## NATIONAL QUALITY FORUM

## National Voluntary Consensus Standards for Pediatric Cardiac Surgery Summary of Review of Measures

**NQF Evaluation Criteria: I**=Importance to measure and report; **S**=Scientific acceptability of measure properties; **U**=Usability; **F**=Feasibility

**Importance to measure and report:** This is a threshold criterion, and the Committee votes: **Y**=yes; **N**=no; or **A**=abstain. Measures that do not pass the importance criterion are not further evaluated and not recommended as voluntary consensus standards.

**Remaining Criteria:** Extent to which the NQF evaluation criteria are met: **H**=high; **M**=moderate; **L**=low. The Committee votes or reaches consensus on ratings.

**Recommendation:** The Committee votes on the overall recommendation for endorsement: **Yes**, **No**, or **Abstain**.

In October 2009, the 12-member Pediatric Cardiac Surgery Steering Committee met in person to evaluate 21 measures in the topic areas of mortality, programmatic structure, and antibiotic use and to make recommendations across the spectrum of pediatric cardiac surgery. During that meeting, the Committee recommended 20 measures for time-limited endorsement and one for endorsement with the condition that its risk-stratification methodology be harmonized with that of another submitted measure. After the meeting, eight of those measures (seven outcome, and one structural) were withdrawn by the developer. At that time, both developers were also given the opportunity to submit additional information to further support the reliability and validity of their measure submissions.

The Steering Committee was subsequently asked to re-evaluate the 13 remaining measures. The details of this subsequent evaluation and Committee vote on each of the 13 measures are reflected below. The evaluation of these 13 measures is also reflected in the May 17, 2010 meeting summary and draft report available on the Pediatric Cardiac Surgery project page.

Meas# / Title/ (Owner)	Steering Committee Evaluation and Recommendation
PCS-001-09 Participation	Recommendation: Time-Limited Endorsement Yes-9; No-0; Abstain-0
in a national database for pediatric and	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-4; M-4; L-1 <u>U</u> : H-9; M-0; L-0 <u>F</u> : H-7; M-2; L-0
congenital	Discussion:
heart surgery (Society of Thoracic Surgeons)	I: The Steering Committee agreed that this measure is important to measure and report. By reporting through a database, it is possible to identify potential quality issues and provide benchmarks. The measure identifies participation in a National Database for Pediatric and Congenital Heart Surgery. Participation in such a national database allows for program evaluation, as well as means for clinical improvement. Given the volume of pediatric surgeries performed, it is important to track them via database outcomes and collect feedback as to what types of interventions increased the likelihood of positive outcomes and also gives the ability to identify opportunities. Research has shown that participation in multi-institutional databases/registries improves patient outcomes.  S: The Steering Committee was divided in regards to the ratings for scientific acceptability; they ranged from high to moderate. Another similar measure was previously endorsed for adult cardiac surgery (NQF measure #0113.  U: The Steering Committee agreed that this measure rated highly for usability. While the measure developers stated that this measure of participation in a database is not limited to the STS database, the STS database is used by a large number of programs already and retains over 90%

