



## Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to sub criterion 1b).

### Brief Measure Information

**NQF #:** 0715

**Corresponding Measures:**

**De.2. Measure Title:** Standardized adverse event ratio for congenital cardiac catheterization

**Co.1.1. Measure Steward:** Boston children's Hospital

**De.3. Brief Description of Measure:** Ratio of observed to expected major adverse events (MAE) among patients undergoing congenital cardiac catheterization, risk-adjusted using the Catheterization for Congenital Heart Disease Adjustment for Risk Method II (CHARM II).

**1b.1. Developer Rationale:** Standardized reporting including a method to adjust for case mix complexity allows meaningful comparisons of performance among institutions. Institutions can also track performance over time and identify opportunities for improvement. If adverse event rates are higher than the expected rate yielding a SAER greater than 1.0, quarterly monitoring can alert the institution to this performance gap in a timely manner. Additional root case analysis can then be conducted to identify system processes requiring changes in order to improve care and mitigate risk of similar events occurring at the facility.

**S.4. Numerator Statement:** Number of diagnostic and interventional cardiac catheterization cases resulting in a major adverse event at an institution performing at least 50 catheterization cases per year meeting the definition of a case type for case type risk categorization in patients with congenital heart disease.

**S.6. Denominator Statement:** Number of diagnostic and interventional cardiac catheterization cases at an institution performing at least 50 cases per year meeting the definition of a case type for case type risk categorization in patients with congenital heart disease.

**S.8. Denominator Exclusions:** The following procedures are excluded: primary electrophysiology cases, ablation cases, pericardiocentesis only, thoracentesis only, and any procedure not performed in the catheterization laboratory, such as a case performed in an intensive care unit. In addition, cases without an assigned case type risk category are excluded.

**De.1. Measure Type:** Outcome

**S.17. Data Source:** Electronic Health Data, Electronic Health Records, Registry Data

**S.20. Level of Analysis:** Facility

**IF Endorsement Maintenance – Original Endorsement Date:** Jan 17, 2011 **Most Recent Endorsement Date:** Jun 29, 2015

**IF this measure is included in a composite, NQF Composite#/title:**

**IF this measure is paired/grouped, NQF#/title:**

**De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?** N/A

### 1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. **Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.**

**1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form**

[0715\\_Evidence\\_Attachment.docx](#)

**1a.1 For Maintenance of Endorsement: Is there new evidence about the measure since the last update/submission?**

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

No

**1b. Performance Gap**

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

**1b.1. Briefly explain the rationale for this measure** (e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)

*If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.*

Standardized reporting including a method to adjust for case mix complexity allows meaningful comparisons of performance among institutions. Institutions can also track performance over time and identify opportunities for improvement. If adverse event rates are higher than the expected rate yielding a SAER greater than 1.0, quarterly monitoring can alert the institution to this performance gap in a timely manner. Additional root case analysis can then be conducted to identify system processes requiring changes in order to improve care and mitigate risk of similar events occurring at the facility.

**1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.** *(This is required for maintenance of endorsement. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

Standardized adverse event ratios are provided to C3PO participating centers and reported as rolling 4Q outcomes. Participants are able to view their performance compared to others (fig. 1b.2.A) for the quarter as well as institution specific SAER outcome over time (fig 1b.2.B). Figures are included in supplemental Appendix of Figures.

**1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.**

The original CHARM model—which contained procedure type risk categories, a hemodynamic vulnerability indicator, and age--allowed for the equitable comparison of adverse event rates among providers and institutions by means of a standardized adverse events ratio (SAER) calculation. The principle of this method for risk adjustment has been extrapolated nationally and internationally as a model for procedural comparisons, and was endorsed by the NQF as a pediatric quality measure in 2014. This model required updates including contemporary case types and a revised weighted hemodynamic score to reflect changes in the field of congenital heart disease and to further refine and improve the SAER tool. Providing operators with a contemporary tool that accurately allows for equitable comparisons of adverse outcomes between and within institutions serves to inform the institution of relative performance among peers. Early self-identification of outlier performance accelerates quality improvement efforts to mitigate risk and reduce adverse event rates, improving the quality of care provided to patients.

