

NQF

NATIONAL QUALITY FORUM

**National Voluntary
Consensus Standards
for Cardiac Surgery**

A
CONSENSUS
REPORT

NATIONAL QUALITY FORUM

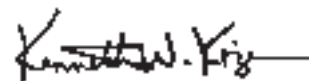
Foreword

Hearth disease is the leading cause of death in the United States and many other countries. Coronary artery bypass graft and other types of heart surgery are some of the most common major surgeries performed in the United States each year and are among the most costly—both in dollars and surgical morbidity. Indeed, cardiac surgical procedures are associated with more than 14,000 in-hospital deaths each year. Standardizing performance measures for common cardiac surgery procedures is needed and should have a significant public health benefit.

This report details 21 national voluntary consensus standards for cardiac surgery. The National Quality Forum (NQF) has endorsed these measures through its formal Consensus Development Process. Although cardiac surgery performance and outcomes measures are featured in a number of efforts aimed at public reporting of health-care quality, this is the first set of national standardized performance measures to assess the performance and outcomes of cardiac surgery.

The primary purpose of this set of voluntary consensus standards is to promote the highest quality of care for cardiac surgery. These standards are intended to inform both quality improvement and public accountability, including the public disclosure of results.

We thank NQF Members and the Cardiac Surgery Performance Measures Steering Committee and its Technical Advisory Panel for their stewardship of this work and for their dedication to improving the quality of healthcare in America by standardizing performance measurement of that most critical of healthcare procedures, cardiac surgery.



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National Voluntary Consensus Standards for Cardiac Surgery

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National Voluntary Consensus Standards for Cardiac Surgery

Executive Summary

Hearth disease is the leading cause of death and disability in the United States. Although many advances have been made in treatment and once seemingly remarkable interventions to treat patients with heart disease are now commonplace, common cardiac surgical procedures are associated with more than 14,000 in-hospital deaths each year. Improving the outcomes of these procedures would have major public health benefits.

This National Quality Forum (NQF) report details 21 consensus standards for cardiac surgery endorsed by NQF. It includes hospital-level structure, process, and risk-adjusted outcome consensus standards and related research and implementation recommendations. The endorsed measures have undergone rigorous vetting under the NQF Consensus Development Process and thus carry the special legal status of national voluntary consensus standards.

The NQF-endorsed cardiac surgery consensus standards were derived from the following priorities: existing NQF-endorsed consensus standards should be used when available and appropriate; the focus should be on the most common surgical procedures and on measures that are condition specific; and standards should address disparities of care. These consensus standards are intended for public reporting and accountability, but they also will inform internal quality improvement efforts.

The report also identifies recommendations for specific action or potential action and a number of high-priority areas for research and measure development. Generally, these are areas of high measurement priority for which candidate measures did not exist or that failed to meet established evaluation criteria. The priority research areas represent significant gaps in this set of voluntary consensus standards. Investigators, measure developers, and performance measurement organizations should view the endorsed research agenda as a roadmap for future progress.

National Voluntary Consensus Standards for Cardiac Surgery*

1. Participation in a systematic database for cardiac surgery
2. Surgical volume for isolated coronary artery bypass graft (CABG) surgery, valve surgery, and CABG+valve surgery
3. Timing of antibiotic administration for cardiac surgery patients**
4. Selection of antibiotic administration for cardiac surgery patients**
5. Pre-operative beta blockade
6. Use of internal mammary artery**
7. Duration of prophylaxis for cardiac surgery patients**
8. Prolonged intubation
9. Deep sternal wound infection rate
10. Stroke/cerebrovascular accident
11. Post-operative renal insufficiency
12. Surgical re-exploration
13. Anti-platelet medications at discharge
14. Beta blockade at discharge
15. Anti-lipid treatment at discharge
16. Risk-adjusted inpatient operative mortality for CABG
17. Risk-adjusted operative mortality for CABG
18. Risk-adjusted operative mortality for aortic valve replacement (AVR)
19. Risk-adjusted operative mortality for mitral valve replacement/repair (MVR)
20. Risk-adjusted operative mortality for MVR+CABG
21. Risk-adjusted operative mortality for AVR+CABG

* See the full report for specifications, risk adjustment (if applicable), additional background, and reference material.

** Also an NQF-endorsed voluntary consensus standard for hospital care.

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National Voluntary Consensus Standards for Cardiac Surgery

Introduction

Hearth disease is the leading cause of death and disability in the United States. Many advances have been made in the treatment of heart disease, including the development of once seemingly remarkable interventions that are now commonplace—for example, coronary artery bypass graft (CABG) surgery, performed on 305,000 patients in 2001, and heart valve surgery, performed 85,000 times.¹ Unfortunately, CABG and heart valve surgery are associated with more than 14,000 in-hospital deaths each year. Improving the outcomes of these procedures will have major public health benefits. Disparities in outcomes for these procedures that occur across patient groups also suggest opportunities for improving performance. For example, women and African Americans are at disproportionately high risk of death following CABG surgery, even after adjustment for clinical factors.^{2,3} For these reasons, heart disease is one of the 23 areas that the National Quality Forum (NQF) has endorsed as priorities for the identification of national healthcare quality voluntary consensus standards.⁴

¹American Heart Association (AHA). *Heart Disease and Stroke Statistics – 2004 Update*. Dallas, TX: AHA; 2003.

²Bridges CR, Edwards FH, et al. The effect of race on coronary bypass operative mortality. *J Am Coll Cardiol*. 2000;36(6):1870-1876.

³Surgenor SD, O'Connor GT, et al. Predicting risk of death from heart failure after coronary artery bypass graft surgery. *Anesth Analg*. 2001;92(3):596-601.

⁴NQF. *National Priorities for Healthcare Quality Measurement and Reporting*. Washington, DC: NQF; 2004. NQF-endorsed priorities are based, in part, on Institute of Medicine (IOM) priorities.

Cardiac surgery performance and outcomes are of considerable public interest and are featured in a number of efforts aimed at public reporting of healthcare quality, beginning with CABG mortality data reported by the federal government and New York state in the 1980s. More recently, public reporting efforts in states including Pennsylvania, California, and New Jersey include CABG outcome measures. Numerous healthcare purchasers also have started to use these measures. At the same time, national and regional groups have developed more detailed cardiac surgery performance measures. For example, the Society of Thoracic Surgeons (STS) has developed measures based on data submitted to its national database for benchmarking and feedback to surgeons and hospitals for quality improvement. (Currently, about 65 percent of hospitals that perform CABG surgery participate in the STS national database.) Thus, both the demand for valid cardiac surgery performance measures and the availability of a broad array of measures are growing rapidly.

National Voluntary Consensus Standards for Cardiac Surgery

This report presents a set of 21 NQF-endorsed national voluntary consensus standards for cardiac surgery, including hospital-level structure, process, and risk-adjusted outcome consensus standards, and related research recommendations.

To obtain the special legal status of national voluntary consensus standards, these measures have undergone rigorous vetting under the NQF Consensus Development Process (CDP) (appendix F), including an assessment of the standards' alignment and compatibility with existing provider requirements, accreditation standards, and recommendations of advisory bodies to federal agencies (e.g., the Institute of Medicine). To minimize the burden to providers, most of the consensus standards have their roots in national hospital initiatives (e.g., those of the Centers for Medicare and Medicaid Services [CMS] and professional organizations [STS]).

Relationship to Other NQF-Endorsed Consensus Standards

This report does not represent the entire scope of NQF work relevant to the quality of cardiac surgery. NQF has completed or is currently working on separate projects relevant to cardiac surgery performance in hospitals and its relationship to quality and patient safety. For example, *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set*⁵ identifies 6 consensus standards (of 39 hospital care performance measures) that pertain to cardiac surgery patients. Another NQF report, *A Comprehensive Framework for Hospital Care Performance Evaluation*, details a framework for constructing a complete and enduring set of hospital care consensus standards; it recommends processes for reporting, implementing, maintaining, evaluating, and improving the set.⁶ The NQF-endorsed framework for cardiac surgery performance measurement builds on both this hospital framework and the hospital consensus standards previously endorsed by NQF.⁷

Identifying the Initial Set

An NQF Steering Committee (appendix C) established the initial approach to identify, assess, and recommend potential consensus standards (appendix D). This approach included identifying a specific purpose, establishing a framework for measurement, defining scope and priority thresholds, and

screening candidate measures through the application of standardized evaluation criteria.

Purpose

The primary purpose of this set of voluntary consensus standards is to promote the highest quality of care for cardiac surgery patients and cardiac surgery candidates. These standards are intended to inform both quality improvement and public accountability, including the public disclosure of the results. They are intended for use by consumers, purchasers, providers, accreditors, quality improvement organizations, and researchers to enable them to make performance-based decisions about provider selection, to enhance value-based purchasing, to promote accountability of providers, to facilitate public use of health-care information, and to stimulate and facilitate the continuous improvement of care.

Applying the Hospital Framework to Cardiac Surgery

The NQF report *A Comprehensive Framework for Hospital Care Performance Evaluation* provided the outline for identifying candidate performance measures for cardiac surgery. The scope and priorities of this set of consensus standards are derived from the larger hospital framework structure to create a subframework focused on cardiac surgery.

⁵NQF. *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set*. Washington, DC: NQF; 2003.

⁶NQF. *A Comprehensive Framework for Hospital Care Performance Evaluation*. Washington, DC: NQF; 2003.

⁷NQF. *A National Framework for Healthcare Quality Measurement and Reporting*. Washington, DC: NQF; 2002.

Scope

The NQF-endorsed voluntary consensus standards for cardiac surgery encompass those that:

- relate to procedures performed by cardiac surgeons;
- are within the control of provider(s) who perform the surgery (whether within the control of the multidisciplinary team of the hospital or the individual surgeon, the continuum of care for cardiac surgery begins at the decision to perform surgery and continues through approximately one month of the post-operative period);
- address at least one of NQF's six aims for healthcare (that it be safe, beneficial, patient-centered, timely, efficient, and equitable); and
- are structure, process, and outcome consensus standards, as well as measures of appropriateness and frequency.

Priority Areas for Cardiac Surgery Performance Measurement

The NQF-endorsed voluntary consensus standards are derived from the following priorities for measurement:

- **Existing NQF-endorsed consensus standards.** The three cardiac surgery voluntary consensus standards and three consensus standards for antibiotic prophylaxis for all surgery patients from the NQF-endorsed hospital set form the basis for this set of voluntary consensus standards.

- **CABG, valve, combination CABG-valve surgeries.** These surgeries represent the largest number of cardiac surgical procedures. Congenital heart surgery and transplants are far less frequent and require different expertise.
- **Address disparities of care.** The measures specifically address disparities and do not simply break down data into subpopulations (e.g., age, gender).
- **Condition-specific, not cross-cutting, consensus standards.** The focus of this set is procedure-specific standards, rather than cross-cutting measures.⁸ Cross-cutting measures for surgical patients and all hospital patients are included in the NQF-endorsed set of hospital consensus standards.

Criteria for Selection of Consensus Standards

Candidate consensus standards were drawn from NQF's *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Set*, national hospital and surgical care performance measurement activities (e.g., CMS, STS, Zynx Health), and published research. Additionally, measures were solicited through a national call for measures that involved more than 70 professional organizations, the more than 180 NQF Member organizations, and public notice. Measures were evaluated based on the criteria endorsed by NQF, as derived from the previous NQF work of the Strategic Framework Board (box A) and

⁸ Cross-cutting issues are those "not specific to a clinical condition but integral to healthcare quality improvement across multiple clinical conditions, systems, or processes." From NQF's *A National Framework for Healthcare Quality Measurement and Reporting*, p. 3.

Box A – Criteria for Evaluation and Selection of Measures in the Cardiac Surgery Performance Measure Set

Proposed measures have been evaluated for their suitability based on four standardized criteria endorsed by NQF in 2003:⁹ important, scientifically acceptable, useable, and feasible. Not all acceptable measures are strong—or equally strong—for each of the four criteria, or strong within each related criteria. Rather, a candidate consensus standard is assessed regarding the extent to which it meets any of the desired criteria.

- 1. Important.** This set addresses the extent to which a measure reflects a variation in quality, low levels of overall performance, and the extent to which it captures key aspects of the flow of care.
 - a. The measure addresses one or more key leverage points for improving quality.
 - b. Considerable variation in the quality of care exists.
 - c. Performance in the area (e.g., setting, procedure, condition) is suboptimal, suggesting that barriers to improvement or best practice may exist.

- 2. Scientifically acceptable.** A measure is scientifically sound if it produces consistent and credible results when implemented.
 - a. The measure is reliable, producing the same results a high proportion of the time when assessed in the same population.
 - b. The measure is valid, accurately representing the concept being evaluated.
 - c. The measure is precise, adequately discriminating between real differences in provider performance.
 - d. The measure is adaptable to patient preferences and a variety of contexts of settings. Adaptability depends on the extent to which the measure and its specifications account for the variety of patient choices, including refusal of treatment and clinical exceptions.
 - e. An adequate and specified risk-adjustment strategy exists, where applicable.
 - f. Consistent evidence is available linking the process measures to patient outcomes.

continued

⁹Ibid.

Box A – Criteria for Evaluation and Selection of Measures in the Cardiac Surgery Performance Measure Set (continued)

- 3. Useable.** Usability reflects the extent to which intended audiences (e.g., consumers, purchasers) can understand the results of the measure and are likely to find them useful for decisionmaking.
 - a. The measure can be used to make decisions.
 - b. The differences in performance levels are statistically meaningful.
 - c. The differences in performance are practically and clinically meaningful.
 - d. Risk stratification, risk adjustment, and other forms of recommended analyses can be applied appropriately.
 - e. Effective presentation and dissemination strategies exist (e.g., transparency, ability to draw conclusions, information available when needed to make decisions).
 - f. Information produced by the measure can/will be used by at least one healthcare stakeholder audience (e.g., public/consumers, purchasers, clinicians and providers, policymakers, accreditors/regulators) to make a decision or take an action.
 - g. Information about specific conditions for which the measure is appropriate has been given.

- 4. Feasible.** Feasibility is generally based on the way in which data can be obtained within the normal flow of clinical care and the extent to which an implementation plan can be achieved.
 - a. The point of data collection is tied to care delivery, when feasible.
 - b. The timing and frequency of measure collection are specified.
 - c. The benefit of measurement is evaluated against the financial and administrative burden of implementation and maintenance of the measure set.
 - d. An auditing strategy is designed and can be implemented.
 - e. Confidentiality concerns are addressed.

the NQF-endorsed framework for hospital care performance evaluation.^{10,11,12}

The NQF-Endorsed National Voluntary Consensus Standards for Cardiac Surgery

The set is composed of 21 hospital-level measures that facilitate efforts to achieve higher levels of patient safety and better outcomes for patients (table 1). These standards are intended for public reporting. Because the consensus standards must be consistently specified to meet the goal of standardization, each measure is further specified for other components, including risk adjustment, in appendix A.

The NQF-endorsed national consensus standards for cardiac surgery constitute a parsimonious set that is intended to:

- be consistent with NQF-endorsed consensus standards for hospital care;
- reduce data collection burden;
- establish the measurement of an outcome or document associations with improved outcomes;
- address a major post-operative complication associated with CABG, which is the most common type of cardiac surgery; or
- improve long-term survival in patients with ischemic heart disease undergoing CABG.

Additional information related to the rationale for each consensus standard is provided in appendix D.

Although the goal of cardiac surgery is to reduce morbidity and mortality and improve quality of life for patients with coronary artery and heart valve disease, these standards do not address the most important outcome—quality of life. Stakeholders agree that a valid assessment of quality of life is the highest priority for assessing quality in cardiac surgery and that the lack of a quality-of-life measure in this set is a major deficiency. Development of a valid measure that can be implemented as soon as possible is urgently needed.

Recommendations to Accompany the Set

In addition to endorsing this set of voluntary consensus standards for cardiac surgery, NQF recommends that specific action or potential action be taken in nine areas of interest: proprietary measures; relationship of these standards to other NQF-endorsed standards related to cardiac surgery; data verification and auditing; use of the surgical volume measure; analysis of data for disparities; reporting of the internal mammary artery (IMA) use measure; level of analysis for public reporting; analysis of procedural frequency based on geography; and review and updating of the set.