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(Owner)	Steering Committee Evaluation and Recommendation
	of active programs in the United States.  F: Members of the Steering Committee rated this measure highly overall for feasibility. It is easy to implement, as so many programs use this database and the mechanism for data procurement. Susceptibilities to errors have been addressed by the measure developers. Although this information is probably kept in the institutions, it is noted that it may be more difficult for smaller institutions to adhere to this measure. There were concerns raised regarding how submission of data to a registry would, as well as this being an expensive endeavor that requires high-level administrative commitment in order to implement. In response to a question about whether the measure requires participation in the STS database, the developer confrimed that the emasure did not specify the STS registry.
PCS-002-09	Recommendation: Time-Limited Endorsement Yes-7; No-1; Abstain-0
Multidisciplin ary preoperative planning	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-2; M-4; L-3 <u>U</u> : H-6; M-3; L-0 <u>F</u> : H-4; M-5; L-0
conference (Society of Thoracic Surgeons)	<ul> <li>Discussion:</li> <li>I: This measure was rated highly for importance by the Steering Committee as a high impact issue. The relationship of this structure measure to outcome is based solely on expert opinion and there does not appear to be strong evidence. While the presence of this conference has not been evaluated in research studies, the Committee thought it made sense that if a program has such a conference, the issues can be aired and discussed before the operation is performed.</li> <li>S: The ratings for scientific acceptability varied widely among the Steering Committee. The question was raised of what constitutes a meeting; it is unclear from the measure specification if there are specific components of this meeting that should be done in order answer "yes".</li> <li>U: Pre-operative conferences enhance both the process of the operation and education for trainees.</li> <li>F: The Steering Committee felt this measure may be fairly easy to implement. However, In order for this measure to be assessed, some form of minutes would have to be maintained in order to monitor the extent to which the cases are discussed. In many cases, some form of standardized minutes would be necessary for retrospective analysis by an evaluating committee. Therefore, the data elements do not derive from electronic sources unless there is a hospital specific documentation requirement. Practically, this is important but the ability to ensure conferences maintain specific standards between centers would be challenging.</li> </ul>
PCS-003-09	Recommendation: Time-Limited Endorsement Yes-9; No-0; Abstain-0
Multidisciplin ary rounds involving multiple	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-2; M-6; L-1 <u>U</u> : H-6; M-2; L-1 <u>F</u> : H-4; M-5; L-0
members of the healthcare team (Society of Thoracic Surgeons)	Discussion: I: There was general consensus that this measure was important to measure and report. Each member of the congenital heart team has expertise in the enterprise. These include: cardiology, cardiac surgery, critical care, anesthesiology, nursing staff, nutrition, and respiratory care. Clear and detailed rounds help to plan the therapeutic interventions. There is strong evidence that multidisciplinary rounds leads to improved clinical outcomes. This measure is of particular importance in advancing the partnership between families and healthcare providers. Given the nature of children with cardiac related issues, it is usually their families and/or caregivers who need to be fully engaged in the care plan. Effective communication among all entities involved in direct patient care should improve outcomes. Superior results in congenital heart surgery have come from programs that have interdisciplinary rounds. These programs should be emulated.  S: The measure is not precisely specified in that the numerator differs from the measure description. While the measure does specify that rounds take place daily, similar to PCS-002-09, there is no definition or description of "rounds" and its components. Specifications will need to be more well defined, specifically how to determine if this has been met or not.  U: Steering Committee members felt this will be easy to assess and was a distinct measure that was understandable and useful.  F: Members of the Steering Committee felt this measure was easy to assess through the presence of the process and notes in the patients' charts. Data can also be easily retrieved through EPIC or a chart review.

