NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for Pediatric Cardiac Surgery
Summary of the Pediatric Cardiac Surgery Steering Committee Conference Call
May 17, 2010, 3:00-5:00 PM ET

Steering Committee Members Present: Lisa Kohr, MS, MPH, RN, CPNP (*Co-Chair*); Howard Jeffries, MD, MPH, MBA (*Co-Chair*); Nancy Ghanayem, MD; Sylvia Lopez, MD; Constantine Mavroudis, MD; John Mayer, MD; Schonay Barnett Jones, MBA

NQF Staff Present: Karen Pace, RN, PhD; Ashlie Wilbon, RN, MPH; Sarah Fanta

Audience Members Registered: Jeff Jacobs, MD, FACS, FACC; Marshall Jacobs, MD; Jane Han, MSW; Kathy Jenkins, MD, MPH

INTRODUCTIONS

Ashlie Wilbon gave a brief overview of where the Pediatric Cardiac Surgery project currently stands. General Counsel for NQF, Ann Hammersmith, asked the group for new disclosures or conflicts of interest.

PROJECT UPDATE AND NEXT STEPS

The purpose of the call was to discuss the 13 updated measures for this project. Following the in-person meeting in October 2009, NQF conducted a review of the untested measures to determine if any reliability or validity testing data for the specified measures were available. In December 2009, the NQF Board reviewed and revised the policy on time-limited endorsement for untested measures. Although NQF has never granted time-limited endorsement to outcome measures requiring risk-adjustment, the revised policy explicitly makes untested outcome measures requiring risk-adjustment ineligible for time-limited endorsement. The revised policy also restricts the use of time-limited endorsement to specific conditions. However, this project's untested structure and process measures will continue to be considered for time-limited endorsement. If the outcome measures submitted did not require risk adjustment they also could be considered for time-limited endorsement. The NQF criteria require risk-adjustment/stratification of outcome and resource use measures, or adequate rationale and analyses to justify that risk-adjustment is not necessary. NQF staff worked directly with the measure developers to clarify these issues. As a result, the developers withdrew eight outcome measures from the process because they agreed that they required risk-adjustment.

The Steering Committee was asked to review the updated information for the 13 remaining measures. The votes submitted on these 13 revised measures will supersede those from the Committee's October meeting to recommend measures. The Committee members did not vote

on the 13 revised measures during the call; rather they voted online after the call using a link that was provided via email. The Committee was instructed to vote for each measure based on individual merit and how well it meets the evaluation criteria, not based on how it compares to other measures. Members who were not on the call were encouraged to review the recording of the call prior to submitting their votes.

Following the voting, a draft report will be compiled by NQF staff and posted online for public comment. The Committee will reconvene after the comment period to discuss submitted comments and to make final recommendations prior to the measures being presented for member voting and CSAC approval. Depending on the measures that are recommended by the Committee, there may also be a need for subsequent discussions to reconcile the Committee's recommendations for similar competing measures (on the same topic and same target population). Similar competing measures may be those that are already endorsed and/or those that have been submitted for this project.

MEASURE DEVELOPERS REVIEW OF UPDATED MEASURES

Each of the measure developers was given the opportunity to provide a brief overview of the changes, updates, and additional information provided for the re-review process.

OVERVIEW OF MEASURES

The information provided in this summary is a combination of written and verbal comments that were provided by the Steering Committee.

Structure Measures Discussion

All of the submitted structure measures are untested; that is, reliability or validity data are not available. Therefore, evaluation of scientific acceptability is limited to review of measure specifications. Although evidence was provided to show that the reliability and validity of the outcome and procedure data in the current Society of Thoracic Surgeons (STS) database have been verified, the measure developer acknowledged that the data for the structure measures have not yet been added to the database. Therefore, these measures are only eligible for time-limited endorsement.

Steering Committee members posed questions about the use of the codes included for the structure measures. The measure developer agreed that the codes are unnecessary (except for the codes submitted for measure PCS-007-09), because the structure measures are "yes" or "no" and are measured at the program rather than the patient level. Additionally, because these structure measures are measured at the program level, the data required will not be captured by paper or electronic medical records.

PCS-001-09 Participation in a national database for pediatric and congenital heart surgery
Participation in at least one multi-center, standardized, data collection, and feedback program

that provides benchmarking of the physician's data relative to national and regional programs and uses process and outcome measures

Importance to measure and report: The Steering Committee agreed that this activity 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 for means for clinical improvement. Given the volume of pediatric surgeries performed, it is important to track them via a database and to collect feedback as to what types of interventions increase the likelihood of positive outcomes, which enhances the ability to identify opportunities. Research has shown that participation in multi-institutional databases/registries improves patient outcomes.