¹⁰McGlynn EA. The Strategic Framework Board's design for a national quality measurement and reporting system. *Med Care*. 2003;41(1)suppl:1-1–I-89.

¹¹NQF. *A National Framework for Healthcare Quality Measurement and Reporting*. Washington, DC: NQF; 2002.

¹²NQF. *A Comprehensive Framework for Hospital Care Performance Evaluation*. Washington, DC: NQF; 2003.

Table 1 – National Voluntary Consensus Standards for Cardiac Surgery

1. **Participation in a systematic database for cardiac surgery.** Does the facility participate in a multicenter data collection and feedback program that provides benchmarking relative to peers and uses process and outcome measures?

2. **Surgical volume for isolated CABG surgery, valve surgery, and CABG+valve surgery.*** Annual procedural volume of three surgeries: isolated CABG surgery, valve surgery, and valve+CABG surgery.

3. **Timing of antibiotic administration for cardiac surgery patients.** Percent of patients undergoing cardiac surgery who received prophylactic antibiotics within one hour of surgical incision (two hours if receiving vancomycin).

4. **Selection of antibiotic administration for cardiac surgery patients.** Percent of patients undergoing cardiac surgery who received prophylactic antibiotics recommended for the operation.

5. **Pre-operative beta blockade.**** Percent of patients undergoing isolated CABG who received beta blockers within 24 hours preceding surgery.

6. **Use of internal mammary artery (IMA).**** Percent of patients undergoing isolated CABG who received an IMA graft.

7. **Duration of prophylaxis for cardiac surgery patients.** Percent of patients undergoing cardiac surgery whose prophylactic antibiotics were discontinued within 24 hours after surgery end time.

8. **Prolonged intubation.***** Percent of patients undergoing isolated CABG (without pre-existing intubation/tracheostomy) who require intubation for more than 24 hours.

9. **Deep sternal wound infection rate.***** Percent of patients undergoing isolated CABG who developed deep sternal wound infection within 30 days post-operatively.

10. **Stroke/cerebrovascular accident.***** Percent of patients undergoing isolated CABG (without pre-existing neurologic deficit) who develop a post-operative neurologic deficit persisting greater than 72 hours.

11. **Post-operative renal insufficiency.***** Percent of patients undergoing isolated CABG (without pre-existing renal failure) who develop post-operative renal failure or require dialysis.

12. **Surgical re-exploration.***** Percent of patients undergoing isolated CABG who require a return to the operating room for bleeding/tamponade, graft occlusion, or other cardiac reason.

13. **Anti-platelet medications at discharge.**** Percent of patients undergoing isolated CABG who were discharged on aspirin/safety-coated aspirin or clopidogrel.

14. **Beta blockade at discharge.**** Percent of patients undergoing isolated CABG who were discharged on beta blockers.

15. **Anti-lipid treatment at discharge.**** Percent of patients undergoing isolated CABG who were discharged on a statin or other pharmacologic lipid-lowering regimen.

16. **Risk-adjusted inpatient CABG mortality.****** Percent of patients who die in hospital after CABG surgery.

17. **Risk-adjusted operative mortality for CABG.***** Percent of patients undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.

Table 1 – National Voluntary Consensus Standards for Cardiac Surgery (continued)

- 18. Risk-adjusted operative mortality for aortic valve replacement (AVR).***** Percent of patients undergoing AVR who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.
-
- 19. Risk-adjusted operative mortality for mitral valve replacement/repair (MVR).***** Percent of patients undergoing MVR who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.
-
- 20. Risk-adjusted operative mortality for MVR+CABG.***** Percent of patients undergoing MVR and CABG who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.
-
- 21. Risk-adjusted operative mortality for AVR+CABG.***** Percent of patients undergoing AVR and CABG who die, including both 1) all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure.
-

* See recommendation that surgical volume should only be used as a quality measure in the absence of other risk-adjusted morbidity or mortality measures.

** Five of the process measures have been recommended for simplicity and ease of data collection and implementation. It is recognized that specific patient-based exclusions exist for each of these care processes. Thus, 100 percent compliance is not desirable.

*** Risk adjusted using multiple logistic regression and hierarchical modeling. Access to the Society of Thoracic Surgeons' risk-adjustment methodology will be available at www.sts.org.

**** Risk adjusted using multivariate logistic regression model available at www.oshpd.cahwnet.gov/HQAD/Outcomes/Clinical.htm.

Proprietary Measures

This set includes many STS proprietary measures. NQF should consider withdrawing its endorsement of the STS measures if any of the following conditions is not maintained:

- the web service providing access to the risk models is updated and free of charge;
- detailed measure specifications are available without charge;
- participants in the STS database (hospitals or surgeons) retain ownership of the data submitted to STS and may share the data with others; and
- STS does not restrict the use of STS-generated reports to hospitals or surgeons, and the providers may share the information without charge.

CABG Consensus Standards in the NQF Hospital Set

NQF's *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set* contains three measures for CABG. The cardiac surgery standards in this current report include an update of the three previously endorsed CABG measures and represent an enhancement of the hospital consensus standards. With respect to the CABG measures in the hospital set:

- The CABG volume measure previously endorsed as part of the hospital set should be replaced with the expanded surgical volume measure, which also includes volume of valve and valve+CABG surgeries and is defined by ICD-9 codes.
- The New York state inpatient CABG mortality measure¹³ in the hospital set should be replaced with the California CABG Mortality Reporting Program¹⁴ inpatient CABG mortality measure because the California measure is based on the same data elements that are used for the STS measures in the cardiac surgery set.
- The "IMA use" measure is identical in both sets.

¹³See www.health.state.ny.us/nysdoh/heart/pdf/1999-2001_cabg.pdf.

¹⁴See www.oshpd.cahwnet.gov/HQAD/HIRC/hospital/Outcomes/CABG/.

Data Verification and Auditing

The credibility of these measures for all stakeholders depends on the integrity of the data. The implementation of these measures must include a mechanism for data verification and accuracy that may include a formal audit.

Surgical Volume as a Quality Measure

Surgical volume has been used as a quality measure because the data that are needed are easy to capture. However, the relationship of volume to outcomes and quality varies. The use of process measures and risk-adjusted outcome measures of morbidity and mortality provides superior information about the quality of cardiac surgery care. Surgical volume should not be used as a primary measure of quality if other severity-adjusted outcome measures are available. If, however, no other severity-adjusted data are available, then surgical volume may be used to provide some information, however limited, about a provider.

Analysis of Data for Disparities

Data elements for race/ethnicity should be collected for the stratification of measures into subgroups. Whether the sample is sufficiently large for public reporting should be determined by the reporting program; however, this information should be collected and used for research and quality improvement purposes.

Reporting Use of the Internal Mammary Artery Measure

Disparities have been identified in the use of IMA in CABG surgery based on age and gender. Specifically, it has been reported that women and older patients receive the beneficial procedure less often. This measure should be reported in five parts: 1) overall IMA use; 2) IMA use in patients under 75 years of age; 3) IMA use in patients 75 years old or older; 4) IMA use in women; and 5) IMA use in men.

Level of Analysis for Public Reporting of Cardiac Surgery Performance

This measure set focuses on hospital-level public reporting. Several state-based public reporting programs for cardiac surgery report both hospital and surgeon-level performance data. Consumers and purchasers are interested in physician-level data; however, so far no other NQF-endorsed voluntary consensus standards set recommends physician-level analysis and public reporting. NQF should establish a policy regarding physician-level public reporting in all areas of healthcare. After NQF has established a policy, these cardiac surgery standards should be re-evaluated through the CDP to determine the level of analysis and reporting that is needed based on scientific and statistical considerations.

A Community-Based Consensus Standard for Policy Use

Analysis of procedural frequency within a population based on geographic area is an important public health measure that

addresses access, equitability, and efficiency. For policy discussions regarding the quality of cardiac surgery performance, frequency of CABG surgery and its relationship to percutaneous coronary interventions within defined populations, as presented by the Dartmouth Atlas¹⁵ (based on Medicare data), should be used to support and frame the discussion.

Review and Updating of the Set

In general, NQF should review the voluntary consensus standards for cardiac surgery annually to revise, evaluate, and identify improvements.¹⁶ Additionally, NQF should develop a policy for rapid refreshment of measures when new information becomes available. Finally, two candidate measures — “quality of life” and “angiotensin converting enzyme (ACE) inhibitors at discharge,” which represent important areas for measurement of quality in cardiac surgery, should be considered for endorsement after issues involving problematic measure specifications are resolved.¹⁷

Research Recommendations

During the course of consensus development, a number of high-priority areas for research and measure development were identified. Generally, these are areas for which high priority exists, but for which candidate measures failed to meet established evaluation criteria. These priority areas are viewed as significant gaps in the initial set of voluntary consensus standards that must be filled. Without rapid advancements in research and measure development, such gaps will contribute to the widening healthcare quality chasm.¹⁸

Quality-of-Life Measure

Development of an efficient implementation mechanism for a measure of quality of life after cardiac surgery is urgently needed to assess this high-priority outcome of surgical intervention.

Efficiency Measures

Length of stay has been a primitive measure of efficiency and is of limited use. Better measures are needed to measure the efficiency of healthcare delivery.

¹⁵See www.dartmouthatlas.com.

¹⁶In *A Comprehensive Framework for Hospital Care Performance Evaluation*, it is recommended that an overall review of the voluntary consensus standards for hospital care should occur no less frequently than every three years.

¹⁷On November 3, 2004, NQF and the Agency for Healthcare Research and Quality co-sponsored a workshop to address the issue of angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) in patients hospitalized with heart failure and myocardial infarction. Participants supported changing the NQF-endorsed hospital measures in a manner proposed by the measure developers, the Joint Commission on Accreditation of Healthcare Organizations, and the Centers for Medicare and Medicaid Services, so that ACE inhibitors and ARBs would be considered equivalent for the purpose of quality measurement. NQF will forward the cardiac surgery measure developer this resolution for its consideration.

¹⁸IOM, Committee on the Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press; 2001.

Appropriateness Measures

Evaluating the appropriateness of treatment for patients with cardiovascular disease should be viewed from the global perspective of the patient and should involve various types of practitioners and disciplines. A patient who enters the system with symptoms or who is at high risk for cardiovascular disease encounters multiple decision points along the care path where appropriateness of treatment can be measured.

Standardized Smoking Cessation Measure for All Hospitalized Patients

Smoking cessation is important for cardiac surgery patients. The NQF hospital set has three smoking cessation standards for different patient populations. Instead of endorsing an additional measure for cardiac surgery patients or having different measures for various populations, a single cross-cutting smoking cessation measure should be developed for all hospital patients.

Combination or “Roll-up” Measures or Index

Combination measures such as an adverse event measure that combines the five morbidity measures with the mortality measure or a combination discharge management measure would be useful for public reporting. Further development is needed to determine the appropriate weightings for the different components as well as the validity and reliability of the measures.

Inpatient Mortality and Process Measures for Heart Valve Disease

The development of process measures for heart valve surgery and the further development of inpatient mortality measures for a national population are needed.

Acknowledgments

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Appendix A

Specifications of the National Voluntary Consensus Standards for Cardiac Surgery

The following table summarizes the detailed specifications for each of the National Quality Forum (NQF)-endorsed cardiac surgery performance measures. All information presented has been derived directly from measure sources/developers without modification or alteration (except when the measure developer agreed to such modification during the NQF Consensus Development Process) and is current as of December 2, 2004.

All NQF-endorsed voluntary consensus standards are open source, meaning they are fully accessible and disclosed. References to related risk-adjustment methodologies and definitions are provided to assure openness and transparency.

Issues regarding any NQF-endorsed consensus standard (e.g., modifications to specifications, emerging evidence) may be submitted to NQF for review and consideration via the “Implementation Feedback Form” found at www.qualityforum.org/implementation_feedback.htm. NQF will transmit this information to the measure developers and/or compile it for consideration in updating the measure set.

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
1. Participation in a Systematic Database for Cardiac Surgery	Society of Thoracic Surgeons (STS) ¹	Does the facility participate in a multicenter, data collection and feedback program that provides benchmarking relative to peers and uses process and outcome measures? (Yes/No)	Not applicable	
2. Surgical Volume - a. Isolated Coronary Artery Bypass Graft (CABG) Surgery b. Valve Surgery c. CABG+Valve Surgery	Centers for Medicare and Medicaid Services (CMS)	a. Number of patients undergoing isolated CABG surgery, ICD-9 codes: ■ 36.10 Aortocoronary bypass for heart revascularization, NOS ■ 36.11 Aortocoronary bypass of one coronary artery ■ 36.12 Aortocoronary bypass of two coronary arteries ■ 36.13 Aortocoronary bypass of three coronary arteries ■ 36.15 Single internal mammary-coronary artery bypass ■ 36.16 Double internal mammary-coronary artery bypass ■ 36.19 Other bypass anastomosis for heart revascularization b. Number of patients undergoing heart valve surgery, ICD-9 codes: ■ 35.10 Open heart valvuloplasty without replacement, unspecified valve ■ 35.11 Open heart valvuloplasty of aortic valve without replacement ■ 35.12 Open heart valvuloplasty of mitral valve without replacement ■ 35.13 Open heart valvuloplasty of pulmonary valve without replacement ■ 35.14 Open heart valvuloplasty of tricuspid valve without replacement		

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
2. Surgical Volume - a. Isolated Coronary Artery Bypass Graft (CABG) Surgery b. Valve Surgery c. CABG+Valve Surgery <i>continued</i>		<ul style="list-style-type: none"> ■ 35.20 Replacement of unspecified heart valve ■ 35.21 Replacement of aortic valve with tissue graft ■ 35.22 Other replacement of aortic valve ■ 35.23 Replacement of mitral valve with tissue graft ■ 35.24 Other replacement of mitral valve ■ 35.25 Replacement of pulmonary valve with tissue graft ■ 35.26 Other replacement of pulmonary valve ■ 35.27 Replacement of tricuspid valve with tissue graft ■ 35.28 Other replacement of tricuspid valve c. Number of patients undergoing valve+CABG surgery, ICD-9 codes: <ul style="list-style-type: none"> ■ 36.10-36.16, 36.19 and 35.10-35.14, 35.20-35.28 		
3. Timing of Antibiotic Administration for Cardiac Surgery Patients	CMS	Cardiac surgery patients who received prophylactic antibiotics within one hour of surgical incision (two hours if vancomycin)	Surgical patients with CABG ICD-9-CM procedure codes: CABG: <ul style="list-style-type: none"> ■ 36.10 Aortocoronary bypass for heart revascularization, NOS ■ 36.11 Aortocoronary bypass of one coronary artery ■ 36.12 Aortocoronary bypass of two coronary arteries ■ 36.13 Aortocoronary bypass of three coronary arteries ■ 36.15 Single internal mammary-coronary artery bypass ■ 36.16 Double internal mammary-coronary artery bypass ■ 36.19 Other bypass anastomosis for heart revascularization 	Exclusions: <ul style="list-style-type: none"> ■ Principal or admission diagnosis suggestive of pre-operative infectious disease ● Infectious diseases 001.0-139.8 ● Meningitis 320.0-326 ● Ear infection 380.0-380.23; 382.0-382.20 ● Endocarditis 421.0-422.99 ● Respiratory 460-466.19; 472-476.1; 480-487.8; 490-491.9; 510-511.9; 513-513.1 ● Digestive 540-542; 575.0 ● Renal 590-590.9; 595.0