**References:**

Bergersen L, Gauvreau K, Foerster SR, Marshall AC, McElhinney DB, Beekman RH, Hirsch R, Kreutzer J, Balzer D, Vincent J, Hellenbrand WE, Holzer R, Cheatham JP, Moore JW, Burch G, Armsby L, Lock JE, Jenkins KJ. Catheterization for congenital heart disease adjustment for risk method (CHARM). *Journal of the American College of Cardiology: Cardiovascular Interventions* 2011; 4:1037-1046.

Chaudhry-Waterman N, Coombs S, Porras D, Holzer R, Bergersen L. Developing tools to measure quality in congenital cardiac catheterization and interventions: the congenital cardiac catheterization project on outcomes (C3PO). *Methodist DeBakey Cardiovascular Journal*. 2014;10:63-67.

Bergersen L, Gauvreau K, Marshall A, Kreutzer J, Beekman R, Hirsch R, Foerster S, Balzer D, Vincent J, Hellenbrand W, Holzer R, Cheatham J, Moore J, Lock J, Jenkins K. Procedure-type risk categories for pediatric and congenital cardiac catheterization. *Circ*

Cardiovasc Interv. 2011;4:188-194.

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. 2010;75:389-400.

**1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability.** *(This is required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.*

To take a first step toward evaluating the impact of social risk factors on the occurrence of MAE, the proportion of cases with government insurance was collected at the institutional level and added to the CHARM II model. Additional details regarding this inquiry are included in Measure Testing document (subcriteria 2a2, 2b1-2b6; Question 2b3.3b).

**1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4**

N/A

## 2. Reliability and Validity—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. **Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.**

**2a.1. Specifications** The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

**De.5. Subject/Topic Area** (check all the areas that apply):

Cardiovascular

**De.6. Non-Condition Specific**(check all the areas that apply):

**De.7. Target Population Category** (Check all the populations for which the measure is specified and tested if any):

Children

**S.1. Measure-specific Web Page** (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

<https://c3po-r3.chboston.org/#/about/background/c3po-charm>

**S.2a. If this is an eMeasure**, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure Attachment:

**S.2b. Data Dictionary, Code Table, or Value Sets** (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment Attachment: 0715\_Data\_Dictionary-637138995071924683.docx

**S.2c.** Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure **Attachment:**

**S.2d.** Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

**S.3.1. For maintenance of endorsement:** Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

Yes

**S.3.2. For maintenance of endorsement,** please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

CHARM I was developed and validated in a pediatric population, age  $\leq 18$  years. The CHARM II model was developed using a dataset of all congenital cardiac catheterization procedures, performed in both pediatric and adult patients with congenital heart disease. Our model has been validated in a population consisting of patients of all ages with congenital heart disease, as well as a pediatric-only population, age  $\leq 18$  years. As such, the model is generalizable to institutions caring for both adult and pediatric patients with congenital heart disease, as well as hospitals limited to only pediatric catheterizations.

Updates to this version of the risk adjustment methodology include modification of predictor criteria, such as new case type risk categories encompassing catheter-based interventions established since the development of the last model and novel case types. In addition we have improved upon the measure for hemodynamic vulnerability by creating a hemodynamic scoring metric. By assigning greater weight to indicators of hemodynamic risk that are more often associated with adverse events, we were able to improve the predictive discrimination of this measure.

Additionally, we have restricted the outcome of the measure to major adverse events, which includes events classified as major (severity level 4) or catastrophic (severity level 5) using internationally recognized nomenclature definitions for event severity. Our original measure also included moderate severity adverse events (severity level 3), however, major and catastrophic adverse events are more reliably recorded and classified in the registry experience, and less susceptible to recording bias.

Reference for the adverse event nomenclature definitions:

Bergersen L, Giroud J, Jacobs J, Franklin R, Béland M, Krogmann O, Aiello V, Colan S, Elliott M, Gaynor J, Kurosawa H, Maruszewski B, Stellin G, Tchervenkov C, Walters H, Weinberg P, Everett A. Report from the international society for nomenclature of paediatric and congenital heart disease: cardiovascular catheterization for congenital and paediatric cardiac disease Part 2 –nomenclature of complications associated with interventional cardiology. *Cardiol Young*. 2011;21:260-265. CHARM I was developed and validated in a pediatric population, age  $\leq 18$  years. The CHARM II model was developed using a dataset of all congenital cardiac catheterization procedures, performed in both pediatric and adult patients with congenital heart disease. Our model has been validated in a population consisting of patients of all ages with congenital heart disease, as well as a pediatric-only population, age  $\leq 18$  years. As such, the model is generalizable to institutions caring for both adult and pediatric patients with congenital heart disease, as well as hospitals limited to only pediatric catheterizations.

