4.6%	1.44	(0.74, 2.51)
B	5.1%	3.9%	1.30	(0.71, 2.18)
C	4.8%	6.2%	0.79	(0.46, 1.24)
D	2.0%	2.0%	0.99	(0.46, 1.94)
E	3.0%	3.4%	0.87	(0.32, 1.89)
F	3.6%	3.3%	1.08	(0.39, 2.35)
G	2.4%	3.5%	0.69	(0.14, 2.02)
Total	3.9%	3.9%	1.00	

In this data set, none of the practitioners differs significantly from average performance.

2g. Comparability of Multiple Data Sources/Methods

2g.1 **Data/sample** *(description of data/sample and size)*: N/A

2g.2 **Analytic Method** *(type of analysis & rationale)*:
Formal evaluation of comparability of multiple data sources has not been performed. However, this measure was designed such that it could be implemented using a variety of different data sources.

2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*:
N/A

2g
C☐ P☐ M☐ N☐ NA☐

2h. Disparities in Care

2h.1 **If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: N/A

2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:**
N/A

2h
C☐ P☐ M☐ N☐ NA☐

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties*?

2

Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?**
Rationale:

2
C☐ P☐ M☐ N☐

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

Eval Rating

3a. Meaningful, Understandable, and Useful Information

3a.1 **Current Use:** In use

3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*):
N/A

3a
C☐ P☐ M☐ N☐

3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** N/A **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) 3a.4 **Data/sample** *(description of data/sample and size)***:** N/A 3a.5 **Methods** *(e.g., focus group, survey, QI project)***:** Testing of interpretability not performed. 3a.6 **Results** *(qualitative and/or quantitative results and conclusions)***:** N/A	
3b/3c. Relation to other NQF-endorsed measures 3b.1 **NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related** endorsed **or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 **Are the measure specifications harmonized? If not, why?**	**3b** C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value 3c.1 **Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** 5.1 **If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:** N/A	**3c** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability*?	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability***, met?** **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes 4a.1-2 **How are the data elements that are needed to compute measure scores generated?** Other Data are generated based on procedural information at the conclusion of a case and documented in the electronic medical record.	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources 4b.1 **Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes	**4b** C☐ P☐ M☐ N☐

4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences **4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.** The most vulnerable aspect of the measure pertains to physician transparency and willingness to report and record adverse events. However, an audit of the C3PO multi-institutional data set (2/07 to 4/08) revealed a 92% event capture rate among high severity clinically important adverse events. The events not captured included sedation or airway management events attributed to anesthesia rather than the catheterization procedure. Admittedly, lower severity events were captured less frequently (81%). However, this measure is based on high severity events with clinical impact, which are more likely to be recognized universally by physicians as events requiring reporting.	**4d** C☐ P☐ M☐ N☐
4e. Data Collection Strategy/Implementation **4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:** Electronic extraction of data recorded as part of the procedure expedites data collection. This strategy offers point of care collection and minimizes time and cost. For wide adoption of the measure, current catheterization databases would require harmonization of data elements. Patient confidentiality is preserved as the data are in aggregate. Physician and/or institutional confidentiality is maintained by deidentified dashboard reports. **4e.2 Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:** Costs to implement has not yet been studied. **4e.3 Evidence for costs:** N/A **4e.4 Business case documentation:** N/A	**4e** C☐ P☐ M☐ N☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?	**4**
Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met? **Rationale:**	**4** C☐ P☐ M☐ N☐
RECOMMENDATION	
(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**	**Time-limited** ☐
Steering Committee: Do you recommend for endorsement? **Comments:**	**Y**☐ **N**☐

A☐

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner)
Co.1 Organization
Children's Hospital Boston, Program for Patient Safety and Quality, 300 Longwood Avenue , Boston, Massachusetts, 02115

Co.2 Point of Contact
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Measure Developer If different from Measure Steward
Co.3 Organization
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Co.4 Point of Contact
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Co.5 Submitter If different from Measure Steward POC
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Co.6 Additional organizations that sponsored/participated in measure development

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
Work group:
Robert Beekman, Cincinnati University
William Hellenbrand, Columbia University
John Cheatham, Columbus Children's Hospital Ohio State University
Ralf Holzer, Columbus Children's Hospital Ohio State University
Susan Foerster, St. Louis University
David Balzer, St. Louis University
John Moore, UCLA
James Lock, Children's Hospital Boston
Audrey Marshall, Children's Hospital Boston
Doff McElhinney, Children's Hospital Boston
Peter Lang, Children's Hospital Boston

The work group's role was to provide input on and finalize the procedure type risk groups used in the risk adjustment method.

Ad.2 If adapted, provide name of original measure: N/A
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 Year the measure was first released: 2008
Ad.7 Month and Year of most recent revision: 05, 2008
Ad.8 What is your frequency for review/update of this measure? Every 3 years.
Ad.9 When is the next scheduled review/update for this measure? 09, 2010

Ad.10 Copyright statement/disclaimers: N/A

Ad.11 -13 Additional Information web page URL or attachment:

Date of Submission (*MM/DD/YY*)**:** 09/21/2010