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
3. Timing of Antibiotic Administration for Cardiac Surgery Patients <i>continued</i>			<ul style="list-style-type: none"> ■ 36.20 Heart revascularization by arterial implant Other cardiac surgery: <ul style="list-style-type: none"> ■ 35.0x Closed heart valvotomy ■ 35.1x Open heart valvuloplasty without replacement ■ 35.2x Replacement of heart valve ■ 35.3x Operations on structures adjacent to heart valves ■ 35.4x Production of septal defect in heart ■ 35.5x Repair of atrial and ventricular septa with prosthesis ■ 35.6x Repair of atrial and ventricular septa with tissue graft ■ 35.7x Other and unspecified repair of atrial and ventricular septa ■ 35.8x Total repair of certain congenital cardiac anomalies ■ 35.91-35.95 Other operations on valves and septa of heart ■ 35.98 Other operations on septa of heart ■ 35.99 Other operations on valves of heart 	<ul style="list-style-type: none"> ● Prostate 601.0-601.9 ● Gynecologic 614-614.9; 616-616.4 ● Skin 680-686.9 ● Musculo-skeletal 711.9-711.99; 730.0-730.99 ● Fever of unknown origin 780.6 ● Septic shock 785.59 ● Bacteremia 790.7 ● Viremia 790.8 ■ Receiving antibiotics at the time of admission ■ Medical records do not include antibiotic start date/time or incision date/time ■ Receiving antibiotics more than 24 hours prior to surgery
4. Selection of Antibiotic Administration for Cardiac Surgery Patients	CMS	Cardiac surgery patients who received prophylactic antibiotics recommended for the specific operation: cefazolin, cefuroxime, cefamandole, or vancomycin*	CABG ICD-9 36.10-36.17, 36.19; and other cardiac surgery: ICD-9 35.0-35.95, 35.98, 35.99	<p>Exclusions:</p> <ul style="list-style-type: none"> ■ Principal or admission diagnosis suggestive of pre-operative infectious disease <ul style="list-style-type: none"> ● Infectious diseases 001.0-139.8 ● Meningitis 320.0-326 ● Ear infection 380.0-380.23; 382.0-382.20 ● Endocarditis 421.0-422.99 ● Respiratory 460-466.19; 472-476.1; 480-487.1; 490-491.9; 510-511.9; 513-513.1

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
4. Selection of Antibiotic Administration for Cardiac Surgery Patients <i>continued</i>				<ul style="list-style-type: none"> ● Digestive 540-542; 575.0 ● Renal 590-590.9; 595.0 ● Prostate 601.0-601.9 ● Gynecologic 614-614.9; 616-616.4 ● Skin 680-686.9 ● Musculo-skeletal 711.9-711.99; 730.0-730.99 ● Fever of unknown origin 780.6 ● Septic shock 785.59 ● Bacteremia 790.7 ● Viremia 790.8 <ul style="list-style-type: none"> ■ Receiving antibiotics at the time of admission ■ Medical records do not include antibiotic start date/time or incision date/time ■ Receiving antibiotics >24 hours prior to surgery ■ No antibiotics received before or during surgery, or within 24 hours after surgery end time (i.e., patient did not receive any prophylactic antibiotics) ■ No antibiotics received during the hospitalization
5. Pre-operative Beta Blockade	STS ¹	<p>*Special consideration: For cardiac and vascular surgery, if patient is allergic to b-lactam, then vancomycin or clindamycin is an acceptable substitute</p> <p>Number of patients coming to isolated CABG with documented pre-operative (24 hours) beta blockade</p>	All patients undergoing isolated CABG	Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
6. Use of Internal Mammary Artery (IMA)	CMS-Quality Improvement Organizations	Patients who received an IMA graft (ICD-9 procedure codes 36.15 and 36.16)	<p>Number of patients undergoing isolated CABG (ICD-9 procedure codes 36.10-36.19) who were discharged, transferred, or expired</p> <ul style="list-style-type: none"> ■ 36.10 Aortocoronary bypass for heart revascularization, NOS ■ 36.11 Aortocoronary bypass of one coronary artery ■ 36.12 Aortocoronary bypass of two coronary arteries ■ 36.13 Aortocoronary bypass of three coronary arteries ■ 36.15 Single internal mammary-coronary artery bypass ■ 36.16 Double internal mammary-coronary artery bypass ■ 36.19 Other bypass anastomosis for heart revascularization 	<p>Exclusions:</p> <ul style="list-style-type: none"> ■ Other heart procedures (ICD-9 procedure codes 37.32, 37.34, 37.35, 36.2, 35.0-35.99) ■ Repeat CABG (ICD-9 status code V45.81)
7. Duration of Prophylaxis for Cardiac Surgery Patients	CMS	Cardiac surgery patients whose prophylactic antibiotics were discontinued within 24 hours after surgery end time	<p>CABG (ICD-9: 36.10-36.17, 36.19; and other cardiac surgery: ICD-9 35.0-35.95, 35.98, 35.99)</p>	<p>Exclusions:</p> <ul style="list-style-type: none"> ■ Principal or admission diagnosis suggestive of pre-operative infectious disease <ul style="list-style-type: none"> ● Infectious diseases 001.0-139.8 ● Meningitis 320.0-326 ● Ear infection 380.0-380.23; 382.0-382.20 ● Endocarditis 421.0-422.99 ● Respiratory 460-466.19; 472-476.1; 480-487.1; 490-491.9; 510-511.9; 513-513.1 ● Digestive 540-542; 575.0 ● Renal 590-590.9; 595.0 ● Prostate 601.0-601.9 ● Gynecologic 614-614.9; 616-616.4 ● Skin 680-686.9 ● Musculo-skeletal 711.9-711.99; 730.0-730.99

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
7. Duration of Prophylaxis for Cardiac Surgery Patients <i>continued</i>				<ul style="list-style-type: none"> ● Fever of unknown origin 780.6 ● Septic shock 785.59 ● Bacteremia 790.7 ● Viremia 790.8 <ul style="list-style-type: none"> ■ Receiving antibiotics at the time of admission ■ Medical records do not include antibiotic start date/time or incision date/time ■ Receiving antibiotics >24 hours prior to surgery ■ No antibiotics received before or during surgery, or within 24 hours after surgery end time (i.e., patient did not receive any prophylactic antibiotics) ■ Diagnosed with and treated for infections within two days after surgery date ■ No antibiotics received during the hospitalization
8. Prolonged Intubation (ventilation)	STS ¹	Number of patients who undergo isolated CABG who require intubation > 24 hours	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p> <p>Inclusion:</p> <ul style="list-style-type: none"> ■ Number of patients undergoing isolated CABG without pre-existing intubation/tracheostomy <p>Exclusion:</p> <ul style="list-style-type: none"> ■ Patients intubated prior to isolated CABG; patients with tracheostomy prior to isolated CABG <p>Risk adjustment:</p> <ul style="list-style-type: none"> ■ Multivariate logistic regression and hierarchical modeling²

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
9. Deep Sternal Wound Infection Rate	STS ¹	<p>Number of patients who developed deep sternal wound infections within 30 days post-operative</p> <p><i>Definition of deep sternal wound infection:</i></p> <p>Patient with a deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention. Must have all of the following conditions:</p> <ul style="list-style-type: none"> ■ Wound opened with excision of tissue (I&D) or re-exploration of mediastinum ■ Positive culture ■ Treatment with antibiotics 	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p> <p>Inclusion:</p> <ul style="list-style-type: none"> ■ All patients undergoing isolated CABG surgery who developed a deep sternal wound infection within 30 days post-operative <p>Exclusions:</p> <ul style="list-style-type: none"> ■ Patients undergoing isolated CABG surgery with superficial wound site infections and no involvement of deeper tissue post-operative <p>Risk adjustment:</p> <ul style="list-style-type: none"> ■ Multivariate logistic regression and hierarchical modeling²
10. Stroke/Cerebrovascular Accident	STS ¹	Number of patients who undergo isolated CABG with post-operative neurologic deficit persisting >72 hours	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p> <p>Exclusion:</p> <ul style="list-style-type: none"> ■ Patients with pre-existing neurologic deficits <p>Risk adjustment:</p> <ul style="list-style-type: none"> ■ Multivariate logistic regression and hierarchical modeling²

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
11. Post-operative Renal Insufficiency	STS ¹	<p>Number of patients undergoing isolated CABG who develop post-operative renal failure/dialysis requirement</p> <p><i>Definition of renal failure/dialysis requirement:</i> Patients with acute or worsening renal failure resulting in one or more of the following:</p> <ol style="list-style-type: none"> Increase in serum creatinine to >2.0 and two times most recent pre-operative creatinine level New requirement for dialysis post-operatively 	All patients undergoing isolated CABG	<p>Age qualification: For patients < 20 years, the data are accepted into the database, but are not included in the national analysis and report</p> <p>Inclusion:</p> <ul style="list-style-type: none"> Number of patients undergoing isolated CABG without pre-existing renal failure <p>Exclusion:</p> <ul style="list-style-type: none"> Patients with documented history of renal failure, baseline serum creatinine >2.0; prior renal transplants are not considered pre-operative renal failure unless since transplantation their Cr has been or is >2.0 <p>Risk adjustment:</p> <ul style="list-style-type: none"> Multivariate logistic regression and hierarchical modeling²
12. Surgical Re-exploration	STS ¹	Number of patients undergoing isolated CABG who require return to the operating room for bleeding/tamponade, graft occlusion, or other cardiac reason	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p> <p>Risk adjustment:</p> <ul style="list-style-type: none"> Multivariate logistic regression and hierarchical modeling²
13. Anti-platelet Medication at Discharge	STS ¹	Number of patients who were discharged on aspirin/safety-coated aspirin or clopidogrel after isolated CABG	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p>
14. Beta Blockade at Discharge	STS ¹	Number of isolated CABG patients discharged on beta blockers	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p>
15. Anti-lipid Treatment at Discharge	STS ¹	Number of isolated CABG patients discharged on a statin or other pharmacologic lipid-lowering regimen	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p>

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
16. Risk-Adjusted Inpatient Operative Mortality for CABG	California CABG Mortality Reporting Program	Number of patients from participating hospitals who had an isolated CABG surgery and died in hospital	Number of patients from participating hospitals who had isolated CABG surgery ³	<p>Exclusions:</p> <ul style="list-style-type: none"> ■ Deaths are not counted after discharge even if the patient dies soon after the operation. If a patient is transferred post-operatively to a rehabilitation or transitional care facility and dies before going home, this death is not counted ■ Procedures performed during the same surgery: <ul style="list-style-type: none"> ● valve procedures ● operations on structures adjacent to heart valves ● ventriculectomy ● repair of atrial and ventricular septa ● excision of aneurysm of heart ● head and neck, intracranial endarterectomy ● other open heart surgeries, such as aortic arch repair, pulmonary endarterectomy ● endarterectomy of aorta ● thoracic endarterectomy ● heart transplantation ● repair of certain congenital cardiac anomalies ● implantation of cardiostimulation system ● any aortic aneurysm repair ● aorta-subclavian-carotid bypass ● aorta-renal bypass ● aorta-iliac-femoral bypass ● caval-pulmonary artery anastomosis ● extracranial-intracranial (EC-IC) vascular bypass ● coronary artery fistula ● resection of a portion of the lung does not include simple biopsy of lung nodule in which surrounding lung is not resected or biopsy of a thoracic lymph node

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
16. Risk-Adjusted Inpatient Operative Mortality for CABG <i>continued</i>				<ul style="list-style-type: none"> ● incisional (ventral) hernia repair ● lumpectomy or mastectomy for breast cancer ● maze procedures, surgical or catheter ● total or partial excision of thymus <p>Inclusions:</p> <ul style="list-style-type: none"> ■ The CABG cases with the following procedures performed concurrently will be considered isolated CABG: <ul style="list-style-type: none"> ● transmyocardial laser revascularization (TMR) ● pericardiectomy and excision of lesions of heart ● repair/restoration of the heart or pericardium ● coronary endarterectomy ● pacemakers ● internal cardiac defibrillators ● fem-fem cardiopulmonary bypass <p>Risk adjustment:</p> <ul style="list-style-type: none"> ■ Multivariate logistic regression. Adjusted for differences in the case mix across hospitals and accounted for the pre-operative condition of each patient⁴
17. Risk-Adjusted Operative Mortality for CABG	STS ¹	Number of patients undergoing isolated CABG who die, including both 1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, unless the cause of death is clearly unrelated to the operation	All patients undergoing isolated CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p> <p>Risk adjustment:</p> <ul style="list-style-type: none"> ■ Multivariate logistic regression and hierarchical modeling²

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
18. Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR)	STS ¹	Number of patients undergoing AVR who die, including both 1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, unless the cause of death is clearly unrelated to the operation	All patients undergoing isolated AVR surgery	Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report Exclusion: <ul style="list-style-type: none"> Patients receiving CABG or other valve or cardiac surgery during this admission Risk adjustment: <ul style="list-style-type: none"> Multivariate logistic regression and hierarchical modeling²
19. Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair (MVR)	STS ¹	Number of patients undergoing MVR who die, including both 1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, unless the cause of death is clearly unrelated to the operation	All patients undergoing isolated MVR surgery	Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report Exclusion: <ul style="list-style-type: none"> Patients receiving CABG or other valve or cardiac surgery during this admission Risk-adjustment: <ul style="list-style-type: none"> Multivariate logistic regression and hierarchical modeling²
20. Risk-Adjusted Operative Mortality MVR+CABG Surgery	STS ¹	Number of patients undergoing combined MVR and CABG who die; including both 1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, unless the cause of death is clearly unrelated to the operation	All patients undergoing combined MVR+CABG	Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report Exclusion: <ul style="list-style-type: none"> Patients receiving other valve or cardiac surgery during this admission Risk-adjustment: <ul style="list-style-type: none"> Multivariate logistic regression and hierarchical modeling²

Appendix A – Specifications of the National Voluntary Consensus Standards for Cardiac Surgery (continued)

Measure	Source of Measure	Numerator	Denominator	Inclusions/Exclusions/Risk Adjustment
21. Risk-Adjusted Operative Mortality for AVR+CABG	STS ¹	Number of patients undergoing combined AVR and CABG who die, including both 1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days, and 2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure, unless the cause of death is clearly unrelated to the operation	All patients undergoing combined AVR+CABG	<p>Age qualification: For patients <20 years, the data are accepted into the database, but are not included in the national analysis and report</p> <p>Exclusion:</p> <ul style="list-style-type: none"> ■ Patients receiving other valve or cardiac surgery during this admission <p>Risk adjustment:</p> <ul style="list-style-type: none"> ■ Multivariate logistic regression and hierarchical modeling²

¹ STS harvests data every six months. NQF notes that the NQF-endorsed frequency for data transmission for hospital consensus standards is no more frequently than quarterly during the calendar year. Additionally, STS uses a “rolling” 4-year dataset to calculate the coefficients for the risk-adjusted outcome measures. Neither the NQF hospital framework nor this report specify an appropriate sampling period for purpose of these calculations, which are to an extent measure specific. Nevertheless, it is noted that current data are generally better than older data.

² The risk model is available from STS at www.sts.org.