Updates to this version of the risk adjustment methodology include modification of predictor criteria, such as new case type risk categories encompassing catheter-based interventions established since the development of the last model and novel case types. In addition we have improved upon the measure for hemodynamic vulnerability by creating a hemodynamic scoring metric. By assigning greater weight to indicators of hemodynamic risk that are more often associated with adverse events, we were able to improve the predictive discrimination of this measure.

Additionally, we have restricted the outcome of the measure to major adverse events, which includes events classified as major (severity level 4) or catastrophic (severity level 5) using internationally recognized nomenclature definitions for event severity. Our original measure also included moderate severity adverse events (severity level 3), however, major and catastrophic adverse events are more reliably recorded and classified in the registry experience, and less susceptible to recording bias.

Reference for the adverse event nomenclature definitions:

Bergersen L, Giroud J, Jacobs J, Franklin R, Béland M, Krogmann O, Aiello V, Colan S, Elliott M, Gaynor J, Kurosawa H, Maruszewski B,

Stellin G, Tchervenkov C, Walters H, Weinberg P, Everett A. Report from the international society for nomenclature of paediatric and congenital heart disease: cardiovascular catheterization for congenital and paediatric cardiac disease Part 2 –nomenclature of complications associated with interventional cardiology. *Cardiol Young*. 2011;21:260-265.

**S.4. Numerator Statement** (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Number of diagnostic and interventional cardiac catheterization cases resulting in a major adverse event at an institution performing at least 50 catheterization cases per year meeting the definition of a case type for case type risk categorization in patients with congenital heart disease.

**S.5. Numerator Details** (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Major adverse events, defined as an untoward event resulting in a change in condition which may be life-threatening if not treated; change in condition may be permanent such as end organ damage, may have required an intensive care unit admission or emergent readmission to the hospital, may have required invasive monitoring or interventions such as electrical cardioversion or unanticipated intubation, or which required major invasive procedures or transcatheter interventions to correct the condition. Major adverse events also include catastrophic events such as death, or emergent surgery or heart/lung bypass support to prevent death, with failure to wean from bypass support.

**S.6. Denominator Statement** (Brief, narrative description of the target population being measured)

Number of diagnostic and interventional cardiac catheterization cases at an institution performing at least 50 cases per year meeting the definition of a case type for case type risk categorization in patients with congenital heart disease.

**S.7. Denominator Details** (All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Cardiac catheterization cases eligible for this measure include the following case types alone or in combination with more than one transcatheter intervention, are listed below:

Diagnostic including angiography and/or hemodynamics only  
Heart biopsy  
Atrial septal defect or patent foramen ovale device closure  
Ventricular septal defect device closure  
Patent ductus arteriosus device or coil closure  
Fontan fenestration or baffle leak device closure  
Systemic pulmonary collateral device or coil closure  
Venous collateral device or coil occlusion  
Transcatheter pulmonary valve implantation  
Aortic valvotomy  
Mitral valvotomy  
Pulmonary valvotomy  
Atrietic valve perforation  
Pulmonary artery (only 1 vessel)  
Pulmonary artery (=2 vessels)  
Right ventricular outflow tract conduit dilation and/or stent  
Aorta (coarctation) dilation and/or stent

Pulmonary vein dilation and/or stent  
Patent ductus arteriosus dilation and/or stent  
Atrial septostomy  
Atrial septum static dilation and/or stent placement

**S.8. Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*

The following procedures are excluded: primary electrophysiology cases, ablation cases, pericardiocentesis only, thoracentesis only, and any procedure not performed in the catheterization laboratory, such as a case performed in an intensive care unit. In addition, cases without an assigned case type risk category are excluded.

**S.9. Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)*

Any catheterization case not meeting the definition for case type as described in Section S.7 is excluded. In the C3PO registry experience approximately 90% of all cases performed in congenital cardiac catheterization labs meet a case type definition. Many of these procedures were novel, with insufficient evidence (either empirical or judgment-based) to allow quantification of their association with adverse event occurrence.

**S.10. Stratification Information** *(Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)*

The measure has been tested in a cohort of all patients meeting inclusion criteria as well a subset of pediatric patients =18 years of age.