Meas# / Title/	
(Owner)	Steering Committee Evaluation and Recommendation
PCS-004-09	Recommendation: Time-Limited Endorsement Yes-9; No-0; Abstain-0
Regularly	The commendation time Emines Emergentative to c, the c, the c, the commendation of
Scheduled	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-4; M-5; L-0 <u>U</u> : H-8; M-1; L-0 <u>F</u> : H-7; M-
Quality	2; L-0
Assurance	Discussion
and Quality Improvement	Discussion: I: Steering Committee members felt this is an important aspect of healthcare. There appears to be
Cardiac Care	indirect evidence from other fields that having such conferences improves quality. Quarterly
Conference	meetings to discuss care and improvement opportunities will provide a foundation to achieve high
(Society of	quality health care. This measure is a high impact aspect because it is believed that based on these
Thoracic	discussions; healthcare teams will be able to maintain those activities which increased outcomes
Surgeons)	and work to better those which did not.  S: Similar to the two previous measures (PCS-003-09, PCD-003-09) the measure does not clearly
	state what are the components of a quality assurance (QA) & quality improvement (QI) care
	conference or if there is selection criteria for the patients discussed in the meeting. There is a lack
	of specificity in the numerator. More precise measure specifications are needed to make sure the
	measure will be comparable across sites.F: This would be easy to measure and implement.
PCS-005-09	Recommendation: Time-Limited Endorsement Yes-9; No-0; Abstain-0
Availability of	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-6; M-3; L-0 <u>U</u> : H-7; M-2; L-0 <u>F</u> : H-8; M-
Intraoperativ	1; L-0
е	
Transesopha	Discussion:
geal	I: The Steering Committee felt TEE is a well-known and well documented imaging technique which
Echocardiogr aphy (TEE)	has been shown to positively affect the outcome of operations for congenital heart disease. There is an unclear gap in range of access to this and its appropriate use; this may be a difficult issue.
(Society of	Committee discussion revolved around the many publications that support the use of TEE.
Thoracic	S: This measure would be used to determine the availability of the TEE, not necessarily whether it's
Surgeons)	being used for those patients who need it, as this is not a patient-level measure.
	<b>U:</b> The measure would be more useful if it include a percentage of patients in which TEE is used. Future inquiries may state that TEE should be used in a certain number of patients.
	<b>F:</b> Easy to measure by any database including the EPIC system and chart review. The measure
	should be available from clinical sources on a patient level, however, that is not required as this is a
	structure measure. Use of TEE or ECLS in individual patients can be captured, but that does not
	always imply consistent availability.
PCS-006-09	Recommendation: Time-Limited Endorsement Yes-8; No-0; Abstain-1
Availability of	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-4; M-5; L-0 <u>U</u> : H-8; M-1; L-0 <u>F</u> : H-7; M-
Institutional	2; L-0
Pediatric	
ECLS	Discussion:
(Extracorpor eal Life	I: The Steering Committee cited that multiple manuscripts have documented the importance of this modality which can rehabilitate hearts, save lives, and in the end serve as a bridge to
Support)	transplantation. Clear evidence exists which is tied to improved outcomes of ECLS therapy in
(Society of	cardiac surgery patients with an estimated 50-60% survival. There was concern regarding the
Thoracic	overlap of ECLS and ECMO programs. Is having one more program more beneficial (in terms of
Surgeons)	outcomes) than the other for cardiac patients?
	<b>S:</b> This measure requires clarification of hospital criteria for eligibility, and also clarification of what having a "program" actually means; having any ECLS capability at all versus how available it is.
	U: The Steering Committee agreed it was an easily understandable and usable measure.
	F: The issue of capturing the data was discussed. Data on use for individual patients can be
	retrieved by the STS database and EPIC systems. However, as it is a structure measure, it does
	not use patient level data and is focused only on the program availability. There was also discussion surrounding the measure being available in other registries.
DCS 007 00	
PCS-007-09 Surgical	Recommendation: Time-Limited Endorsement Yes-7; No-0; Abstain-1
Volume for	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-5; M-3; L-1 <u>U</u> : H-6; M-3; L-0 <u>F</u> : H-8; M-
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## Meas# / Title/ (Owner) Steering Committee Evaluation and Recommendation Pediatric and 1; L-0 Congenital Heart Discussion: Surgery I: The difficulty in this measure is to determine at what point the cut-off is. It is unclear about the link (STS) of volume to outcome, though there is likely a floor below which outcome suffers. (Society of S: It is necessary to review procedure codes to take out non-cardiac surgery and non-surgery Thoracic processes. There is a need to address the capturing of surgery in adults for congenital vs. acquired Surgeons) disease. This measure requires use of STS codes or a crosswalk from ICD-9-CM for those who do not use the STS database, for example. It requires careful attention to the definitions of what are enough cases and what the cases should be. Harmonization with existing pediatric cardiac surgery volume measure vs. value-added of this measure needs to be addressed. U: It is not harmonized with NQF-endorsed measure #0340. Some thought that data derived from a clinical dataset is a more valid representation of number of procedures than the administrative data used in the existing NQF-endorsed measure. In response to a question of why both this measure and PCS-008 were needed, the developer responded that the total by mortality level would not equal the total for this measure. **F:** This measure can be calculated with simple addition. PCS-008-09 Recommendation: Time-Limited Endorsement Yes-9; No-0; Abstain-0 Surgical Volume for Final Measure Evaluation Ratings: I: Y-9; N-0 S: H-6; M-3; L-0 U: H-9; M-0; L-0 F: H-9; M-Pediatric and 0: L-0 Congenital Heart Discussion: Surgery, I: Overall, the Steering Committee agreed this measure met the importance criteria. The STS-Stratified by EACTS Mortality Score is a stratified schema based on true data. This score was implemented by the Five STSseveral authors based on actual data from the STS database. This measure is used in conjunction with the STS mortality measure stratfied by risk level (PCS-018) **EACTS Mortality S:** This being risk-stratified basically requires the use of STS codes. Levels (STS) U: The Steering Committee believes that this is a unique and understandable measure, which adds to its value. It can be useful for comparisons across centers. This is not harmonized to previously (Society of Thoracic NQF-endorsed measure #0339, as this uses a more robust identification of procedures. F: The Committee agreed on a high feasibility rating. Surgeons) Recommendation: Time-Limited Endorsement Yes-8: No-0: Abstain-1 PCS-010-09 Timing of **Antibiotic** Final Measure Evaluation Ratings: I: Y-8; N-0 S: H-6; M-2; L-0 U: H-6; M-2; L-0 F: H-6; M-Administratio 2: L-0 n for Pediatric and Discussion: Congenital I: The Steering Committee believes this measure is clinically relevant and has a clear linkage to Cardiac improve outcome measures. There is data to support that the timely administration of antibiotics will prevent infections. Many manuscripts support the notion of this measure. There is evidence that Surgery adherence to timing improves outcomes in pediatric cardiac surgery, however it is limited. (Society of Thoracic S: The Steering Committee felt that exclusions for numerator should match denominator. This measure is very similar to measure NQF #0125, but this measure is more specific for congenital Surgeons) heart surgery. The denominator exclusions (e.g., pts who were excluded because they were on antibiotics on admission) are examples of true exclusions. Adults with surgery for acquired heart disease or pts of any age with non-cardiac surgery are not exclusions per se; they were never in the INCLUDED class of pts in the first place (i.e. "Any operation that is not a pediatric or congenital Cardiac Operation. Cardiac operations are defined as operations that are of operation types of "CPB" or "No CPB Cardiovascular" (CPB is cardiopulmonary bypass)"). This distinction is important because you would want to track the number of true exclusions for a given measure. Also, knowing the number of patients excluded from some measure because of inadequate documentation of things like incision and/or antibiotic start times would itself be important and should not be exclusion. U: The Committee was divided over whether this measure should be combined with the antibiotic selection measure (PCS-011-09). Proponents of this approach expressed that selecting and administering the appropriate antibiotic is pointless if it is not done in a timely manner and is not