³ The definition of isolated CABG for participating hospitals is a clinical definition. The California CABG Mortality Reporting Program (CCMRP) uses administrative data to identify the numbers of procedures for non-participating hospitals in its reports as follows: Number of isolated CABG surgeries calculated using the following ICD-9-CM codes:

Any record with 36.1x, excluding the following:
 35.1x, 35.2x, 35.3x, 35.4x, 35.5x, 35.6x, 35.7x, 35.8x, 35.9x, 36.1x, 36.2x, 36.3x, 36.4x, 36.5x, 36.6x, 36.7x, 36.8x, 36.9x, 37.1x, 37.2x, 37.3x, 37.4x, 37.5x, 37.6x, 37.7x, 37.8x, 37.9x, 38.1x, 38.2x, 38.3x, 38.4x, 38.5x, 38.6x, 38.7x, 38.8x, 38.9x, 39.1x, 39.2x, 39.3x, 39.4x, 39.5x, 39.6x, 39.7x, 39.8x, 39.9x, 40.1x, 40.2x, 40.3x, 40.4x, 40.5x, 40.6x, 40.7x, 40.8x, 40.9x, 41.1x, 41.2x, 41.3x, 41.4x, 41.5x, 41.6x, 41.7x, 41.8x, 41.9x, 42.1x, 42.2x, 42.3x, 42.4x, 42.5x, 42.6x, 42.7x, 42.8x, 42.9x, 43.1x, 43.2x, 43.3x, 43.4x, 43.5x, 43.6x, 43.7x, 43.8x, 43.9x, 44.1x, 44.2x, 44.3x, 44.4x, 44.5x, 44.6x, 44.7x, 44.8x, 44.9x, 45.1x, 45.2x, 45.3x, 45.4x, 45.5x, 45.6x, 45.7x, 45.8x, 45.9x, 46.1x, 46.2x, 46.3x, 46.4x, 46.5x, 46.6x, 46.7x, 46.8x, 46.9x, 47.1x, 47.2x, 47.3x, 47.4x, 47.5x, 47.6x, 47.7x, 47.8x, 47.9x, 48.1x, 48.2x, 48.3x, 48.4x, 48.5x, 48.6x, 48.7x, 48.8x, 48.9x, 49.1x, 49.2x, 49.3x, 49.4x, 49.5x, 49.6x, 49.7x, 49.8x, 49.9x, 50.1x, 50.2x, 50.3x, 50.4x, 50.5x, 50.6x, 50.7x, 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NATIONAL QUALITY FORUM

Appendix B

Members and Board of Directors

Members

CONSUMER COUNCIL

AARP
 AFL-CIO
 AFT Healthcare
 American Hospice Foundation
 California Health Decisions
 Consumer Coalition for Quality Health Care
 Consumers Advancing Patient Safety
 Consumers' Checkbook
 Foundation for Accountability
 Last Acts
 March of Dimes
 National Citizens' Coalition for Nursing Home Reform
 National Coalition for Cancer Survivorship
 National Consensus Project for Quality Palliative Care
 National Partnership for Women and Families
 Service Employees International Union

HEALTH PROFESSIONAL, PROVIDER, AND HEALTH PLAN COUNCIL

Adventist HealthCare
 Aetna
 Alexian Brothers Medical Center
 Alliance for Quality Nursing Home Care
 American Academy of Family Physicians

American Academy of Orthopaedic Surgeons
 American Academy of Physician Assistants
 American Association of Homes and Services for the Aging
 American Association of Nurse Anesthetists
 American College of Cardiology
 American College of Obstetricians and Gynecologists
 American College of Radiology
 American College of Surgeons
 American Health Care Association
 American Heart Association
 American Hospital Association
 American Managed Behavioral Healthcare Association
 American Medical Association
 American Medical Group Association
 American Nurses Association
 American Optometric Association
 American Osteopathic Association
 American Society for Therapeutic Radiology and Oncology
 American Society of Clinical Oncology
 American Society of Health-System Pharmacists
 America's Health Insurance Plans
 Ascension Health
 Bayhealth Medical Center

Baylor Health Care System	Memorial Sloan-Kettering Cancer Center
Beacon Health Strategies	The Methodist Hospital
Beverly Enterprises	National Association of Chain Drug Stores
BJC HealthCare	National Association of Children's Hospitals and Related Institutions
Blue Cross and Blue Shield Association	National Association Medical Staff Services
Blue Cross Blue Shield of Michigan	National Association of Public Hospitals and Health Systems
Bon Secours Health System	National Hospice and Palliative Care Organization
Bronson Healthcare Group	Nemours Foundation
Catholic Health Association of the United States	New York Presbyterian Hospital and Health System
Catholic Health Initiatives	North Carolina Baptist Hospital
Catholic Healthcare Partners	North Shore-Long Island Jewish Health System
Child Health Corporation of America	Oakwood Healthcare System
CHRISTUS Health	PacifiCare
CIGNA Healthcare	PacifiCare Behavioral Health
College of American Pathologists	Partners HealthCare
Community Hospital of the Monterey Peninsula	Premier
Connecticut Hospital Association	ProHealth Care
Council of Medical Specialty Societies	Robert Wood Johnson University Hospital-Hamilton
Dialog Medical	Robert Wood Johnson University Hospital-New Brunswick
Empire BlueCross/BlueShield	Sentara Norfolk General Hospital
Exempla Healthcare	Sisters of Charity of Leavenworth Health System
Federation of American Hospitals	Sisters of Mercy Health System
First Health	Society of Thoracic Surgeons
Gentiva Health Services	Spectrum Health
Greater New York Hospital Association	State University of New York-College of Optometry
HCA	Sutter Health
Healthcare Leadership Council	Tampa General Hospital
HealthHelp	Tenet Healthcare
HealthPartners	Triad Hospitals
Health Plus	Trinity Health
Henry Ford Health System	UnitedHealth Group
Hoag Hospital	University Health Systems of Eastern Carolina
Horizon Blue Cross and Blue Shield of New Jersey	University Hospitals of Cleveland
Hudson Health Plan	University of California, Davis Medical Group
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INTEGRIS Health	University of Pennsylvania Health System
John Muir/Mt. Diablo Health System	University of Texas-MD Anderson Cancer Center
Kaiser Permanente	US Department of Defense-Health Affairs
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MedQuest Associates	
Memorial Health University Medical Center	

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BoozAllenHamilton

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Centers for Medicare and Medicaid Services

Central Florida Health Care Coalition

Employer Health Care Alliance Cooperative
(The Alliance)

Employers' Coalition on Health

Ford Motor Company

General Motors

Greater Detroit Area Health Council

HealthCare 21

Leapfrog Group

Maine Health Management Coalition

Midwest Business Group on Health

National Association of State Medicaid Directors

National Business Coalition on Health

National Business Group on Health

New Jersey Health Care Quality Institute

Pacific Business Group on Health

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Abbott Laboratories

ACC/AHA Taskforce on Performance Measures

ACS/MIDAS+

Agency for Healthcare Research and Quality

AI Insight

American Academy of Nursing

American Association of Colleges of Nursing

American Board for Certification in Orthotics and
Prosthetics

American Board of Internal Medicine Foundation

American Board of Medical Specialties

American College of Medical Quality

American Health Quality Association

American Pharmacists Association Foundation

American Society for Quality-Health Care Division

Anesthesia Patient Safety Foundation

Aspect Medical Systems

Association of American Medical Colleges

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Battelle Memorial Institute

California HealthCare Foundation

Cancer Quality Council of Ontario

Cardinal Health, Inc.

CareScience

Center to Advance Palliative Care

Centers for Disease Control and Prevention

Cleveland Clinic Foundation

Coral Initiative

Council for Affordable Quality Healthcare

CRG Medical

Delmarva Foundation

Dialog Medical

eHealth Initiative

Eli Lilly and Company

First Consulting Group

Florida Initiative for Children's Healthcare Quality

Forum of End Stage Renal Disease Networks

GlaxoSmithKline

Health Care Excel

Health Grades

Health Resources and Services Administration

Illinois Department of Public Health

Institute for Clinical Systems Development

Institute for Safe Medication Practices

Integrated Healthcare Association

Integrated Resources for the Middlesex Area

IPRO

Jefferson Health System, Office of Health Policy and
Clinical Outcomes

Joint Commission on Accreditation of Healthcare
Organizations

Long Term Care Institute

Loyola University Health System Center for
Clinical Effectiveness

Lumetra

Maine Quality Forum

Medical Review of North Carolina

National Academy for State Health Policy

National Association for Healthcare Quality

National Committee for Quality Assurance

National Committee for Quality Health Care
 National Institutes of Health
 National Patient Safety Foundation
 National Research Corporation
 New England Healthcare Assembly
 Northeast Health Care Quality Foundation
 Ohio KePRO
 OmniCare
 Pennsylvania Health Care Cost Containment Council
 Pfizer
 Physician Consortium for Performance Improvement
 Press, Ganey Associates
 Professional Research Consultants
 Qualidigm
 Research!America
 Roswell Park Cancer Institute
 Sanofi-Synthelabo
 Select Quality Care
 Solucient
 Stratis Health
 Substance Abuse and Mental Health Services
 Administration
 Texas Medical Institute of Technology
 Uniform Data System for Medical Rehabilitation
 United Hospital Fund
 University of North Carolina-Program on Health
 Outcomes
 URAC
 US Food and Drug Administration
 US Pharmacopeia
 Virginia Cardiac Surgery Quality Initiative
 Virginia Health Quality Center
 West Virginia Medical Institute

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* During project period

¹ Through February 2004

² Vice-Chair since
November 2004

³ Since May 2004

⁴ Through November 2004

⁵ Since April 2004

⁶ Since February 2004

⁷ Through September 2004

NATIONAL QUALITY FORUM

Appendix C

Steering Committee, Technical Advisory Panel, and Project Staff

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Vice President, Programs

Lawrence D. Gorban, MA
Vice President, Operations

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Sabrina Zadrozny
Research Assistant

NATIONAL QUALITY FORUM

Appendix D Commentary

Introduction

In February 2004, the National Quality Forum (NQF) initiated a project to achieve consensus on an initial set of voluntary consensus standards for cardiac surgery performance. As with other NQF consensus projects, a Steering Committee (appendix C) representing key healthcare constituencies—including consumers, providers, purchasers, and research and Quality Improvement Organizations (QIOs)—was convened. In June 2004, the Steering Committee recommended a set of measures that was forwarded to NQF Members and the public for comment in accordance with NQF’s Consensus Development Process (CDP) (appendix F). A Technical Advisory Panel (TAP) (appendix C) also was formed to assist NQF staff on measure evaluation, advise the Steering Committee on the technical aspects of measures, and make recommendations to the Steering Committee.

This appendix summarizes the deliberations of the Steering Committee and the TAP, as well as the discussion following the initial review period of the Steering Committee’s recommendations.

Approach to Measure Screening and Evaluation

The Steering Committee’s approach to measure screening and evaluation followed a six-step process:

1. Agree on a purpose statement for the measure set.
2. Use the framework spelled out in *A Comprehensive Framework for Hospital Performance Evaluation* (the “hospital framework”¹) to provide contextual underpinnings and identify the gaps.

¹National Quality Forum (NQF). *A Comprehensive Framework for Hospital Care Performance Evaluation*. Washington, DC: NQF; 2003.

3. Identify the scope of the measure set in order to establish the boundaries, such as, When does surgery begin or end? Which outcomes should be included?
4. Identify priorities to narrow the universe of candidate measures to a number that is feasible.
5. Identify candidate measures based on the scope and priorities.
6. Make voting recommendations to NQF Members.

Purpose of the Measure Set

In the development of this project, a planning group suggested two groups of measures that share common data elements: one group for public disclosure and accountability and another for quality improvement. Steering Committee members reviewed the two related pathways of measurement described in the NQF consensus report *A National Framework for Quality Measurement and Reporting*² and considered the planning group's suggestion for separating measure sets by purpose. In a robust discussion, the following themes emerged:

- the purpose of measurement should be to improve the quality of care;
- the set of measures should address both process and outcomes;
- good measures can be efficiently implemented and effectively used by a variety of stakeholders, including payers, purchasers, and providers;
- prevailing opinion preferred interchangeable measures, with the goal

of all measures being useful for both accountability and quality improvement, thereby creating a single set that would serve both public reporting and quality improvement purposes;

- the measure set should be useable/relevant to consumers; help stakeholders select a provider; hold providers accountable; and include process measures that are helpful to providers even if they are not significant to consumers; and
- the default position should be to share information with the consumer. Some measures may not be appropriate for public reporting, but if measures deemed inappropriate for accountability are included in the set, it should be explained why it is against the interest of consumers to share those data publicly.

The Steering Committee recommended the following purpose statement:

The primary purpose of this standardized set of performance measures is to promote the highest quality of care for cardiac surgery patients and cardiac surgery candidates. These standardized performance measures are intended to inform both quality improvement and public accountability, including the public disclosure of the results. The measures are intended for use by consumers, purchasers, providers, accreditors, quality improvement organizations, and researchers, to enable performance-based decisions about provider selection, enhance value-based purchasing, promote accountability of providers, facilitate public use of healthcare information, and stimulate and facilitate the continuous improvement of care.

²NQF. *A National Framework for Healthcare Quality Measurement and Reporting*. Washington, DC: NQF; 2002.

Framework

To build a framework for cardiac surgery measures, the Steering Committee began with NQF's *A Comprehensive Framework for Hospital Performance Evaluation*. The hospital framework is an application of the more general guiding report *A National Framework for Healthcare Quality Measurement and Reporting*. The cardiac surgery framework, like the others, is focused around NQF's six aims for healthcare (that it should be safe, beneficial, patient centered, timely, equitable, and efficient).

Not all parts of the hospital framework are applicable to cardiac surgery. Priorities are arrayed against the six aims. Timeliness and efficiency are typically difficult aim areas in which to identify measures. Some measures can serve multiple aims, which serves to keep the measure set deliberately parsimonious. Populations are considered in the equitable measures aim category, and the Committee proposed that equity should be a specific focus of this measure set, with demographic populations being considered independently and not just as subset of other measures. The cardiac surgery framework is displayed in table 2 of this report, on page D-33.

Scope

The Steering Committee addressed several questions to identify boundaries for the set:

- When does cardiac surgery begin and end?
- How should cardiac surgery be defined? What procedures should be included?
- What is the “locus of control” for accountability? The hospital/surgical team? The individual surgeon?
- Should appropriateness measures or criteria be included in the set?

Boundary of Cardiac Surgery

The Committee first established that the process and outcomes measured should be under the control of the hospital team performing the surgery. It then looked at the continuum of care that is encompassed and decided that cardiac surgery begins with the decision to perform surgery and ends with the post-operative outcome and followup, which is generally assessed at about 30 days. The Committee expressed interest in longer-term outcomes as desirable information about a surgical procedure, but limited the scope of its current work to the immediate post-operative period because other providers may influence the longer-term outcomes.

Definition of Cardiac Surgery

The Committee discussed whether a procedure-based (e.g., coronary artery bypass graft [CABG] surgery, stents) approach versus a disease-based (e.g. atherosclerotic heart disease) approach would be more useful. It determined that the disease approach must include other clinicians, such as cardiologists, and the impact of the spectrum of treatment options from medication to percutaneous coronary intervention (PCI) to CABG. The NQF hospital measures set³ includes measures of PCI volume and mortality. The Committee

³NQF. *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set*. Washington, DC: NQF; 2003.

acknowledged that the evolving nature of the treatment of ischemic heart disease is likely to result in shifts in the focus of care in the future. Based on these considerations, the Committee decided to focus this project on procedures performed by cardiac surgeons while acknowledging that a wider scope is desirable in the future.

Among cardiac surgery procedures, CABG predominates. The Committee determined that the many surgeries related to congenital heart disease and transplantation should be addressed separately. Data and measures exist for valve and valve+CABG combination surgeries, although these are much fewer in number than isolated CABG surgery, and the data have not been collected as long. The processes and outcomes of valve and CABG surgeries do not overlap significantly. The Committee decided to include all cardiac surgery procedures within the scope of this project but that CABG, valve, and valve+CABG combination procedures would be the priorities.

Locus of Control

Currently, several states (including New York, Pennsylvania, and New Jersey) publicly report CABG surgery outcomes both for hospitals and for individual surgeons. The Steering Committee acknowledged that the level of analysis is controversial, but that it should be addressed. The Committee discussed multiple issues:

- With quality improvement programs, differences among surgeons can disappear. For example, the Northern New England group cannot differentiate among hospitals based on risk-adjusted outcomes. New York data suggest that there is relatively little variation among hospitals, but that there is variation among surgeons.
- Heart surgery is a team effort. The same surgeon can have different outcomes in different hospitals with different surgical teams. The improvement in outcomes reported by the Society of Thoracic Surgeons (STS) over the past decade has occurred at the hospital level.
- A hospital with good overall outcomes still can have individual surgeons who vary greatly in quality. Patients should have access to this information.
- Not all subpopulations benefit equally from surgery or have the same outcomes. Reporting at the surgeon level may aid in analyzing data at the subgroup level for populations that are routinely receiving less-than-optimal care.
- Individual surgeon data can be difficult to interpret and may become outdated quickly.
- Variation occurs more noticeably at the institutional level rather than at the provider level.
- Depending on their level of experience, some surgeons might handle more difficult procedures. Surgeons facing measurement at the individual level may refuse to take on higher-risk cases.
- Once data are available for hospitals, people will want surgeon-level data too. New York state reports physician data because state law requires it.
- Studies by STS and the Department of Veterans Affairs (VA) show that outcomes improve and mortality decreases without individual physician reporting.⁴

⁴Grover FL, Shroyer AL, et al. A decade's experience with quality improvement in cardiac surgery using the Veterans Affairs and Society of Thoracic Surgeons National Database. *Ann Thorac Surg.* 2001;234(4):464-472; discussion 472-474.

