

NATIONAL QUALITY FORUM

Measure Evaluation 4.1 January 2010

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 sub-criteria and most of the footnotes from the evaluation criteria are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). 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 sub-criterion 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 sub-criteria (yellow highlighted areas).*

Steering Committee: Complete all **pink** highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, 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 sub-criteria 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 <18 years of age undergoing cardiac catheterization.			
De.2 Brief description of measure: Ratio of observed to expected clinically important 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 Not part of composite measure			
De.4 National Priority Partners Priority Area: safety			
De.5 IOM Quality Domain: safety			
De.6 Consumer Care Need: Living With Illness			

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
<p>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>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.</i></p> <p>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</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: agreement signed and submitted</p> <p>A.4 Measure Steward Agreement attached: NQF Measure Stewards-634006372321361164.pdf</p>	<p>A</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

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 <input type="checkbox"/> N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► Purpose: public reporting, quality improvement 0,0,0,	C Y <input type="checkbox"/> N <input type="checkbox"/>
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 24 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 <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
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. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.</i> (evaluation criteria) 1a. High Impact	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: a 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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
1b. Opportunity for Improvement 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	1b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/>

definitions. Standardized reporting including a method to adjust for case mix complexity will allow meaningful comparisons of performance among institutions and physicians.

N

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

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 comparisons of performance among institutions and physicians.

1c
C
P
M
N

<p>1c.2-3. Type of Evidence: other (specify) N/A</p> <p>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</p> <p>1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom): N/A</p> <p>1c.6 Method for rating evidence: N/A</p> <p>1c.7 Summary of Controversy/Contradictory Evidence: N/A</p> <p>1c.8 Citations for Evidence (other than guidelines): N/A</p> <p>1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): N/A</p> <p>1c.10 Clinical Practice Guideline Citation: N/A</p> <p>1c.11 National Guideline Clearinghouse or other URL: N/A</p> <p>1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom): N/A</p> <p>1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF): N/A</p> <p>1c.14 Rationale for using this guideline over others: N/A</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Importance to Measure and Report</i>?</p>	<p>1</p>
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	<p>1 Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p style="text-align: center;">2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</p>	
<p>Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)</p>	<p>Eval Rating</p>
<p style="text-align: center;">2a. MEASURE SPECIFICATIONS</p>	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p> <p>2a. Precisely Specified</p>	
<p>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): Number of diagnostic and interventional cardiac catheterization cases for children < 18 years of age resulting in a clinically important adverse event, performed by a provider performing at least 50 cases per year in pediatric patients < 18 years of age.</p>	<p>2a- specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

2a.2 Numerator Time Window (*The time period in which cases are eligible for inclusion in the numerator*):

During the hospital admission prior to discharge

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).

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/ recanalization of jailed vessel in stent
 Interventional techniques / recanalization 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*):

Number of diagnostic and interventional cardiac catheterization cases for children < 18 years of age, performed by a provider performing at least 50 cases per year in pediatric patients < 18 years of age.

2a.5 Target population gender: Female, Male

2a.6 Target population age range: Age < 18 years

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,*

<p><i>including all codes, logic, and definitions</i>): Primary electrophysiology cases, ablation cases, pericardiocentesis only, thoracentesis only.</p>
<p>2a.11 Stratification Details/Variables (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>): N/A</p>
<p>2a.12-13 Risk Adjustment Type: case-mix adjustment</p> <p>2a.14 Risk Adjustment Methodology/Variables (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>): Variables are procedure type risk group and indicator of hemodynamic vulnerability. Details are provided in attachment Item 2a.15.</p> <p>2a.15-17 Detailed risk model available Web page URL or attachment: Attachment Item 2a.15 Risk Adjustment-634007193146101876.doc</p>
<p>2a.18-19 Type of Score: ratio 2a.20 Interpretation of Score: better quality = lower score 2a.21 Calculation Algorithm (<i>Describe the calculation of the measure as a flowchart or series of steps</i>): The measure is a standardized adverse event ratio for children and adults undergoing cardiac catheterization for congenital heart disease.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The standardized adverse event ratio (SAER) is then calculated as the observed AE rate divided by the expected AE rate.</p> <p>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.</p> <p>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. <i>Congenital Heart Disease</i> 2008; 3:230-240.</p>
<p>2a.22 Describe the method for discriminating performance (<i>e.g., significance testing</i>): 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</p>