Scientific acceptability of the measure properties: The Steering Committee members' ratings for scientific acceptability ranged from high to moderate.

Usability: The Steering Committee agreed that this measure rates highly for usability. Although the measure developers stated that participation in a database is not limited to the STS database, the STS database is already used by a large number of programs and includes more than 90 percent of the active programs in the United States. A similar measure was previously endorsed for adult cardiac surgery (NQF measure #0113).

Feasibility: The Steering Committee rated this measure highly overall for feasibility. It is easy to implement, because many programs use the STS database and the mechanism for data procurement. The measure developers have addressed susceptibilities to errors. Although the required information is most likely maintained within the institutions, several committee members believed that it may be more difficult for smaller institutions to adhere to this measure. Other members raised concerns about how submission of data to a registry would work with EHR's, as well as about the expenses that might be incurred to implement a measure that requires a high level of administrative commitment. When asked if the measure requires participation in the STS database, the measure developer confirmed that the measure does not specify the STS registry.

PCS-002-09 Multidisciplinary preoperative planning conference *Occurrence of a pre-operative multidisciplinary planning conference to plan pediatric and congenital heart surgery cases. This conference will involve multiple members of the healthcare team, with recommended participation, including but not limited to: cardiology, cardiac surgery, anesthesia, and critical care.*

Importance to measure and report: The Steering Committee rated this measure highly for importance because it addresses a high-impact issue. The relationship of this structure measure to outcome is based solely on expert opinion rather than on strong evidence. Although this type of conference has not been evaluated in research studies, the Committee thought it was reasonable

to expect that issues will be aired and discussed before surgery is performed if a program has such a conference.

Scientific acceptability of the measure properties: The ratings for scientific acceptability varied widely among the Steering Committee members. The question of what constitutes a meeting was raised. Furthermore, it is unclear from the measure specifications if there are specific components of this meeting that should exist in order to answer "yes."

Usability: Preoperative conferences enhance both the process of the operation and education for trainees.

Feasibility: The Steering Committee believed that this measure will be fairly easy to implement. However, for the measure to be assessed, some form of minutes must be maintained to allow for monitoring of the extent to which cases are discussed. In many cases, standardized minutes will be necessary for retrospective analysis by an evaluating committee. Therefore, the data elements will not derive from electronic sources unless there is a hospital-specific documentation requirement. Practically, this is important, but ensuring that standards for conferences are maintained across centers will be challenging.

PCS-003-09 Multidisciplinary rounds involving multiple members of the healthcare team
Occurrence of multidisciplinary rounds for pediatric and congenital cardiac surgery patients involving multiple members of the healthcare team, with recommended participation, including but not limited to: cardiology, cardiac surgery, critical care, primary caregiver, family, nurses, pharmacist, and respiratory therapist. Involvement of the family is encouraged.

Importance to measure and report: There was general consensus that this activity is important to measure and report. Each member of the congenital heart team has experts in the enterprise; these include: cardiology, cardiac surgery, critical care, anesthesiology, nursing staff, nutrition, and respiratory care. Clear and detailed rounds help with planning of the therapeutic interventions. There is strong evidence that multidisciplinary rounds lead 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.

Scientific acceptability of the measure properties: The measure is not precisely specified because the numerator differs from the measure description. Although the measure specifies that rounds should take place daily, similar to PCS-002-09, there is no definition or description of a "round" and its components. Specifications need to be better defined, specifically with regard to how the requirements have or have not been met.

Usability: Steering Committee members believed that this measure is distinct, understandable, and useful and will be easy to assess.

Feasibility: Steering Committee members believed that this measure will be easy to assess through the presence of the process and notes in the patients' charts. Information on whether this activity has occurred for a specific patient can be retrieved through a chart review.

PCS-004-09 Regularly scheduled quality assurance and quality improvement cardiac care conference *Occurrence of a regularly scheduled quality assurance and quality improvement cardiac care conference to discuss care provided to patients who undergo pediatric and congenital cardiac surgery operations and to discuss opportunities for improvement. This conference should be held at least every three months (quarterly).*

Importance to measure and report: Steering Committee members believed that this is an important aspect of healthcare. There appears to be indirect evidence from other fields that having such conferences improves quality. Quarterly meetings to discuss care and opportunities for improvement will provide a foundation for high-quality healthcare. This measure will have a high impact because healthcare teams will be able to maintain those activities that increased outcomes and work to better those that did not.