- The number of cases performed for individual surgeons is an important issue. For example, California requires that a surgeon perform 200 or more procedures in 2 years in order to report at the surgeon level. At this threshold, 70 percent of surgeons would not report.
- Stakeholders need to be educated regarding what it means to have data at different levels.
- The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is looking at the usefulness of physician-level data in context of the measures it already collects.
- There are issues regarding the accuracy of reporting regarding whether surgery should be performed.
- Sometimes patients request surgery despite a surgeon's recommendation to the contrary. The public should have appropriateness measures for the benefit of surgeons as well as for patients.
- A measure of the frequency of a procedure in a population (e.g., populations at risk, patients 65 years and older, women, minorities) may be useful. Information is needed about those who are not referred for care.

The Steering Committee requested that the “locus of control” for each measure be included in the measure evaluations.

Appropriateness

In general, the Steering Committee supported including measures that address the appropriateness of care. The discussion regarding appropriateness measures focused on the following points:

- Appropriateness metrics should be considered as compliance with guidelines. All procedures carry risk, but if a given procedure is the most appropriate course of action at that time for that patient, it can significantly impact outcomes.
 - Disparities in the quality of care delivered to racial and ethnic minorities are a concern. We should be able to determine whether patients with the same appropriateness for surgery receive the same care.
 - Appropriateness is understandable and appealing to consumers and should be included.
- In summary, the Committee defined the scope of the proposed cardiac surgery measure to be:
- Procedures performed by cardiac surgeons. The Committee considered the spectrum of revascularization procedures and the influence of PCI on the group of patients that undergoes surgery. A disease-based approach to the spectrum of revascularization procedures should be considered in the future.
 - Measures that are within the control of the provider(s) who perform the surgery. The continuum of care includes the decision to perform surgery through approximately 30 days post-operation. Although longer-term outcomes are desirable, the surgical team is not in control and data are not readily available.
 - Measures that address the six NQF-endorsed aims for healthcare.
 - Structure, process, and outcome measures, including appropriateness (to be considered further) and frequency.

Priorities

The Committee established four priorities for the measure set during its discussions:

- NQF-endorsed measures. The NQF hospital set contains six measures applicable to cardiac surgery. These measures will be reviewed for possible updating or improvement but will remain in the set;
- condition-specific measures rather than cross-cutting measures. The conditions that are priorities for this set are ischemic heart disease and acquired heart valve disease;
- CABG, heart valve, and CABG+valve combination procedures; and
- measures that address disparities of care.

Identifying Candidate Measures

NQF staff identified more than 100 potential candidate measures using previously identified measures, results from the public call for measures, and a staff literature review. After applying the scope and priorities decisions, the list of candidate measure was reduced significantly. The final list of measures undergoing complete evaluation was then reduced to 33 through several activities: NQF staff combined all like measures (e.g., lipid management at discharge) together; discussions were held with measure developers to clarify specifications, which resulted in two measures being combined into one; and the TAP removed several measures from consideration.

In addition to the standard evaluation criteria outlined in *A Comprehensive Framework for Hospital Performance Evaluation*, the Steering Committee identified two additional criteria to be used in evaluating measures: data privacy/medico-legal concerns and locus of control.

The Steering Committee posed several overarching questions for the TAP:

- Should appropriateness measures be within the scope of this set?
- To address issues of equitability, should it be recommended that some or all measures be broken down into populations of risk (i.e., patients 65 years of age or older, women, racial groups, rural populations)? What are the technical issues, limitations, and evidence for doing so?
- What is the appropriate level of analysis for this set—hospital or surgeon?

NQF staff prepared detailed measure evaluations using standardized criteria. The evaluations were then distributed to the TAP for review. For measures with several versions, a side-by-side comparison of the measure specifications was included in the evaluation. TAP members made specific suggestions regarding the evaluations and provided summary comments on the perceived strengths and weaknesses of many of the measures, in particular noting whether there were technical reasons for a measure not being recommended further.

From March 23, 2004, through May 24, 2004, the TAP met in four 2-hour conference calls to address the issues raised by the Steering Committee and to assist NQF staff with measure evaluations.

Appropriateness Measures

The TAP did not agree that the six “appropriateness measures” initially proposed by STS were truly measures of appropriateness and asked NQF staff to research additional information regarding other possible measures of appropriateness, including the work performed by RAND in the early 1990s.⁵ The TAP reviewed the methodology of the appropriateness analyses developed by RAND and noted that the methodology is labor intensive and is in need of updating. Other possible measures of appropriateness, such as adherence to American College of Cardiology/American Heart Association guidelines,⁶ were considered, but the TAP did not believe that there were appropriateness measures ready for use.

The TAP emphasized that appropriateness measures are very important and that development of useful appropriateness measures should be a high priority. The TAP recommended that appropriateness should be viewed from the patient’s perspective. In this way, for a patient with coronary artery disease the appropriateness of care would be measured from referral to catheterization laboratory and to subsequent therapy, including surgery, PCI, and medical therapy. The goal of measurement is to measure possible overuse and underuse of therapies, as well as overall appropriateness.

Disparities of Care

The TAP noted that the risk models for outcome measures include age, gender, and race variables and that the outcomes are adjusted for these factors. Mortality measures can be stratified into gender and age cohorts, but race/ethnicity and geographical subsets could present small sample size difficulties in the statistical analysis at the hospital level for some institutions.

Some process measures may identify disparities of care delivery that influence outcomes. Noted was an ongoing study to determine whether the increase in operative mortality in women relative to men results from lower use of internal mammary artery (IMA) grafts. Similarly, a Technical Expert Panel for the Centers for Medicare and Medicaid Services (CMS) has recommended focusing the IMA measure on patients 75 years of age or older because of literature reports of lower use of IMA in that age group.⁷ The TAP recommended reporting the measure “IMA use” as an overall measure, as well as report by gender and by less than 75 years of age and 75 years of age and older.

Level of Analysis

The TAP did not make a specific recommendation regarding level of analysis, but it did identify several issues for the

⁵Leape LL, Hilborne LH, et al. *Coronary Artery Bypass Graft – A Literature Review and Ratings of Appropriateness and Necessity*. Santa Monica, CA: RAND; 1991.

⁶Eagle KA, Guyton RA, Davidoff R, et al. ACC/AHA guidelines for coronary artery bypass graft surgery – executive summary and recommendations: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1991 Guidelines for Coronary Artery Bypass Graft Surgery). *Circulation*. 1999;100:1464-1480.

⁷Arkansas Foundation for Medical Care. *Final Report to CMS: Coronary Artery Bypass Graft Surgery: Performance Measures and Risk Adjustment Methodology*; September 2002.

Steering Committee to consider in its deliberations:

- Care of a cardiac surgery patient is a team effort involving a large number of practitioners who should be included in any incentive for quality improvement. The measures should foster team work, not competition, among surgeons.
- Collection of data at the surgeon level usually requires several years to be included in the reporting period in order to achieve adequate sample size for statistical robustness. The oldest data may be four to five years old, and trends up or down may introduce statistical problems.
- Surgeon-level reporting has induced some avoidance of complicated patients and “gaming” of discharge management.
- If surgeon-level data are collected, the data may be available through Freedom of Information laws, as occurred in New York (or other states), which forced the reporting of surgeon-level outcomes. Some states have specific laws to protect the information from being released.

Mortality Measures

The TAP reviewed several well-regarded measures and risk models for mortality. In general, all perform similarly, as evidenced by similar risk-adjusted mortality rates. Additionally, all measures demonstrated a reduction in mortality from 1987 to 2003, regardless of whether the risk model was based at the state, regional, or national level. Each model has advantages and disadvantages. Because the overall performance of the models is essentially equivalent, the TAP considered other factors on which to base its recommendation:

Operative mortality versus in-hospital mortality

- Operative mortality captures more surgery-related deaths and provides a better conceptual picture of mortality related to the procedure.
- Length of stay, discharge practices, and local availability of rehabilitation facilities or other post-acute facilities may influence in-hospital mortality.
- The difficulty of reliably capturing deaths not occurring during the primary hospitalization is the main reason that states such as New York and California continue to report in-hospital mortality data. Both states are considering a change to operative mortality, which is conceptually a better measure, but data reliability is the stumbling block—patients ultimately may die in another hospital, another city, or another state. Data reliability may be a significant implementation issue for an operative mortality measure.

State models versus national models

- The TAP discussed the statistical validity of using a risk model developed on one population, such as a state, and applying it to the national population. Essentially the result is that the nation is benchmarked against the state performance. The model may not fit with a different population.
- New York, New Jersey, Pennsylvania, California, and other states have public reporting programs based on state-generated risk models. The data are audited and verified against administrative databases, vital statistics, and a sampling of chart audits.
- STS and VA have the only national models, and VA does not represent a typical national population. The STS

database is composed of voluntary, self-reported data from approximately 550 facilities (approximately 65 percent of facilities in the United States). Some TAP members expressed concern that a model based on unaudited data may not be as valid as a model based on audited, verified data.

Data collection burden

- Sixty-five percent of facilities currently submit data to the STS database. Several states, including California, New Jersey, and Massachusetts, use STS variables in their state reporting programs to reduce the burden of data collection. Of note, the California program had to provide clarification for several of the STS data elements to foster uniform coding by facilities.
- New York, Pennsylvania, and the seven facilities in the Northern New England group use their own variables and risk models. Many providers report that they cannot afford to submit data to both STS and the state if they are different.
- STS has proposed several complication measures that use many of the same variables as the STS mortality model. Using the same variables in several risk models is efficient.

After lengthy consideration of all of the advantages and disadvantages, the TAP expressed a preference for the STS operative mortality measure for three reasons: it is derived from a large number of facilities throughout the country; operative mortality is a conceptually better outcome than in-hospital mortality; and the variables in common with other STS measures of morbidity that may be included in the set would minimize the data collection burden.

Additionally, the TAP discussed whether cardiac surgery measures are robust enough to report risk-adjusted morbidity outcomes. The TAP agreed that the five STS risk-adjusted morbidity measures (stroke, renal failure, prolonged ventilation, deep sternal wound infection, and re-operation) are important measures and should be strongly considered by the Steering Committee.

Measures Not Recommended

The TAP reviewed several measures but did not recommend.

Intra-aortic Balloon Pump (IABP) (Pre-operative and Intra-operative)

The TAP agreed that no guidelines exist for IABP use and that there is no evidence of a linkage to outcome.

Off-pump Bypass Procedure

The TAP believed that no guidelines exist and that there is no evidence that a difference exists between off-pump and standard procedures.

Duration of Intubation (In Surgery)

The TAP agreed that prolonged intubation or duration of intubation is better as a post-operative measure than this intra-operative measure.

Post-operative Beta Blockers Within 24 Hours

The TAP identified issues with the measure, including changes in practice. The care process is difficult to interpret and has never been evaluated in contemporary cardiac surgical patient populations, and it is not equivalent to acute myocardial infarction (AMI). Two other beta blocker measures were judged to be more appropriate.

Auditing and Data Verification

The TAP members involved in state reporting programs emphasized the need to perform extensive audits and data verification, including site visits and medical record review. Auditing and data verification are time consuming and costly, but they are essential for the credibility of a public accountability program. The TAP recommended that guidance for data verification and auditing should accompany the measure set.

Recommendation of Individual Measures

To review and recommend candidate measures for the set of voluntary consensus standards, the Steering Committee held a 2-day meeting along with follow-up conference calls and electronic communications.

Criteria for Recommending Measures

The Steering Committee used the following criteria as it deliberated on the measures:

- no category of measure type should be excluded if related to quality;
 - a measure should meet one of the six NQF-endorsed aims, as modified slightly from the Institute of Medicine's work;
 - measures under development should be excluded;
 - a measure should be evaluated without regard to data source, but burden should be considered if a similar measure exists;
 - a measure should be considered regardless of unit of analysis, but a unit of analysis should be recommended; and
- pairing of measures should be specified, if appropriate.

Disparities

The Steering Committee reviewed the TAP recommendations regarding disparities. The Committee discussed the sample size issue using experience from the STS database. Committee members noted, however, that a sampling bias might stem from an urban or underserved population that cannot afford to report to the STS database. The STS database may contain data from more affluent practices, which, for example, would not be representative of where African Americans generally have heart surgery. This can make assessing disparities difficult.

The Committee suggested that process measures are particularly important in the discussion of disparities, because they influence outcomes. Part of the problem may start prior to cardiac surgery if the patient is not referred for cardiac surgery, which ties into the appropriateness issue and access.

The Committee recommended that data that can be stratified into subgroups based on race/ethnicity should be collected. Whether the sample is sufficient to be used for public reporting (and not just quality improvement or research) can be determined after evaluation.

Level of Analysis

The Committee reviewed the points highlighted by the TAP and discussed the fact that consumers are interested in physician-specific information. For example,

New York and Pennsylvania report at the physician level, and these data have been long made available—although it is unclear whether the information has been useful for patient decisionmaking. In contrast, although physician-specific reporting has not been shown to influence a patient’s decision, it does significantly affect physician improvement.

Some Committee members said that they believed that physician-level, not hospital-level, reporting is appropriate. They drew the analogy that healthcare cannot yet be compared to airline travel, where the public can look beyond the performance of an individual pilot and make decisions based upon the performance of the airline. Some Committee members believed that the default should be public reporting at the physician level.

CMS advised that it grapples with reporting at the physician level, but that it currently believes that the most important work is at the system (hospital) level, because it is thought that such reporting provides the agency the largest benefit. Accordingly, CMS has moved away from individual data in favor of greater interest in data about the system, because focusing on the errors of individuals can squander the opportunity for systemic improvements.

The following concerns were raised about reporting physician-level data for cardiac surgeons:

- Cardiac surgery is unique (in being subject to public reporting at the surgeon level in multiple state reporting programs) compared with other areas of medicine, and the experience has created an ongoing dialogue regarding the benefits of public reporting of CABG data at the surgeon level that does not occur in other areas of healthcare where there are no physician-level data.
- If reporting is mandated at the physician-specific level, what are the implications for the surgeon just finishing his or her residency? Physician-level public reporting without strong evidence of the benefits could dissuade people from entering the field.
- No evidence exists that public reporting at the individual provider level is of benefit compared with reporting at the hospital level.
- Data have shown that the same surgeons operating in one hospital may have a two-fold difference in performance compared to their operations in another hospital. This difference is primarily attributable to the risk to patients seen at one facility versus the other.
- Hospital-level data may be misleading to consumers if not all surgeons provide the same level of quality.
- In a voluntary situation, buy-in for public reporting of cardiac surgery at the hospital level likely will not be difficult. The surgeon-specific level might undermine voluntary participation.

The Committee suggested that the issue of level of analysis for public reporting should be undertaken broadly by NQF for all areas of healthcare delivery and not for a single kind of provider, such as cardiac surgeons.

The Steering Committee initially recommended the following:

- NQF should develop a policy addressing the issue of unit of analysis—for example, physician versus hospital-level public reporting and analysis—across the healthcare delivery system rather than project by project.

- The focus of this project should be public reporting of hospital data.
- Physician-level/surgeon-level data initially should be collected for internal quality improvement. NQF might reconsider the matter in the future, if warranted.

Following the review period, the Steering Committee again discussed this issue and decided not to change its recommendation that the NQF Board of Directors establish a policy on level of analysis, which to date has been largely driven by contractual requirements and/or lack of availability of evidence related to physician-level reporting for other NQF projects. The Committee did note that once a policy is established, further decisions on recommendations for level of reporting (physician level versus hospital level) should be determined through the CDP in the context of individual candidate measures, as is currently the case.