Meas# / Title/	
(Owner)	Steering Committee Evaluation and Recommendation
	weight appropriate; all of these things need to be done in order for the antibiotic to be useful. Those who felt the measure should stand alone argued that for quality improvement purposes it would be better to keep them separate to determine where the issues may have occurred; ordering or administration.  F: Easy to measure since most programs have a "Time-out" that includes the administration of antibiotics. This information is monitored by the staff and can be retrieved.
PCS-011-09	Recommendation: Time-Limited Endorsement Yes-5; No-2; Abstain-2
Selection of Antibiotic Administratio n for	Final Measure Evaluation Ratings: <u>I</u> : Y-8; N-1 <u>S</u> : H-4; M-3; L-1 <u>U</u> : H-3; M-5; L-0 <u>F</u> : H-2; M-4; L-1
Pediatric and Congenital Cardiac Surgery Patients (Society of Thoracic Surgeons)	Discussion:  I: The Steering Committee believes that this is a relevant measure with high impact; surgical site infection in cardiac patients is a major complication. The Steering Committee is not sure that there are data as to the "best" antibiotics to administer to patients. This measure would be hard to monitor because of the large number of antibiotics that might be used around the country.  S: There is an array of acceptable antibiotics that could be used and they change often. Experience with measures in other fields indicates that options for quickly changing the approved drug list in the specifications need to be in place. Body weight is not the only factor that determines appropriate dosages of antibiotics in high-risk patients. Clinicians take into account renal/liver dysfunction and anticipated drug clearance. The measure does not clearly identify who is responsible for selecting the dose.  U: The measure is usable and distinct from other NQF cardiac surgery measures. Recommend adoption by itself or combined with PCS-010-09.  F: The Steering Committee felt this should be easy to obtain from electronic medical records. Once the type of antibiotic has been established for the measure, the implementation should be easy since it is a matter of record in the chart.
PCS-012-09	Recommendation: Time-Limited Endorsement Yes-8; No-1; Abstain-0
Use of an Expanded Pre- Procedural	<b>Final Measure Evaluation Ratings: <u>I</u>:</b> Y-9; N-0 <u><b>S</b></u> : H-3; M-5; L-1 <u><b>U</b></u> : H-5; M-4; L-0 <u><b>F</b></u> : H-3; M-4; L-2
and Post- Procedural Time-Out (Society of Thoracic Surgeons)	Discussion:  I: This is an emerging area of research with evidence that has been shown to relate "time-outs" to improved outcomes. Data are not amassed yet to determine whether this measurement will yield excellent results, but it makes sense and most places around the country are already doing this as a policy. This is a critical component of knowledge sharing for the healthcare team.  S: This measure needs to specify if this is an all-or-nothing measure with all four of the areas.  U: The Steering Committee thought this measure needed to be specified as all-or-none or not to improve usability, but that it is easy to use.  F: Measuring presence of the "time-outs" in the program may be difficult. This information is not routinely documented and it is unclear if it has to occur for every patient. However, this measure of care is something that is important to implement and monitor.
PCS-018-09	Recommendation: Endorsement Yes-8; No-1; Abstain-0
Operative Mortality Stratified by the Five STS-	Final Measure Evaluation Ratings: <u>I</u> : Y-9; N-0 <u>S</u> : H-8; M-1; L-0 <u>U</u> : H-6; M-2; L-0 <u>F</u> : H-8; M-1; L-0
EACTS Mortality Levels (Society of Thoracic Surgeons)	<b>Discussion:</b> I: Understanding comparative mortality across institutions following congenital and pediatric cardiac surgery is immensely important.  S: At NQF's request to standardize this measure, one method of risk stratification was selected by the developer. The capture of post-discharge mortality, especially for distant referrals needs to be assured for this measure to work. This measure requires use of STS codes. Similar to the concerns expressed above for the process measures regarding the selection of STS codes, this also applies for this outcome measures as they share the same code set. STS-EACTS mortality score is based mostly on actual data that have been assessed by the STS and EACTS databases.