Scientific acceptability of the measure properties: Similar to the two previous measures (PCS-002-09, PCS-003-09) the specifications do not clearly identify the components of a quality assurance (QA) and quality improvement (QI) care conference and the criteria for selecting the patients to be discussed during the conference. There is a lack of specificity in the numerator. More precise measure specifications are needed to ensure that the measure is comparable across sites.

Feasibility: This measure will be easy to measure and implement.

PCS-005-09 Availability of intraoperative transesophageal echocardiography (TEE) *Availability of intraoperative transesophageal echocardiography (TEE) for pediatric and congenital heart operations*

Importance to measure and report: The Steering Committee believed that TEE is a well-known and well-documented imaging technique that has been shown to positively affect the outcome of operations for congenital heart disease. It is unclear how accessible this tool is to facilities and the range of appropriate use, which may be a difficult issue. The Committee's discussion revolved around the many publications that support the use of TEE.

Scientific acceptability of the measure properties: Because this is not a patient-level measure, it will be used to determine the availability of TEE, not necessarily whether it is being used for patients who need it.

Usability: The measure will be more useful if it includes a percentage of patients for which TEE is used. Future inquiries may state that TEE should be used in a certain number of patients.

Feasibility: This measure will be easy to report using any database including the EPIC system and chart review. Although not required because this is a structure measure, data from the patient level should be available from clinical sources. Use of TEE or extracorporeal life support (ECLS) in individual patients can be captured, but that does not always imply consistent availability.

PCS-006-09 Availability of institutional pediatric ECLS (extracorporeal life support) *Availability of an institutional pediatric extracorporeal life support (ECLS) program for pediatric and congenital cardiac surgery patients.*

Importance to measure and report: 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 transplantation. Clear evidence exists that ties improved outcomes to ECLS therapy in cardiac surgery patients with an estimated 50 to 60 percent chance of survival. Some Committee members expresses concern about the overlap of ECLS and ECMO programs: Does one program produce better outcomes than the other for cardiac patients?

Scientific acceptability of measure properties: The measure specifications must better clarify the criteria for eligibility and what having a "program" actually means (e.g., having any ECLS capability at all, existing program components, and how available it is).

Usability: The Steering Committee agreed that the measure is easily understandable and usable.

Feasibility: The Steering Committee discussed the issue of capturing the measure data. Data on ECLS use for individual patients can be retrieved by the STS database and EPIC systems. However, the measure does not require patient-level data because it is a structure measure focused only on the program availability. There was also discussion surrounding the availability of measure data in other registries.

PCS-007-09 Surgical volume for pediatric and congenital heart surgery *Surgical volume for pediatric and congenital heart surgery*

Importance to measure and report: The Steering Committee concluded that the difficulty in this measure is in determining at what point the cut-off should be. The relationship between volume and outcome is unclear, although there is likely a volume below which outcome suffers.

Scientific acceptability of measure properties: The Steering Committee identified the following issues with this measure: 1) the need to review procedure codes to remove non-cardiac surgical and non-surgical procedures; 2) the capture of surgery in adults for congenital versus acquired disease; 3) the requirement to use STS codes or a crosswalk from ICD-9-CM for those who do not use the STS database; and 4) the need to pay careful attention to the definitions of what is enough cases and what the cases should be.

Usability: This measure is similar to NQF-endorsed measure #0340; the added value of this measure versus the existing measure will need to be discussed. Several Committee members stated that data derived from a clinical dataset more validly represent the number of procedures than do the administrative data used in the NQF-endorsed measure. In response to the question of why both this measure and PCS-008-09 are needed, the measure developer stated that the total by mortality level would not equal the total for this measure.

Feasibility: This measure can be calculated with simple addition.

PCS-008-09 Surgical volume for pediatric and congenital heart surgery, stratified by the five STS-EACTS Mortality Levels *Surgical volume for pediatric and congenital heart surgery stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool*

Importance to measure and report: Overall, the Steering Committee agreed that this measure meets the importance criteria. The STS-EACTS Mortality Score is a stratified schema based on true data. This score was implemented by several authors based on actual data from the STS database. This measure is used in conjunction with the STS mortality measure stratified by risk level (PCS-018-09).

Scientific acceptability of measure properties: Risk-stratification basically requires the use of STS codes.