Proprietary Issues

Before reviewing the individual measures, Committee members noted that many of the measures in the candidate list are proprietary measures – specifically those from STS and Zynx Health (for the Leapfrog Group). The Committee was advised that the NQF Board of Directors’ policy for proprietary measures does not preclude their endorsement, but it does require that the level of detail in specifications, methodology, and data elements be sufficiently disclosed (i.e., open source) to permit an entity to reach the “same answer” as it would if it had paid to participate in the

measure developer’s (or affiliate’s) program. STS has provided NQF with sufficient information about its measures to be deemed open source (see below) and has signed NQF’s standardized intellectual property agreement. Discussions with representatives from Zynx Health (used by the Leapfrog Group) indicate a willingness to cooperate with NQF’s intellectual property policy.

STS Web Site for Data Analysis

For providers that do not subscribe to the STS database, STS plans to deploy a web site where all the data collection tools and risk models are available without charge. Specifically, STS said that if its measures are endorsed, it would construct a web site where data can be entered and morbidities and mortalities calculated using the STS model. A facility can decide after using the web service whether it might want to submit data to STS. STS will not “own” the data, and those data will not be included in reports or the database unless the facility subscribes to the STS program in order to compare its performance to other hospitals/regions. Of note, STS currently reports national aggregate data on an annual basis on its web site. Thus, providers that do not participate in the STS database can collect data within their own groups for comparison to the national data.

Some Steering Committee members expressed concern that this method is not an open architecture system for reporting. The measures themselves meet the open-architecture requirements, but the database architecture is still STS property. An STS

representative advised the Committee that a hospital could provide its STS data to a payer. The feedback report has the site data compared to regional data, best practices, and national data. A hospital may share the information at its own discretion. During the comment period, however, STS members expressed concern that the phrase “at their own discretion” may conflict with STS policy that prohibits a participant’s use of the data for unethical reasons, such as advertising “better results” that are not statistically different. Given these concerns, the phrase “at their own discretion” was deleted from the recommendation concerning the use of proprietary measures.

CMS Interests in STS’s Proprietary Database

CMS advised that it has an interest in being able to measure and publicly report quality, and it currently has efforts related to surgery. CMS is looking closely at this NQF project in this regard and is evaluating 9 to 10 of the 33 measures considered by the Steering Committee for this set. The Steering Committee expressed its support for the CMS effort and asked NQF staff to make sure its recommendations for proposed cardiac surgery voluntary consensus standards are amenable for CMS adoption. The Committee agreed that CMS acceptance of the measure development, reporting, collection, and updating was crucial if STS measures were chosen. CMS indicated a need to have an opportunity to provide input and make comments on the STS measures and the determination of variables. CMS’s representative, David Hunt, MD, suggested that the measure methodology could be placed in “escrow” so that in

the event that changes in STS policy occur in the future, the implementation of the measures would not be affected.

Additional Issues Regarding the STS Database

Prior to its discussion of outcome measures, some Steering Committee members again expressed concerns about supporting measures derived from a proprietary dataset—in particular in terms of access and finance—given that endorsement means that the measures are national voluntary consensus standards. In response, the STS measure developer and those Committee members familiar with the STS database noted that the STS risk-adjustment model would be available as it is updated and that the algorithms are published. Thus, this information is available. Similarly, the odds ratio and c-statistic for the risk models are published.

Additionally, NQF staff described the details of the intellectual property agreement required by NQF’s policy and assured the Steering Committee that STS has provided sufficient information to meet the requirements to have its measures considered. STS proposed to provide all the information and the Internet-based tool to derive the same answer for a non-participating provider. It also was noted that this does not mean that an entity can use the information to create its own database, but rather that the fundamental issue is that the hospital must be able to get the same answer as though it had participated and paid for the STS services. The Committee discussed the fact that large payers may need to consider additional arrangements and conditions with STS to support

implementation, but it determined that these issues are beyond the Committee's scope.

The Committee concluded that the benefits of the STS proprietary measures (which were developed and are used by the majority of cardiac surgeons in the country) outweighed the concerns regarding endorsing proprietary measures. However, the Committee recommended that NQF consider withdrawing its endorsement of the STS proprietary measures if any of the following conditions are not maintained:

- the web service providing access to the risk models is updated and free of charge;
- detailed measure specifications are available without charge;
- participants in the STS database (hospitals or surgeons) retain the ownership of data submitted to the STS and may share the data with others at their own discretion; and
- STS does not restrict the use of STS-generated reports to hospitals or surgeons, and providers may share the information at their own discretion without charge.

Process Measures

The Committee discussed 14 process measures and recommended 9 of these measures for the set. During the discussion of these measures, Committee members returned several times to the benefits of simple process measures with few or no exclusions for which the target would not be 100 percent use/application. It was noted that the burden of data collection is

reduced with simple process measures. There is often poor documentation in hospital records of the information regarding specific exclusions (such as comorbid conditions or risk factors) and there is less likely to be "gaming" in the use of exclusions. Some members also noted that for process measures, a goal can be set to bring low performers up to the level of the highest performers rather than an arbitrary target. Another possible benefit might be that those facilities that "push the envelope" by using therapies in patients with relative or borderline contraindications may demonstrate a benefit for these groups as well. The Committee discussed how this approach is distinct from the Six Sigma model, which describes a measure of quality that strives for near perfection.

Three Prophylactic Antibiotic Measures

(Endorsed by NQF in its Hospital Set):

- 1) Pre-operative Antibiotics Within One Hour;
- 2) Antibiotic Selection; and
- 3) Antibiotics Discontinued Within 24 Hours

The Committee reviewed ongoing discussions with CMS and its Surgical Infection Project regarding two potential changes in measure specifications:

- alternative antibiotics in beta-lactam allergic patients; and
- the discontinuation of antibiotics within 24 hours.

Cardiac surgeons have argued that it is acceptable to leave patients on antibiotics until the chest tubes are removed. Specifically, instead of discontinuing antibiotics within 24 hours as the measure is currently specified, discontinuation between 24 to

48 hours should be acceptable for cardiac surgery. An announcement from CMS regarding the possible changes in the measure specifications is expected soon; the Committee supports these possible changes.

The Committee recommended the following:

- Forward all three prophylactic antibiotic measures as currently specified for cardiac surgery patients to NQF Members. However, because CMS has recommendations forthcoming for the beta-lactam allergy and the antibiotic duration, these two changes should be adopted when CMS acts.
- NQF should develop a strong process to review and/or refresh measures.

IMA Use

The Committee was advised that in addition to the NQF-endorsed CMS measure for the hospital set of voluntary consensus standards, two alternative measures from STS and Zynx may be considered for this project. The TAP recommended against the Zynx measure because it thought there were too many inappropriate exclusions. The STS measure is similar to the CMS measure, but its specifications differ slightly, and the STS measure is risk adjusted.

The major discussion points raised by the Steering Committee concerning the IMA use measure included:

Disparities

- This measure should be considered for reporting by age and potentially by gender, because variation in quality exists mainly between those groups. Substantial opportunity for improvement also exists in these areas.

- Mortality is twice as high for women as for men, but IMA is used less frequently. Underuse of IMA in women may be related to more mortality in women—i.e., mortality may be similar if IMA were used at same rate in women as in men.

Existing NQF-endorsed measures. Because NQF has endorsed the CMS measure, the Steering Committee concluded that a recommendation to change the existing endorsed measure should represent an improvement. In this regard, the following observations were made:

- The STS IMA measure uses the same variables in its model as other STS morbidity and mortality measures that will be considered.
- Differences between the CMS and STS measures result from the definition of data fields, specifically the sources of data and the circumstances for performing IMA grafting. Definitions impact the safe use of an IMA graft.
- STS uses risk adjustment. The STS risk adjustment does not account for prior use of IMA. Given this, there is not much benefit to risk adjustment for this measure.
- The STS and CMS measures are essentially alike, although CMS uses ICD-9 codes to define the procedure codes, and STS uses clinical terms.
- Using ICD-9 codes allows the best way to get to the data.
- CMS uses administrative data. Some surgeons believe that the STS clinical data are easier to get, but only for those hospitals that participate in the STS database. Purchasers and consumers will want to ensure that data can be obtained from all hospitals.

- CMS's definition of this measure is clearer, but it should be amended for sex/age stratification.
- Dr. Hunt, the CMS liaison, advised that the ongoing Premier, Inc., demonstration project (which is using the CMS IMA measure and the three prophylactic antibiotic measures for CABG patients only) should not influence the decision, because the Premier project is limited and finite. He recommended that the Steering Committee look at how well the measures are specified and the extent to which they are replicable.
- A list of ICD-9 codes and the clinical terms that they represent would serve as a simple tool to facilitate the cross-walking of definitions between the CMS and STS versions. In fact, it was noted that some facilities use ICD-9 codes to identify cases to submit to STS.

Use/meaning of the measure. The target for IMA use should not be 100 percent, because there are appropriate reasons for not utilizing an IMA in some instances. The goal is to bring the low users up to the level of the high users. Accordingly, the Steering Committee recommended that endorsement should include an explanation of why the target should not be 100 percent.

Level of reporting

- This measure, more than any other under consideration for this set, is under the control of the surgeon, who decides whether an IMA graft should be used.
 - CMS is now reporting hospital-level data. STS can migrate to physician-level reporting. With the CMS version, reporting at surgeon level is currently possible, but as noted earlier provider-level reporting is not the agency's focus.
- The Committee recommended the following:
- Retain the CMS/NQF-endorsed measure for IMA use, but include the clinical terms with the ICD-9 codes in the measure specifications to facilitate crosswalking among the various users.
 - Report the measure in several forms at the hospital level:
 - overall IMA use,
 - IMA use in patients under 75 years AND in patients 75 years of age and older, and
 - IMA use in males AND females.
 - Note that 100 percent use is not the target for this measure.

Pre-operative Beta Blockade

Surgeons on the Committee advised that the main rationale for the use of beta blockers is that more than 70 percent of patients who undergo bypass surgery have a history of myocardial infarction (MI). Years of data on MI patients demonstrate that these patients live longer if they are on beta blockers. This measure also reflects the coordination of care between the cardiologist and the surgeon. The TAP recommended inclusion of this measure in the set. Areas of discussion included the following:

- CMS is considering this issue, and this measure fits in well with its plans.
- Not everyone undergoing CABG should receive beta blockers. Because there are absolute and relative contraindications, specifications should note that 100 percent use is not expected.
- New York is looking at peri-operative beta blocker use as a measure. The extension from pre-operative to peri-operative use includes the 24-hour

period after surgery; also because contraindications can be specified, a peri-operative definition makes sense. Beta blocker therapy within the peri-operative period can be initiated by surgeons if it is beneficial and beta blockers have not already been administered to the patient.

- As a systems measure, beta blocker use should be assessed pre-operatively, because its measurement before surgery will encourage communication between surgeons and cardiologists.
- The use of pre-operative beta blockers can provide benefits up to two days after surgery and is beneficial in preventing silent ischemia and MI.

The Committee recommended the following:

- Include the measure in the set.
- Note that 100 percent use is not the target for the measure.

Prolonged Intubation

The TAP recommended this measure as an important assessment of post-operative morbidity. Areas of Steering Committee discussion encompassed the following:

- The STS and Zynx (used by the Leapfrog Group) measures are the inverse of each other. For the STS measure, a higher number indicates poorer performance (percent of people intubated longer than 24 hours). For the Zynx measure, a higher number indicates better performance (percent of people extubated before 24 hours).
- The STS measure can be risk adjusted using logistic regression.
- Both rely on clinical data.

- The STS version measures complications, while the Zynx version measures success.
- The Zynx measure might provide incentive to inappropriately extubate patients. Thus, if the Zynx measure is recommended, it should be paired with the duration of intubation measure.
- This measure may be viewed as a process or outcome measure.

The Committee recommended the following:

- Include the STS measure in the set.

Anti-platelet Medications at Discharge

The TAP recommended that this measure should be included in the set because the benefits of this practice are well documented. The Steering Committee discussion included the following issues:

- Numerator and denominator specifications are not consistent between the STS and Zynx versions.
- Aspirin is the only medication that has a proven benefit in the literature – that is, it is the only agent shown to have impact on the mortality of a surgical population. Thus, the CMS and Zynx measures are not evidence based because each includes in the numerator medications in addition to aspirin. Also, some studies demonstrate that dipyridamole is not beneficial.
- For patients with stents, adding clopidogrel is necessary. This justifies its inclusion in the STS specification. Otherwise, the eligible anti-platelet agents should be aligned with the evidence reported in the literature.
- Experience reflected in the STS database reveals that results for the metric are already above 90 percent. Thus, there is not much variability.

- The STS specifications are most narrowly defined and consistent with the evidence.

The STS measure developer present at the meeting supported eliminating the exclusions in its measure for simplification, with the understanding that the target would not be 100 percent. (Note: Changes in specifications—that is, the creation of a new measure—are not permitted unless the measure developer concurs *and* the developer can assert and/or verify that evidence indicates that the new measure is valid. Because the STS measure developer was at the meeting, changes proposed by the Steering Committee could be discussed in real-time.)

The Committee recommended the following:

- Include the STS measure (without exclusions) in the set.
- Note that 100 percent use is not the target for the measure.

In the review, several comments were received noting that the use of clopidogrel should be limited (e.g., only with stents or not coincident with aspirin). The Committee reviewed the comments and advised that the indications for anti-platelet medication at discharge for post-CABG patients are not the same as for acute coronary syndrome (ACS) and heart failure patients. The use of aspirin and clopidogrel continue to evolve for cardiac surgery patients. For example, surgeons on the Committee reported that both aspirin and clopidogrel are used in patients undergoing off-pump CABG.

Beta Blocker at Discharge

The surgeons on the Committee advised that providing patients with beta blockers

at discharge has proven beneficial for reduction of myocardial work; it also prevents stroke. The TAP recommended this measure, stating that all patients should be on beta blockers. Data support prescribing beta-blockers post-operatively for hypertension, and there is some benefit for prevention of post-operative atrial fibrillation. Patients who have ischemic heart disease have class I and II indications for beta blockers. Some clinicians are using beta blockers in patients with relative contraindications, because the agents are improved and more selective and better tolerated by patients.

The Committee discussed the benefits of the simpler STS measure (easier data collection, in use by many providers, less amenable to gaming) compared with the Zynx measure, with multiple exclusions. It was noted that although Zynx measures may be more elegant, they are more burdensome to collect. As noted elsewhere, for several reasons the target should not be 100 percent.

The Committee recommended the following:

- Include the STS measure in the recommended set.
- Note that 100 percent use is not the target for the measure.

Lipid Management/Counseling

The TAP recommended this measure. The Steering Committee's discussion focused on the distinctions between lipid management and lipid counseling; it is very difficult to achieve effective dietary change. Patients are prescribed statins at discharge in an effort to reduce their lipids,

and the evidence is strong for use of statins compared to other drugs. Ideally, they will be prescribed along with counseling and diet, but capturing that information for measurement is a burden. The following points were made during the Committee's deliberations:

- The STS numerator, which includes isolated CABG patients who are discharged on a "statin or other lipid-lowering regimen," did not intend the definition to be interpreted as something non-pharmacological. There are patients who cannot take statins. The STS measure developers will include "other pharmacologic agents" in the specifications.
- The CMS measure rolls up several different strategies, including counseling, diet, and medications. These diet and counseling components are harder to document, and counseling is difficult to standardize. Focusing on medications is much simpler, and the evidence supports the benefit of statin use with this population regardless of lipid levels.
- The CMS and Zynx measures refer to measurement of lipid levels or specific test results in the specifications. Measuring lipid levels during hospitalization for major surgery is not appropriate. The LDL levels specified in the Zynx measure are outdated.
- VA patients have their cholesterol measured in the outpatient setting. Thus, when patients arrive at the hospital for surgery, cholesterol is not measured, which equals a missing variable under the CMS measure. The newest evidence suggests that it is not necessary to measure lipid levels, because regardless of lipid level, all cardiac surgery patients should be on statins.