<p>reference group.</p>	
<p>2a.23 Sampling (Survey) Methodology <i>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):</i> 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.</p>	
<p>2a.24 Data Source <i>(Check the source(s) for which the measure is specified and tested)</i> lab data, Management data, organizational policies and procedures</p>	
<p>2a.25 Data source/data collection instrument <i>(Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):</i> Multi-center registry for congenital cardiac catheterization procedures.</p>	
<p>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</p>	
<p>2a.29-31 Data dictionary/code table web page URL or attachment: Attachment Item 2a.29 Data Dictionary.doc</p>	
<p>2a.32-35 Level of Measurement/Analysis <i>(Check the level(s) for which the measure is specified and tested)</i> Can be measured at all levels</p>	
<p>2a.36-37 Care Settings <i>(Check the setting(s) for which the measure is specified and tested)</i> Hospital</p>	
<p>2a.38-41 Clinical Services <i>(Healthcare services being measured, check all that apply)</i> Clinicians: Physicians (MD/DO)</p>	
TESTING/ANALYSIS	
<p>2b. Reliability testing</p>	
<p>2b.1 Data/sample <i>(description of data/sample and size):</i> Formal testing of reliability/repeatability has not yet been performed.</p>	
<p>2b.2 Analytic Method <i>(type of reliability & rationale, method for testing):</i> N/A</p>	
<p>2b.3 Testing Results <i>(reliability statistics, assessment of adequacy in the context of norms for the test conducted):</i> N/A</p>	<p>2b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2c. Validity testing</p>	
<p>2c.1 Data/sample <i>(description of data/sample and size):</i> Preliminary Validation of Risk Adjustment Model (additional validation has not yet been performed) (1) Single institutional database (Children's Hospital Boston); 1404 cases in children < 18 years of age 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); 5743 cases from 6 institutions over the 23-month period February 2007 through December 2008.</p>	
<p>2c.2 Analytic Method <i>(type of validity & rationale, method for testing):</i> Discrimination of the risk adjustment method has been quantified using the area under the receiver-operator characteristic (ROC) curve (c statistic); calibration was assessed using the Hosmer-Lemeshow test.</p>	
<p>2c.3 Testing Results <i>(statistical results, assessment of adequacy in the context of norms for the test conducted):</i></p>	<p>2c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>(1) Area under the ROC curve 0.743; p value for Hosmer-Lemeshow test 0.49. (2) Area under the ROC curve 0.679; p value for Hosmer-Lemeshow test 0.90.</p>	
<p>2d. Exclusions Justified</p> <p>2d.1 Summary of Evidence supporting exclusion(s): Formal testing of measure exclusions has not been performed. See Analytic Method below (2d.4).</p> <p>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. <i>Congenital Heart Disease</i> 2008; 3:230-240.</p> <p>2d.3 Data/sample (description of data/sample and size): N/A</p> <p>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.</p> <p>2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): N/A</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (description of data/sample and size): N/A</p> <p>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.</p> <p>2e.3 Testing Results (risk model performance metrics): N/A</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (description of data/sample and size): Single institutional database (Children’s Hospital Boston); 1404 cases performed by 7 practitioners over the 18-month period January 2004 through June 2005.</p> <p>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.</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance): 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</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>practitioner.</p> <table border="1"> <thead> <tr> <th>Operator</th> <th>Observed Adverse Event Rate</th> <th>Expected Rate for Case Mix</th> <th>SAER</th> <th>95% Confidence Interval</th> </tr> </thead> <tbody> <tr> <td>A</td> <td>13.2%</td> <td>11.3%</td> <td>1.17</td> <td>(0.74, 1.76)</td> </tr> <tr> <td>B</td> <td>9.2%</td> <td>9.5%</td> <td>0.97</td> <td>(0.62, 1.44)</td> </tr> <tr> <td>C</td> <td>16.0%</td> <td>14.7%</td> <td>1.08</td> <td>(0.81, 1.43)</td> </tr> <tr> <td>D</td> <td>4.3%</td> <td>5.1%</td> <td>0.85</td> <td>(0.49, 1.38)</td> </tr> <tr> <td>E</td> <td>7.8%</td> <td>8.8%</td> <td>0.89</td> <td>(0.49, 1.50)</td> </tr> <tr> <td>F</td> <td>6.7%</td> <td>8.4%</td> <td>0.80</td> <td>(0.32, 1.65)</td> </tr> </tbody> </table> <p>In this data set, none of the practitioners differs significantly from average performance.</p>	Operator	Observed Adverse Event Rate	Expected Rate for Case Mix	SAER	95% Confidence Interval	A	13.2%	11.3%	1.17	(0.74, 1.76)	B	9.2%	9.5%	0.97	(0.62, 1.44)	C	16.0%	14.7%	1.08	(0.81, 1.43)	D	4.3%	5.1%	0.85	(0.49, 1.38)	E	7.8%	8.8%	0.89	(0.49, 1.50)	F	6.7%	8.4%	0.80	(0.32, 1.65)	
Operator	Observed Adverse Event Rate	Expected Rate for Case Mix	SAER	95% Confidence Interval																																
A	13.2%	11.3%	1.17	(0.74, 1.76)																																
B	9.2%	9.5%	0.97	(0.62, 1.44)																																
C	16.0%	14.7%	1.08	(0.81, 1.43)																																
D	4.3%	5.1%	0.85	(0.49, 1.38)																																
E	7.8%	8.8%	0.89	(0.49, 1.50)																																
F	6.7%	8.4%	0.80	(0.32, 1.65)																																
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (<i>description of data/sample and size</i>): N/A</p> <p>2g.2 Analytic Method (<i>type of analysis & rationale</i>): 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.</p> <p>2g.3 Testing Results (<i>e.g., correlation statistics, comparison of rankings</i>): N/A</p>	<p>2g</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>																																			
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>): N/A</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A</p>	<p>2h</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>																																			
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>																																			
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met? Rationale:</p>	<p>2</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>																																			
<p style="text-align: center;">3. USABILITY</p>																																				
<p>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)</p>	<p>Eval Rating</p>																																			
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: in use</p> <p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>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</i>): N/A</p> <p>3a.3 If used in other programs/initiatives (<i>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</i>): N/A</p>	<p>3a</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>																																			