Usability: The Steering Committee believed that this is a unique and understandable measure, which adds to its value. It can be useful for comparisons across centers. The measure is not harmonized to NQF-endorsed measure #0339, because it uses a more robust identification of procedures.

Feasibility: The Steering Committee agreed on a high feasibility rating.

PCS-012-09 Use of an expanded pre-procedural and post-procedural time-out *Use of an expanded pre-procedural and post-procedural "time-out" that includes the following elements: 1) The conventional pre-procedural "time-out", which includes identification of patient, operative site, procedure and history of any allergies; 2) A pre-procedural briefing wherein the surgeon shares with all members of the operating room team the essential elements of the*

operative plan; including diagnosis, planned procedure, outline of essentials of anesthesia and bypass strategies, anticipated or planned implants or device applications, and anticipated challenges; 3) A post-procedural debriefing wherein the surgeon succinctly reviews with all members of the operating room team the essential elements of the operative plan, identifying both the successful components and the opportunities for improvement. This debriefing should take place prior to the patient leaving the operating room or its equivalent, and may be followed by a more in-depth dialogue involving team members at a later time. (The actual debriefing in the operating room is intentionally and importantly brief, in recognition of the fact that periods of transition may be times of instability or vulnerability for the patient.); 4) A briefing or hand-off protocol at the time of transfer (arrival) to the Intensive Care Unit at the end of the operation, involving the anesthesiologist, surgeon, physician staff of the Intensive Care Unit (including critical care and cardiology) and nursing.

Importance to measure and report: This is an emerging area of research with evidence that shows that "time-outs" are related to improved outcomes. Data are not yet amassed to determine whether this measurement will yield excellent results, but it makes sense, and most centers around the country are already using time-out as a policy. Time-out is a critical component of knowledge sharing for the healthcare team.

Scientific acceptability of measure properties: The measure specifications must specify if this is an all-or-nothing measure with all four of the areas.

Usability: The Steering Committee believed that this measure will be easy to use but must be specified as all-or-none or not to improve usability.

Feasibility: Measuring the presence of time-outs in a program may be difficult. Such information is not routinely documented, and it is unclear if time-outs have to occur for every patient. However, this is a measure of care that is important to implement and monitor.

Process Measures Discussion

Both of the submitted process measures are untested; reliability or validity data are not available. Therefore, evaluation of scientific acceptability is limited to review of measure specifications. Although evidence was provided to show that the reliability and validity of the current STS data have been verified, the measure developer acknowledged that the measures have not yet been added to the database. Therefore, these measures are only eligible for time-limited endorsement.

Steering Committee members expressed concern about the codes used for these measures. For all measures specified with STS codes, centers that don't participate in the STS registry can still use STS codes to identify appropriate cases for reporting. This requires cross-walking from some other coding system (e.g., ICD-9-CM or PCCC) to STS, or manual review of cases to see which

ones fit the text descriptions associated with the STS codes. Although it can be inferred from the listed codes, it should perhaps be clarified that "heart" surgery includes surgery on the thoracic great vessels. The reason for inclusion of STS V3.0 codes for procedures that are not cardiac surgery (e.g., 1340 [transcatheter], 1860 [mediastinal], others) is unclear. To include adult cases, it would appear that STS V3.0 diagnosis codes for congenital lesions would need to be included when the repair is for acquired rather than congenital disease. It should not be assumed that all cases of congenital conditions such as valve disease would have been treated in childhood; all cases of valve disease in adults are acquired such that valve repairs in adults would therefore not be included here. Consequently, the use of these measures requires revision of codes for surgery.

Consideration should also be given to how many procedures must be performed in a certain timeframe in order for the measure to be applicable. For example, is 1 versus 5 versus 50 pediatric cardiac surgery cases a year enough to qualify for being judged on a given measure?

PCS-010-09 Timing of antibiotic administration for pediatric and congenital cardiac surgery *Percent of patients undergoing pediatric and congenital cardiac surgery who received prophylactic antibiotics within one hour of surgical incision (two hours if receiving vancomycin)*

Importance to measure and report: The Steering Committee believed that this measure is clinically relevant and has a clear linkage to improved outcome measures. There is data to support that the timely administration of antibiotics prevents infections. There is also evidence that adherence to timing improves outcomes in pediatric cardiac surgery, although on a limited basis.

Scientific acceptability of the measure properties: The Steering Committee believed that exclusions for the numerator should match the denominator. The denominator exclusions (e.g., patients who were excluded because they were on antibiotics on admission) are examples of true exclusions. Adults with surgery for acquired heart disease or patients of any age with non-cardiac surgery are not exclusions per se; they are never in the included class of patients 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 it is desirable 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 such things as incision and/or antibiotic start times is itself important and should be captured.