- The CMS measure is more inclusive, creating the danger that a recommendation for diet counseling will supercede the use of statins but will still be counted in the numerator in a measure while not impacting outcomes by decreasing mortality/morbidity. The STS measure assures that patients are prescribed statins or other pharmacologic agents.

The Committee recommended the following:

- Include the STS measure in the set, provided that STS specifies "other pharmacologic agents."

Process Measures Not Recommended for Inclusion in the Set

The Steering Committee tabled the following measure until further scientific evidence resolves the controversies surrounding the care process being measured:

Angiotensin converting enzyme (ACE) inhibitor at discharge. The STS specification is identical to the CMS specification. The TAP recommended this measure and suggested that patients on angiotensin receptor blockers (ARBs) be excluded. The Steering Committee discussed the following points:

- This care process has significant room for improvement.
- The single greatest cause of mortality/morbidity is renal failure; therefore, this complication needs to be addressed.
- Steering Committee members discussed the potential result of choosing the STS measure, the likelihood that CMS will adopt it, and whether the change would be significant.

- The patient population of the CMS measure is more limiting than that of the STS definition, and the STS specification is consistent with what the American College of Cardiology is currently recommending.

During additional discussion it was noted that a major issue with ACE inhibitors is the development of a new class of drugs for the same purpose, ARBs. However, there is still no agreement regarding which class is better and which patients should get which class of drug. No data are available on ARBs in patients undergoing cardiac surgery.

A similar measure for heart failure and AMI patients developed by JCAHO and CMS-Quality Improvement Organizations and endorsed by NQF has been reviewed regarding the issue of ACE inhibitors and ARBs. As of January 2004, JCAHO and CMS have decided not to change the measure specifications to include ARBs.⁸

Additionally, the Steering Committee did not recommend the following four process measures for the reasons noted:

Smoking cessation counseling. The NQF hospital set includes three smoking cessation measures similar to the STS and CMS measures, but addressing different conditions – ACS, heart failure, and pneumonia. The Committee also noted that the definition of a smoker differs between measures. CMS and JCAHO categorized patients who have smoked within a year as smokers, while STS defines smokers as those who have smoked within three weeks of surgery. The STS definitions are based on empirical data that demonstrate that if individuals stop smoking for three

weeks prior to surgery, their lung capacity improves and pneumonia is less likely. Committee members expressed concern about endorsing another smoking measure that is specified differently from the smoking cessation measure currently being collected on other hospitalized patient populations and did not recommend any of the smoking cessation measures considered for the set. Instead, the Committee recommended that NQF pursue a general smoking cessation measure for all hospital patients rather than individual measures for various populations.

Referral to outpatient cardiac rehabilitation.

The Steering Committee concurred with the TAP's recommendation to exclude this measure because of the significant role of local referral patterns and the availability of rehabilitation facilities. Additionally, CMS is changing guidelines for rehabilitation centers, and some centers will close because they cannot accommodate the CMS requirement that a physician be present at each facility after the event/person arrives.

Red blood cell transfusion. The Steering Committee concurred with the TAP's recommendation to exclude this STS measure. Although the risks of transfusion are known, sometimes a transfusion is imperative. Additionally, there are no guidelines on transfusion use. Accordingly, it is difficult to measure something when there is no agreed-upon use and method.

Re-intubation rate. This measure was not recommended by the TAP, because avoiding re-intubation may encourage unnecessary longer intubation in patients, with possible attendant complications.

⁸See www.jcaho.org/pms/core+measures/latest+core+measure+news.htm.

The Steering Committee agreed, but it noted that the measure could be paired with early extubation; early extubation usually means a higher re-intubation rate. Because the prolonged extubation measure has been recommended, however, this measure would focus on only 3 to 5 percent of cases, and the Committee believed that it would not provide enough information when weighed against the burden of data collection and reporting.

Outcome Measures

The Committee reviewed 15 outcome measures and recommended that 10 be included in the set. Prior to discussing the individual outcome measures, however, the Steering Committee discussed several global issues related to mortality measures, as summarized in the following section. As part of the discussions on these global issues, the Committee made recommendations other than those specific to the inclusion or exclusion of a measure; these are summarized in the following section as well.

Overall View of Mortality Measures

The TAP discussed mortality measures in depth, with discussion focusing on the distinctions between in-hospital mortality measures versus 30-day operative mortality measures. Overall, the TAP viewed 30-day operative mortality measures as more appealing because they represent a picture of overall outcome superior to in-hospital mortality, which may be subjective to local behavior regarding discharge situations and length of stay. The 30-day mortality

measures include both in-hospital deaths and post-discharge deaths within 30 days. The TAP discussion also focused on the nature of the databases underlying the risk assessment for mortality measures: The VA and STS models are based on national populations, and the New York, California, and New Jersey models are based on state populations. Additionally, the TAP's deliberations included discussion of the systems used for auditing the databases. STS does not have a strict data auditing system. Thus, there may be an issue around developing a model in which data elements are not verified. Another issue raised by the TAP was difficulty in reliably collecting data on deaths after the primary hospitalization. Despite these issues, the TAP recommended the STS's 30-day operative mortality measures over an in-hospital measure because of the more appealing timeframe and because it is a measure with which most surgeons are familiar. Additionally, the STS measures of major morbidities that were also recommended by the TAP use the same data elements, thereby streamlining data collection.

The Steering Committee's discussion generally reflected the TAP's concerns about mortality measures. It especially focused on data validation, auditing of databases, and hospital verification of data accuracy. In these deliberations, the following points were made in each area:

Data validation. Some Committee members felt more strongly than others that implementation concerns are important with outcomes measures, while others considered the measures without regard to implementation issues.

The STS developer reported that STS has conducted a comparative analysis between STS data harvests and Medicare data to match for data validation. Because there were more Medicare patients in the STS database than there were in the Medicare database, STS thought that its database was more accurate. The VA representative advised that VA had its own database previously and tried to compare results with the STS database. The VA database was abandoned because the variables were not identical and comparisons could not be made. Another member reported that providers in Virginia attempted to use the New York model for their data, but their statisticians found that the fit was poor and that the STS model was more applicable.

An STS representative explained the data quality process for the STS database, as follows: Data managers from the hospitals continually evaluate the performance and definition of the measures. For example, the Duke Clinical Research Institute has built data quality tools into the STS database. At the end of every performance report a data quality report is created in which every data element is compared with what is considered to be its national benchmark. If the data element is more than two standard deviations from the norm, the data are not accepted into the database unless verification is provided that the data are real.

Auditing. The Committee noted that auditing is a cross-cutting concern for all data collection. Members generally agreed that recommendation of a measure does not imply that the existing auditing mechanisms would necessarily be used in a new setting (e.g., implementation of New York's CABG mortality measure

outside of New York may not include the same data auditing process that New York uses). However, the Committee concluded there was a need to establish an expectation for data verification regardless of a particular measure/dataset—and especially because many of the recommended measures are originating from a provider organization, STS. To provide measure credibility, consumers, purchasers, and plans must have some reassurance that the data have been verified and are accurate. An STS representative did note that STS is establishing a national data audit process that should be ready by the end of 2004.

In the review period, NQF received several comments related to appropriate validation methods and data verification. Additional information related to data verification and auditing was received, as follows:

- CMS reported plans that it is considering for auditing and data verification. Specifically, CMS advised that fast track talks with STS have been initiated to work out details for implementation of the endorsed set of consensus standards with an auditing mechanism.
- CMS will use the Clinical Data Abstraction Center for sample chart review as is done in the Hospital Quality Alliance's initiative for CMS-JCAHO measures.
- CMS plans to link with the Social Security Administration database to verify deaths, which contains high-quality data on deaths at 18 months.
- CMS can verify that all cases are reported for Medicare patients, who comprise more than 60 percent of CABG patients.

- The Surgical Care Improvement Project (SCIP) already is working out a mechanism of linking to claims files of other purchasers (e.g., Blue Cross/Blue Shield and Leapfrog payers) for the non-Medicare group (due August 2005).

STS representatives also advised that STS is finalizing plans for data auditing of its database using onsite chart review of a 10 percent sample beginning in 2005. STS noted that the costs of auditing cannot be carried by STS alone and must be shared with others. STS considers the data in the database to be of high quality because of the numerous checks and data quality feedback to the participants. STS representatives again noted the recently published results of a one-time audit performed in 3 rounds at 12 sites in Iowa and compared with Medicare, Part A Data Files, which demonstrated that most of the data elements evaluated were 95 percent reliable. In the second part of the study, validity of the STS data was evaluated by comparison with Medicare records. The STS database captured all of the Medicare patients and identified several cases not included in the Medicare files. An additional evaluation of STS data compared to Medicare records identified several more patients in the STS dataset that were not identified in the Medicare files.⁹ Other studies comparing the STS dataset against administrative claims data have repeatedly identified more cases in the STS database.

Hospital verification of data accuracy. For subscribers to the STS database, the surgeon is the senior person who signs off on data accuracy. The Committee noted a concern with this process for purposes of public reporting, because this self-reporting may not be viewed as reliable or accurate. Some Committee members noted that there could be a motive based on economics and public image to not report fully if results are less than perfect.

One Committee member advised that California requires a “CEO attestation” to the accuracy of the data. At the hospital there is a designated individual who signs for the CEO. The Committee considered adding a requirement for CEO attestation to the STS measure specifications for the mortality measures, but this was not acceptable to the measure developer. The Committee continued to support a hospital attestation of the accuracy of the data for hospitals that are not participating in a system that includes a formal auditing process. The Committee decided to include a recommendation to accompany the measure set that implementation of the set must include a mechanism for data verification and accuracy that may be a formal audit or, in the absence of a formal auditing process, attestation from the ranking executive from the data-submitting enterprise (hospital, physician group).

Several comments were received during the review period expressing concerns about the proposed mortality consensus standards—for example, that they should be risk adjusted and that a post-operative mortality measure was not within the

⁹Welke KF, Ferguson TB, Coombs LP, et al. Validity of the Society of Thoracic Surgeons National Adult Cardiac Surgery Database. *Ann Thorac Surg.* 2004; 77:1137-1139.

control of the hospital and thus should be excluded from the set. As a result, the measures' names were changed to more accurately reflect that the proposed consensus standards are risk adjusted. However, in reviewing the other comments raised about the "operative mortality measures," the Committee concluded that the TAP and the Steering Committee had considered them at length. The Committee emphasized that both inpatient and operative mortality measures have methodological concerns. Inpatient mortality is significantly influenced by discharge policies and availability of post-acute and rehabilitative care and is susceptible to manipulation by providers. Operative mortality is a conceptually better assessment of the outcome of surgical care and is the measure most widely used by surgeons. Additionally, although it may be easier to capture data for inpatient mortality at this time, the need to develop data collection capabilities for operative mortality is compelling and agencies, including CMS, are proceeding with plans to establish data collection and auditing methodologies for the implementation of operative mortality measures.

CABG Mortality

The Steering Committee discussed the possibility that it might not make sense to approve both the STS (30-day) and the New York (in-hospital) mortality measures, because each is based on different risk-adjustment methods and involves collection of different data elements. The Committee also considered the impact of endorsing a different measure from the current NQF-endorsed New York inpatient mortality measure for CABG. It concluded

that having two different NQF measures would be problematic and thus decided that if the Committee endorses a different measure, it should make a recommendation regarding the disposition of the current NQF-endorsed CABG mortality consensus standard.

The Committee discussed at length the advantages and disadvantages of 30-day mortality versus in-hospital mortality, attempting to clarify a rationale for selecting one measure over the other. It was noted that validating mortality data in a reliable manner for patients who die after the initial hospitalization is a significant issue. Patients may die at another hospital, in another city, or in another state, and accurately collecting those data may be quite difficult or considerably delayed. The concern was raised for the 30-day mortality measure regarding whether hospitals would expend effort to search for out-of-hospital deaths that will only make them look bad. For example, state reporting programs have found a need to cross-check against administrative databases to ensure mortality data are accurate and all deaths are captured. On the other hand, it was generally agreed that a 30-day mortality measure is more inclusive and provides a better clinical picture of overall care, including complications.

With respect to concerns about the issue of data reliability for the 30-day mortality measure in light of both its derivation from a currently unaudited database, as well as the difficulty of gathering such data in general, CMS stated that it might be able to provide post-discharge mortality data from the Social Security database, which provides very solid death data at 18 months

(after data scrubbing and normalization). CMS stated it would be able to facilitate the compilation and validation of high-quality 30-day mortality data for long-term trending, although death data less than 12 to 18 months old are less reliable.

The Committee also discussed the advantages and disadvantages of national versus state risk-assessment models:

- In published work, Edwards and Grover note that the mortality rates for valve surgery patients in the New York and STS databases were very similar.¹⁰ Of note, currently few surgeons in New York participate in both the New York (mandatory) and STS (voluntary) programs for cost reasons.
- In California, the California CABG Mortality Reporting Program and the STS data have been compared, with approximately the same results.
- The New York state model has not been tested outside of New York.
- Currently, the STS measure is in wide use nationally. The state reporting programs in California and New Jersey use STS variables to derive their state-based outcomes. Participation in the STS database is low in states such as New York and Pennsylvania, which have public reporting programs based on different variables and methods.
- Concern was raised that the STS non-participants will constitute a large number that will not be in the database and will consequently not be represented in the risk model. It was noted, however, that this concern is magnified if a state model is considered. An STS representative stated that the variables used in the

STS database are formed with huge numbers and should not change much due to non-participants – that is, a single hospital's, or a region's, contribution to the overall information in the database will be negligible with respect to changing the mean and coefficients.

Because the set was based on a national database and because it represented a more complete clinical picture, the Committee initially recommended that it should include the STS “operative 30-day CABG mortality” measure and that the “operative 30-day mortality” measure (STS) should replace the existing NQF-endorsed “inpatient CABG mortality” measure (New York) in the hospital consensus standards set. Upon further consideration, however, the Committee recommended that an inpatient CABG mortality measure should be included and that it should be the California version – that is, the STS 30-day CABG mortality should be added and the California inpatient CABG mortality should replace the New York version previously endorsed.

During the deliberations, some Committee members reported that consumers and purchasers are familiar and comfortable with inpatient CABG mortality and would need to learn about the 30-day mortality measure and that including two measures will provide consumers with additional information. Thus, although most Committee members agreed that the 30-day operative mortality measure is superior as it relates to quality of care, it was agreed that a transition period that

¹⁰Grover FL, Edwards FH. Similarity between the STS and New York state databases for valvular heart disease. *Ann Thorac Surg.* 2000;70:1143-1144.

includes both types of mortality measures would be useful. Because the California measure uses STS variables and definitions to create its state-based risk model, while New York has its own risk model based on a different set of data elements and definitions, the Committee recommended the California measure to avoid the burden of collecting new/different data elements separate from those already collected for other measures recommended for this set. Of note, New York representatives advised the Committee that it collects more data than are used in its risk model. Thus, it may be possible to map the New York data to the California measure, even though this has not been attempted. Finally, the Committee noted that reporting of both mortality measures would require detailed explanation and that stakeholders would require such explanation to help them interpret the results correctly.

Valve and Valve+CABG Surgery Mortality Measures: 1) In-hospital Valve Mortality; 2) In-hospital Valve+CABG Mortality; 3) 30-day Operative Mortality—Aortic Valve Replacement (AVR); 4) 30-day Operative Mortality—Mitral Valve Replacement (MVR); 5) 30-day Operative Mortality—AVR+CABG; and 6) 30-day Operative Mortality—MVR+CABG

Similar points made during the CABG mortality measure discussion carried over to the discussions of other cardiac surgery outcome measures; the TAP did not specifically discuss these measures separately from the CABG mortality measure and mortality measures in general.

The Committee noted that the issues are the same but are applied to a different

surgical population, with the only difference being that valve surgery is less common and hence sample size issues are more prevalent. The point also was made that separation of valves into aortic valve and mitral valve involves different risks—that is, there is an important distinction, and the two procedures should be measured separately, which is not done in the in-hospital mortality measures. New York state representatives advised that their risk model for valve surgeries requires a rolling 3-year data collection to collect sufficient cases. The STS 30-day mortality measures use a risk model generated from a much larger data set.