<p>Testing of Interpretability (<i>Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement</i>) 3a.4 Data/sample (<i>description of data/sample and size</i>): N/A 3a.5 Methods (<i>e.g., focus group, survey, QI project</i>): Testing of interpretability not performed. 3a.6 Results (<i>qualitative and/or quantitative results and conclusions</i>): N/A</p>	
<p>3b/3c. Relation to other NQF-endorsed measures 3b.1 NQF # and Title of similar or related measures:</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures:</p>	
<p>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 <u>or</u> different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why?</p>	<p>3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures: 5.1 Competing Measures 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</p>	<p>3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p style="text-align: center;">4. FEASIBILITY</p>	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>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.</p>	<p>4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4b. Electronic Sources 4b.1 Are all the data elements available electronically? (<i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i>) Yes 4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p>	<p>4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>4c. Exclusions</p> <p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</p>	<p>4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p> <p>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.</p>	<p>4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4e. Data Collection Strategy/Implementation</p> <p>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.</p> <p>4e.2 Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>): Costs to implement has not yet been studied.</p> <p>4e.3 Evidence for costs: N/A</p> <p>4e.4 Business case documentation: N/A</p>	<p>4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
RECOMMENDATION	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/></p>
CONTACT INFORMATION	

<p>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</p> <p>Co.2 Point of Contact Nina Rauscher, MS, RN, CPHQ nina.rauscher@childrens.harvard.edu 617-355-6567</p>
<p>Measure Developer If different from Measure Steward Co.3 Organization Children's Hospital Boston Department of Cardiology, 300 Longwood Avenue Boston Massachusetts 02115</p> <p>Co.4 Point of Contact Nina Rauscher, MS, RN, CPHQ nina.rauscher@childrens.harvard.edu 617-355-6567</p>
<p>Co.5 Submitter If different from Measure Steward POC Nina Rauscher, MS, RN, CPHQ nina.rauscher@childrens.harvard.edu 617-355-6567- Children's Hospital Boston</p>
<p>Co.6 Additional organizations that sponsored/participated in measure development</p>
<p>ADDITIONAL INFORMATION</p>
<p>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</p> <p>The work group's role was to provide input on and finalize the procedure type risk groups used in the risk adjustment method.</p>
<p>Ad.2 If adapted, provide name of original measure: N/A Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>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: 2008-05 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? 2010-09</p>
<p>Ad.10 Copyright statement/disclaimers: N/A</p>
<p>Ad.11 -13 Additional Information web page URL or attachment:</p>
<p>Date of Submission (MM/DD/YY): 02/17/2010</p>