Usability: The Steering Committee was divided over whether this measure should be combined with the antibiotic selection measure (PCS-011-09). Proponents of this approach believed that the selection and administration of the appropriate antibiotic is pointless if it is not done in a timely manner and is not weight appropriate. Those Committee members who opposed combining the measures argued that for quality improvement purposes it would be better to keep them separate to determine when the issues may have occurred: selection or administration. This

measure is very similar to NQF-endorsed measure #0125, but it is more specific to congenital heart surgery.

Feasibility: This process will be easy to measure because most programs have a time-out that includes the administration of antibiotics and because this information is monitored and can be retrieved by the staff.

PCS-011-09 Selection of antibiotic administration for pediatric and congenital cardiac surgery patients *Percent of patients undergoing pediatric and congenital cardiac surgery who received body weight appropriate prophylactic antibiotics recommended for the operation*

Importance to measure and report: The Steering Committee believed 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, however, that data on the "best" antibiotics to administer to patients exist. This measure would be hard to monitor because of the large number of antibiotics that are used nationwide.

Scientific acceptability of measure properties: There are many acceptable antibiotics that can 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 must be in place. Body weight is not the only factor that determines the appropriate dosages of antibiotics in high-risk patients. Clinicians also take into account renal/liver dysfunction and anticipated drug clearance. The measure does not clearly identify who is responsible for selecting the dose.

Usability: The measure is usable and distinct from other NQF cardiac surgery measures. The Steering Committee recommended adoption of the measure by itself or combined with PCS-010-09.

Feasibility: The Steering Committee believed that the required information will be easy to obtain from electronic medical records. Implementation of the measure will be easy once the type of antibiotic has been established for the measure, because it is a matter of record in the chart.

Outcome Measures Discussion

Two outcome measures were submitted to this project: one a measure of operative mortality stratified by risk and the other a standardized mortality ratio (SMR) using the RACHS-1 in a statistical risk-adjustment model. Although these measures will be reviewed and voted on according to their individual merits and how well they meet the criteria, they measure similar outcomes in the same population of patients. Steering Committee members asked if the measures could co-exist as endorsed measures. Because these measures use different data sources and time periods—one (STS-EACTS) uses registry data and in-hospital or 30-day mortality, the other (SMR) uses administrative data in-hospital mortality—they could co-exist, if they both

meet the evaluation criteria. However, if they both meet the criteria, and given that they are similar measures, the Steering Committee may need to discuss whether they should co-exist and determine if there is a best-in-class measure between the two measures.

PCS-018-09 Operative mortality stratified by the five STS-EACTS Mortality Levels *Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool*

Importance to measure and report: Understanding comparative mortality following congenital and pediatric cardiac surgery across institutions is immensely important.

Scientific acceptability of measure properties: In an effort to standardize this measure, NQF asked the measure developer to select one method of risk-stratification. The capture of post-discharge mortality, especially for distant referrals, needs to be assured for this measure to work. This measure requires use of the same set of STS codes as do the process measures discussed above; therefore the same concerns regarding the selection of STS codes apply. The STS-EACTS mortality score is based mostly on actual data that have been assessed by the STS and EACTS databases.

Feasibility: There is the need to use the STS-EACTS database to generate the measure and to determine complexity levels.

PCS-021-09 Standardized mortality ratio for congenital heart surgery, Risk Adjustment for Congenital Heart Surgery (RACHS-1) method *Operative mortality stratified by the five STS-EACTS Mortality Levels, a multi-institutional validated complexity stratification tool*

Importance to measure and report: This is an important outcome measure for this at-risk surgical population.

Scientific acceptability of the measure properties: The Steering Committee agreed that this measure demonstrates scientific acceptability. 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 program's performance on the basis of O/E. A score of 1.0 or higher indicates that the observed mortality is greater than the expected mortality, and, therefore, the program is underachieving. Concerns have been expressed in the literature about the use of administrative datasets, particularly in areas in which the coding choices are limited. Some Committee members expressed concerns about the conversion of the ICD-9-CM codes to ICD-10-CM; however, the measure developer confirmed that it has already begun the mapping process for this measure.

Feasibility: The data required for this measure can be easily collected through manual chart abstraction to determine the RACHS-1 score and from administrative data. Particularly with administrative data, the burden of gathering data to calculate the measure is low.