**S.11. Risk Adjustment Type** (Select type. Provide specifications for risk stratification in measure testing attachment)

Statistical risk model

If other:

**S.12. Type of score:**

Ratio

If other:

**S.13. Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*

Better quality = Lower score

**S.14. Calculation Algorithm/Measure Logic** *(Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.)*

This measure is a standardized adverse event ratio (SAER) for children and adults undergoing cardiac catheterization for congenital heart disease.

It is defined as the ratio of observed to expected rates of major adverse events (MAE) 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 MAE rate is calculated for each institution. The observed rate is defined as the number of diagnostic and interventional cardiac catheterization cases performed in a congenital cardiac catheterization lab resulting in a major adverse event divided by the total number of cardiac catheterization cases performed in the congenital cardiac catheterization lab meeting measure inclusion criteria.

Next, the expected MAE rate is calculated for each group. To do this, a multivariable logistic regression model with the outcome any MAE is fitted. Three clinical characteristics are incorporated as explanatory covariates: 1) case type risk category, modeled as binary indicator variables representing categories 2, 3, 4, and 5, with category 1 as the reference group; 2) hemodynamic score, modeled as binary indicator variables representing scores of 1, 2, and =3, with a score of 0 (no hemodynamic vulnerability) as the reference



group; and 3) age category, modeled as binary indicator variables for age <1 month, 1-11 months, and ≥19 years, with category 1-18 years serving as the reference group. This logistic model is used to estimate the predicted probability of a MAE for each individual case in the dataset. The average predicted probability of MAE for all cases in a group, calculated by summing the predicted probabilities for each case and dividing by the total number of cases, represents the expected MAE rate for the group, adjusting for case mix.

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

If the observed MAE 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 MAE rate for a group is lower than would be expected, indicating better than anticipated performance, the SAER is less than 1.

The measure calculation algorithm can be accessed through the following link:  
<http://c3po-r3.chboston.org/#/about/background/c3po-charm>

Reference for the original CHARM risk adjustment model:

Bergersen L, Gauvreau K, Foerster SR, Marshall AC, McElhinney DB, Beekman RH, Hirsch R, Kreutzer J, Balzer D, Vincent J, Hellenbrand WE, Holzer R, Cheatham JP, Moore JW, Burch G, Armsby L, Lock JE, Jenkins KJ. Catheterization for congenital heart disease adjustment for risk method (CHARM). *Journal of the American College of Cardiology: Cardiovascular Interventions* 2011; 4:1037-1046.

**S.15. Sampling** (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed. Institutions performing at least 50 catheterization cases per year meeting the definition of a case type for case type risk categorization in patients with congenital heart disease.

**S.16. Survey/Patient-reported data** (If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)

Specify calculation of response rates to be reported with performance measure results.

N/A

**S.17. Data Source** (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.18.

Electronic Health Data, Electronic Health Records, Registry Data

**S.18. Data Source or Collection Instrument** (Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Multi-center registry for congenital cardiac catheterization procedures. The congenital cardiac catheterization project on outcomes (C3PO) is a multi-center registry for cardiac catheterization available to participants since 2007 with unrestricted participation since 2014 and international availability since 2019. Participants use a web-based data entry tool to prospectively record patient and procedural characteristics for all cases performed at the institution.

In addition, transparent methodology for metric calculation is publicly available on the external website for unrestricted local use through collection of a limited data set and application of published model coefficients.

**S.19. Data Source or Collection Instrument** (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

Available at measure-specific web page URL identified in S.1

**S.20. Level of Analysis** (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)

Facility

**S.21. Care Setting** (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Inpatient/Hospital

If other:
<b>S.22. <u>COMPOSITE Performance Measure</u></b> - Additional Specifications <i>(Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)</i> N/A
<b>2. Validity – See attached Measure Testing Submission Form</b> <a href="#">0715_Testing_Attachment.docx</a>  <b>2.1 <u>For maintenance of endorsement</u></b> <i>Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.</i> Yes  <b>2.2 <u>For maintenance of endorsement</u></b> <i>Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.</i> Yes  <b>2.3 <u>For maintenance of endorsement</u></b> <i>Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.</i> Yes - Updated information is included
<b>3. Feasibility</b>
Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.
<b>3a. Byproduct of Care Processes</b> For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).  <b>3a.1. Data Elements Generated as Byproduct of Care Processes.</b> Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry), Other If other: Data are generated based on procedural information at the conclusion of a case and documented in the electronic medical record in the procedural description.
<b>3b. Electronic Sources</b> The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.  <b>3b.1. To what extent are the specified data elements available electronically in defined fields</b> <i>(i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)</i> Update this field for <b><u>maintenance of endorsement.</u></b> ALL data elements are in defined fields in a combination of electronic sources  <b>3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a</b>



**credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.** For maintenance of endorsement, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

**3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.**

**Attachment:**

### 3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

**3c.1. Required for maintenance of endorsement.** Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

**IF instrument-based,** consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

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. The C3PO registry offers a no-fee vendor export for upload of harmonized data elements from local databases. However, not all data elements are harmonized and not all institutions have robust databases to allow for electronic transfer, therefore manual data entry is primarily required. For adoption of the measure, users must collect data in harmony with the structure of the two key data elements in the CHARM II model, specifically case type and hemodynamics. This limited data set with age and the occurrence of major adverse events, using internationally published definitions for adverse event severity, allows risk adjustment of the outcome MAE and SAER reporting for populations. Ideally, data is collected and recorded at the time of the procedure in accordance with local procedural reporting and quality control. Complete population data is required; missing cases meeting inclusion criteria at a facility will invalidate the metric. Patient confidentiality is preserved at the population level as the data are in aggregate and do not include patient level unique identifiers. Physician and/or institutional confidentiality is maintained by deidentified Quarterly Outcome Reports.

**3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).**

The measure methodology and model coefficients are publicly available for CHARM and will be published for CHARM II. There are no proprietary relationships, fees, or licensing required to use the CHARM methodology for SAER calculation.

## 4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

### 4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

#### 4.1. Current and Planned Use

*NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.*

Specific Plan for Use	Current Use (for current use provide URL)
Public Reporting	Quality Improvement (external benchmarking to organizations) Congenital Cardiac Catheterization Project on Outcomes - Registry Risk Reporting
Public Health/Disease Surveillance	<a href="https://c3po-r3.chboston.org/#/about/background/c3po-charm">https://c3po-r3.chboston.org/#/about/background/c3po-charm</a>

<p>Payment Program</p> <p>Regulatory and Accreditation Programs</p> <p>Professional Certification or Recognition Program</p>	<p>Quality Improvement (Internal to the specific organization)</p> <p>Congenital Cardiac Catheterization Project on Outcomes - Registry Risk Reporting</p> <p><a href="https://c3po-r3.chboston.org/#/about/background/c3po-charm">https://c3po-r3.chboston.org/#/about/background/c3po-charm</a></p>
--	---

**4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:**

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Name: Congenital Cardiac Catheterization Project on Outcomes  
Sponsor: Boston Children's Hospital  
Purpose: Quality Improvement and Registry Risk Reporting  
Geographic area and number and percentage of accountable entities and patients included: United States currently 20 participating centers nationally  
Number: approximately 15 thousand cases/year at 20 pediatric hospitals  
Level of measurement: case/population in healthcare facility

**4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons?** (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

External SAER metric reporting has not been sought or mandated by accreditation or payment programs. The measure developer/steward is restricted from sharing metric results generated in the C3PO registry with outside entities in accordance with data use agreements.

**4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement.** (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

Objective Physician Performance Evaluations (OPPE) are required and externally reported by institutions. The SAER metric is being used by some institutions as a metric to evaluate performance in physicians performing congenital cardiac catheterization procedures and is currently the only outcome based metric for these providers, other than volume, which satisfies OPPE requirements.

**4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.**

**How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.**

In the C3PO registry performance results are provided to each participating institution as a Quarterly Outcome Report and includes the SAER metric. Hospitals that have contributed 4 or more quarters of data in the registry are eligible for the SAER metric section of the report. Assistance with interpretation has been provided with educational materials, webinars, and is summarized in the quarterly report cover letter.

**4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.**

Registry data extracts are generated one month following the completion of each quarter. Quarterly Outcome Reports are then distributed to institutions every 3 months. Reports include comparative SAER institutional outcomes, as well as site-specific SAER outcomes over time.

Education on interpretation of these reports and the metrics used in generating them are offered to participants in various forms including report cover letters, educational webinars explaining sample reports, and direct email correspondence to address

questions.

**4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.**

**Describe how feedback was obtained.**

Feedback was obtained via a survey sent at the end of 2019 to Quarterly Outcome Report recipients and via email communication soliciting feedback on report content.