Meas# / Title/ (Owner)	Steering Committee Evaluation and Recommendation
	<b>F:</b> There is the need to use the STS-EACTS database to generate the measure and determine complexity levels.
PCS-021-09 Standardized Mortality Ratio for Congenital Heart Surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) method (Children's Hospital, Boston)	Recommendation: Endorsement Yes-8; No-1; Abstain-0  Final Measure Evaluation Ratings: I: Y-9; N-0 S: H-7; M-1; L-1 U: H-5; M-2; L-1 F: H-6; M-2; L-1  Discussion: I: This is an important outcome measure in this at-risk surgical population. S: The Committee agreed this measure demonstrated scientific acceptability based on the submitted information. This measure uses the RACHS-1 system of risk analysis based on observed mortality (numerator) as related to expected mortality (denominator). The risk analysis takes into account all risk levels and condenses the programs performance on the basis of O/E. any score of 1.0 or over would indicate the observed mortality is greater than the expected mortality and therefore should indicate that the program is underachieving. Although there have been concerns expressed in the literature with the use of administrative datasets, particularly in areas in which the coding choices are limited. There was some concerned addressed about the conversion of the ICD-9-CM codes to ICD-10-CM, however the developer confirmed they have already began the mapping process for this measure.  F: The data items required for this measure can be easily collected through manual chart abstraction for information to determine the RACHS-1 score and administrative data. Particularly with administrative data, the burden of gathering data items to calculate the measure is low.