Recipients reported that the CHARM II SAER metric was “very easy” in 80% of respondents and “somewhat easy” to understand in the remaining 20%. Monthly webinars and cover letter explanations of the Quarterly Outcome Reports were described as the most helpful educational resources for understanding the metric.

**4a2.2.2. Summarize the feedback obtained from those being measured.**

Feedback from centers and providers being measured by the SAER has been positive. Survey respondents felt that the metric assessed their site’s performance “very well” or “well” in all respondents. 90 % of respondents felt comfortable asking the sponsor clarification questions on quarterly reports.

**4a2.2.3. Summarize the feedback obtained from other users**

All feedback is summarized above by the users for the institutions being measured.

**4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.**

Quarterly Outcome Reports include SEAR outcomes at an institutional level. We have had several requests for provider-specific outcome data from individual centers.

**Improvement**

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

**4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)**

**If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.**

The amount of time elapsed since developing the CHARM II model for the SAER metric is insufficient to make conclusions on performance or trends among the users. However, we expect that quarterly monitoring prospectively will alert institutions to potential performance gaps in a timely manner. Then root case analysis can then be conducted to identify system processes requiring changes in order to improve care and mitigate risk of similar events occurring at the facility.

**4b2. Unintended Consequences**

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

**4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.**

There have been no negative unintended impacts on patients. An improved understanding of the associated risk with different case types allows preemptive planning to mitigate risk and we anticipate will result in lower major adverse event rates and improved patient procedural safety.

**4b2.2. Please explain any unexpected benefits from implementation of this measure.**

Case risk types are informing relative risk of planned procedures at participating institutions resulting in improved scheduling and safety through risk recognition and mitigation.

## 5. Comparison to Related or Competing Measures

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

### 5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

No

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

### 5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

No

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

N/A - there are no competing measures

### 5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

OR

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

N/A

## Appendix

**A.1 Supplemental materials may be provided in an appendix.** All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Attachment Attachment: 0715\_Appendix\_of\_Figures.docx

## Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Boston children's Hospital

Co.2 Point of Contact: Lisa, Bergersen, [lisa.bergersen@cardio.chboston.org](mailto:lisa.bergersen@cardio.chboston.org), 617-355-6529-

Co.3 Measure Developer if different from Measure Steward: Boston children's Hospital

Co.4 Point of Contact: Lisa, Bergersen, [lisa.bergersen@cardio.chboston.org](mailto:lisa.bergersen@cardio.chboston.org), 617-355-6529-

Additional Information
<p><b>Ad.1 Workgroup/Expert Panel involved in measure development</b>  <b>Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.</b>  All working group members provided expert opinion during risk adjustment model development.</p> <p>David Balzer (Children's Hospital St. Louis)  Lisa Bergersen (Boston Children's Hospital)  Darren Berman (Nationwide Children's Hospital)  Susan Foerster (Children's Hospital of Wisconsin)  Kimberlee Gauvreau (Boston Children's Hospital)  Bryan Goldstein (Children's Hospital of Pittsburgh)  Michael Hainstock (University of Virginia Children's Hospital)  Ralf Holzer (Weill Cornell Medicine of New York-Presbyterian)  Dana Janssen (Monroe Carell Jr. Children's Hospital at Vanderbilt)  David Nykanen (Arnold Palmer Hospital for Children)  Michael O'Byrne (Children's Hospital of Philadelphia)  Brian Quinn (Boston Children's Hospital)  Alejandro Torres (Morgan Stanley Children's Hospital of New York-Presbyterian)  Sara Trucco (Children's Hospital of Pittsburgh)  Wendy Whiteside (University of Michigan C.S. Mott Children's Hospital)</p>
<p><b>Measure Developer/Steward Updates and Ongoing Maintenance</b>  <b>Ad.2 Year the measure was first released:</b> 2010  <b>Ad.3 Month and Year of most recent revision:</b> 01, 2019  <b>Ad.4 What is your frequency for review/update of this measure?</b> Every 4 years  <b>Ad.5 When is the next scheduled review/update for this measure?</b> 12, 2021</p>
<p><b>Ad.6 Copyright statement:</b> N/A  <b>Ad.7 Disclaimers:</b> N/A</p>
<p><b>Ad.8 Additional Information/Comments:</b> N/A</p>