As with CABG mortality, the Committee supported the 30-day mortality measure because it captures a more robust view of mortality related to surgery and is the measure currently used by many cardiac surgeons. Additionally:

- The Committee's major concern again related to sample size, which can be as low as 5 percent of all cardiac surgeries. Committee members noted that in hospitals in California and the VA, about 10 to 15 percent of cardiac procedures are valve surgeries.
- To report data for valve surgery on anything other than an institutional basis is not scientifically valid. The fact that each type of valve surgery can be broken out for analysis is unique and only possible due to the large numbers in the STS database.

The Committee recommended the following:

- Do not include the in-hospital valve and valve+CABG mortality measures.

- Recommend further research to develop a more robust inpatient mortality measure.
- Include all 4 30-day mortality measures in the set.

Morbidity Measures: 1) Deep Sternal Wound Infection; 2) Stroke; 3) Renal Insufficiency; and 4) Surgical Re-exploration

The Committee considered four STS morbidity measures, which were all recommended by the TAP. All are risk adjusted and use many of the same variables and data elements used for the STS mortality measures. During the discussion, the following general points were made (with additional points on the “deep sternal wound infection” measure and the “re-exploration” measure further noted below):

- Committee members believed that the complication measures were more important than the mortality measures, because they distinguish practice more than the mortality measures by providing more information about processes and performance;
- these four complications also lead to prolonged stays, and the only major complication missing is pneumonia, which is addressed by the intubation measure; and
- data for these measures are not difficult to collect.

Deep sternal wound infection. Definitions for sternal wound infection vary among STS, VA, and the Centers for Disease Control and Prevention (CDC). The VA definition strives to eliminate the “quasi” wounds to focus on injuries that require further care and are considered a serious complication; accordingly, VA

defines sternal wound infection more narrowly, capturing the more serious infections. This definition, which STS adopted, is not the same as that used by CDC for its nosocomial infection database. Using the VA/STS definition would represent a deviation from the CDC definition, but would more specifically identify sternal wound infections of interest to quality of cardiac surgery. In particular, this definition is a subset of the most severe surgical site infections that have significant consequences for the patient.

CMS used the CDC definition for SCIP, but also used a definition of “severe” mediastinitis for patients that are returned to the operating room. This latter definition matches the VA/STS definition. The Committee thought that this distinction, to identify the most serious infections and exclude minor or superficial infections, is important for a quality measure.

Surgical re-exploration. The TAP thought that there are valid reasons to take people back into surgery and that the measure may create a potential bias not to do so, which could be harmful to patients. Nevertheless, the Steering Committee noted that re-exploration can be a quality issue that is too often forgotten; the measure would address this situation. In particular, the Committee acknowledged that this metric will have some variation within itself and will have some variation between and within hospitals; as such, however, it will facilitate the identification of outliers. Additionally, it was noted that re-exploration seems to have more variables contributing to whether it occurred due to an error or a quality issue. That is, if one team goes back to

the operating room more than another, this measure would be a way of looking at a complication at a reasonable level. If a hospital has a 7 to 8 percent re-exploration rate, this should raise concern.

The Committee recommended the inclusion of all four morbidity measures in the set.

Outcome Measures Not Recommended for Inclusion in the Set

The Steering Committee tabled the following measure until a feasible implementation strategy is developed:

Quality of life. The TAP advised the Steering Committee that this measure was not sufficiently developed to be considered at this time and that additional research and clearer specifications are needed; it did note that post-operative cognitive decline is somewhat addressed by the post-operative stroke measure. The Committee generally concurred, but emphasized that quality of life and return to productivity is important to consumers and payers. Concern was expressed about the cost of the 3-month follow-up for the measure, although other Steering Committee members thought that cost is an implementation issue that should not be a barrier to recommending the measure and that implementing a valid quality-of-life measure is worth the cost, because it is consumers' most important issue. Finally, the Steering Committee took into account the fact that a commonly used and publicly available instrument, the SF-36, has recently been updated, and the updated version is not in the public domain.

Although the Committee did not recommend the measure, all members agreed that it was the most important

measure considered. Members recommended that the report should begin with a statement that a quality-of-life measure is the highest priority and should specifically include a recommendation that although quality-of-life measures are available, the development of an efficient, implementation mechanism for a clearly specified and validated measure is urgently needed.

The Steering Committee did not recommend the following two outcome measures for the reasons noted:

Post-operative length of stay. This is an STS risk-adjusted measure, but the TAP was not convinced anything would be added to the set by including the measure, and it noted that claims data would be a better source than the STS database. The Steering Committee agreed that the measure should not be recommended because length-of-stay data, although easy to obtain, do not indicate why a stay is long; the set includes complication measures that are much more valuable. Additionally, concern was expressed that having a length-of-stay measure without pairing it with a readmission measure was problematic – that is, patients could be discharged quickly, which might be detrimental unless the readmission rate also is measured. Although acknowledging the problems with this measure, some Committee members noted that a measure of length of stay is valuable to payers, because it is an efficiency measure, albeit a poor proxy. The Committee agreed that instead of recommending a poor efficiency measure, the report should emphasize the need to develop better, valid efficiency measures, as efficiency is one of the six aims. A readmission measure might serve such a purpose, and CMS reported that it was looking into this matter.

Adverse Outcome. The TAP thought that the different components of this combination measure should be weighted and that the measure needed further development. The Steering Committee concurred and recommended against its inclusion in the set.

Structural Measures

The Committee reviewed six structural measures and recommended that five be included in the set (one as a “policy measure”).

Surgical Volume: 1) CABG Volume; 2) Valve Volume; and 3) Valve+CABG Volume

NQF has endorsed a CABG volume measure (New York) as part of its hospital set. Other procedural volumes consistent with the measures recommended by this Committee are valve and valve+CABG. Although the TAP declined to make a recommendation on the volume measures, the Steering Committee ultimately concluded that, in the absence of a risk-adjusted mortality measure, volume is an acceptable proxy.

CABG volume. As noted, the NQF-endorsed CABG volume measure in the hospital set is the New York measure, because it is related to the NQF-endorsed CABG mortality measure. Given that the Committee recommended that this measure be replaced with the STS CABG mortality measure, discussion focused on whether to recommend a volume measure with different specifications (i.e., other than New York) for purposes of minimizing the data collection burden.

Ultimately, the Committee recommended using the CMS definition for volume (ICD-9 based) to specify the measure. Although there was concern about recommending the use of an ICD-9-based volume measure when the mortality measures are based on clinical data specifications, the Committee decided this was offset when balanced against CMS’s confirmation that it uses ICD-9 codes for the three prophylactic antibiotic and IMA use measures, and it agreed to “own” the volume measure compatible with these process measures.

Minimum volume threshold. The Steering Committee discussed a minimum threshold for CABG volume, because there is a small volume/outcome relationship. Specifically, centers performing fewer than 50 cases per year have higher mortality. For every 100 increases in cases, there was a 0.07 percent decrease in mortality; the average number of cases for hospitals that submit data to STS is 265.¹¹ It was noted that the Leapfrog Group supports a volume threshold of 450 cases, which was based on employers’ identification of a threshold of the top 15 percent of centers in the United States; restricting referral to just these hospitals would save 50 lives per year. Overall, the Committee did not support recommending a minimum volume threshold, viewing it as an arbitrary limit.

Reporting of volume measures. The Committee generally viewed volume data as a measure of quality only when risk-adjusted mortality or morbidity data were not available. CMS expressed enthusiasm for a mechanism under which a hospital that does not report endorsed cardiac surgery measures would receive

¹¹ Peterson ED, Coombs LP, et al. Procedural volume as a marker of quality for CABG surgery. *JAMA*. 2004;291(2):195-201.

a 0.4 percent pay decrement. (This would be similar to what will occur for the 10 NQF-endorsed measures for which mandatory reporting will be in effect for fiscal year 2005 under the Medicare Modernization Act.)

The Committee recommended the following:

- Include CABG volume in the set, but replace the NQF-endorsed measure for CABG volume that uses the New York specifications with the CABG volume measure of CMS, which uses ICD-9 codes.
- Include valve and valve+CABG volume in the set.
- Include a recommendation that volume should be used as a quality measure only in the absence of other risk-adjusted morbidity or mortality measures.

Frequency of CABG

There is great variation in the frequency that CABG is performed, mostly at the regional level. Frequency differs from volume, because it is a geographic issue addressing volume per population, not volume per hospital. Accordingly, this is not a hospital level measure, but a geographic regional measure that provides information about access.

The TAP did not discuss this measure. In its deliberations, some Committee members noted that the availability of services significantly impacts frequency, and frequency data are difficult to interpret—for example, in addition to issues of access, cardiology groups also vary in their referral patterns for surgery. On the other hand, some Committee members thought that frequency of procedure is an important

public health measure of variation, access, and disparities—that is, based on the NQF aims, frequency could be considered a very crude measure of equity and possibly a very crude measure of efficiency and effectiveness. Overall, however, the Committee agreed that frequency should be viewed as a public policy access measure, not as a quality measure at the hospital level.

The Committee recommended the following:

- Include frequency in the set as a “policy measure,” not a hospital-level quality measure.
- Recommend that the measure be used as frequency of CABG and frequency of PCI to monitor the public policy issues of accessibility, variation, equitability, and efficiency.

Systematic Database Participation

Evidence exists that producing and using data for benchmarking and feedback is demonstrably related to improved quality of care; the measure is not specific to a particular database. The TAP recommended that this STS measure be included, and the Steering Committee concurred. CMS noted, however, that as long as “participation” does not encompass ALL of the process/outcome measures, it can support the measure and will have the capacity for it. Additional discussion centered on defining a “qualifying database,” because there was no support to limit the specifications to “participation in the STS database.”

The Committee recommended that the measure be included in the set, with the specifications to define database participation as “a multicenter data collection and

feedback program that provides benchmarking relative to peers and uses process and outcome measures to improve quality” (agreed to by the STS measure developer).

Structural Measure Not Recommended for Inclusion in the Set

The Steering Committee recommended against including one structural measure:

Hospital charges. This measure includes only charges, not costs or payments. The TAP did not comment on this measure. The Steering Committee noted that there is great variability even within a single system when charges are compared and therefore this measure may not be ready for generalized use. Some Committee members thought that although the measure might be crude, it might have some merit because it is an efficiency measure. Ultimately, however, the Committee agreed that other measures should be pursued.

The Committee recommended the following:

- Exclude the measure from the set;
- Reinforce the need to develop better measures of efficiency; and
- Recommend that NQF pursue cross-cutting measures of efficiency for all hospital patients, rather than for certain populations.

Additional Issues

During the review period (July 2004 to August 2004), a few comments were received on issues not previously discussed or not discussed in detail, but that merited summarization in this commentary.

Data “Freshness”

Comments were received noting that “data freshness cut points” should be specified, in particular with the STS consensus standards.

STS harvests data every six months; the NQF-endorsed frequency for data transmission for hospital consensus standards occurs no more frequently than quarterly during the calendar year. Additionally, STS uses a “rolling” four-year dataset to calculate the coefficients for the risk-adjusted outcome measures. Neither the NQF hospital framework nor this report specifies an appropriate sampling period for the purpose of these calculations, which are to an extent measure specific. Nevertheless, it is noted that current data are generally better than old data.

Additional Measures Recommended During Review

Four additional measures were recommended for inclusion in the cardiac surgery set during the review period:

- “Post-surgical patients who develop MI.” Members of the Steering Committee reported that STS has evaluated the measure but has found the data unreliable in confirming the diagnosis of MI. STS concluded that further development is needed.¹² The Committee reviewed the material forwarded on the four recommended measures and noted that STS has evaluated the suggested measure “post-surgical patients who develop MI,” but found that the data are unreliable in confirming the diagnosis of MI and that further development is needed.

¹²Shroyer LA, Coombs LP, Peterson ED, et al. The Society of Thoracic Surgeons: 30-day operative mortality and morbidity risk models. *Ann Thorac Surg.* 2003;75:1856-1865.

■ NQF staff attempted to complete measure evaluations for the other three measures recommended, but significant gaps exist based on the evaluation criteria – that is, information to address the criteria is unknown based on the references provided with the recommended measures. Additionally, the authors of the two cited articles were contacted, and NQF staff did not receive a response. Specifically, the following was noted with respect to the three measures recommended for inclusion:

- “Change in mental functioning.”
The reference provided describes a research methodology to assess mental functioning using five different assessment tools. No guidelines for care processes have been identified. This measure does not appear to be fully developed.
- “Did the surgeon explain the risks of surgery in a way you could understand?” There is no evidence that the single question taken from the Picker survey instrument and modified significantly has been tested for scientific validity.
- “Longitudinal cost efficiency.”
The measure cited is a performance measure for end-of-life care. Further evaluation is needed on whether it is appropriate to use the methodology on any other area.

Appeals

After the full set was endorsed by the NQF Board of Directors, NQF received two letters of appeals, requesting NQF reconsider the entire measure set: one from the New York State Cardiac Advisory Committee, with a supporting letter from the New York Commissioner of Health; and one from the California Office of Statewide Health Planning and Development. Neither appeal requested reconsideration of any specific measures or measure specifications. Rather, the appeals related instead to potential use of the consensus standards by CMS in future quality initiatives or payment incentive programs. The NQF Board denied the appeals because CMS’s actions are beyond the reach of NQF; in essence, the NQF does not have “jurisdiction” over CMS.

Table 2 – Cardiac Surgery Framework (including recommended measures)*

	Safe	Beneficial	Patient Centered	Timely	Efficient	Equitable
PROCEDURE SPECIFIC						
CABG	CABG volume	CABG mortality				
Heart valve surgery		Mortality (4 measures)				
CABG+valve		Mortality (2 measures)				
CONTINUUM OF CARE						
Decision to perform surgery						
Pre-operative management	Antibiotic timing Antibiotic selection			Pre-operative beta blocker Antibiotic timing		
Surgery		IMA use				IMA use
Post-operative care	Antibiotic duration	Prolonged intubation Deep sternal wound infection Stroke Renal insufficiency Re-exploration				
Secondary prevention/ discharge plan		Anti-platelet medications Beta blocker Lipid management				
Post-hospital recovery and rehabilitation		Operative mortality				
DEMOGRAPHIC POPULATION						
Age						IMA use
Gender						IMA use
Race/ethnicity						
Socioeconomic Status						
Geographic						

* For explanation, see page D-3.

NATIONAL QUALITY FORUM

Appendix E

Selected References

This appendix summarizes the key literature considered during the screening, evaluation, and selection of candidate measures for the set of National Quality Forum-endorsed national voluntary consensus standards for cardiac surgery. It includes the literature that supports the responsiveness of the measures to the evaluation criteria: importance, scientific acceptability, usability, and feasibility.

1. Participation in a Systematic Database for Cardiac Surgery

Ferguson TB, Peterson ED, et al. Use of continuous quality improvement to increase use of process measures in patients undergoing coronary artery bypass graft surgery: a randomized controlled trial. *JAMA*. 2003;290:49-56.

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c. CABG+valve surgery

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18. Risk-Adjusted Operative Mortality for Aortic Valve Replacement (AVR)

19. Risk-Adjusted Operative Mortality for Mitral Valve Replacement/Repair (MVR)

20. Risk-Adjusted Operative Mortality for AVR+CABG Surgery

21. Risk-Adjusted Operative Mortality for MVR+CABG Surgery

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NATIONAL QUALITY FORUM

Appendix F

Consensus Development Process: Summary

The National Quality Forum (NQF), a voluntary consensus standards-setting organization, brings together diverse healthcare stakeholders to develop consensus on voluntary consensus standards to improve healthcare quality. The primary participants in the NQF Consensus Development Process are NQF member organizations, which include:

- consumer and patient groups;
- healthcare purchasers;
- healthcare providers and health plans; and
- research and quality improvement organizations.

Any organization interested in healthcare quality measurement and improvement may apply to be a member of NQF. Membership information is available on the NQF web site, www.qualityforum.org.

Members of the public with particular expertise in a given topic also may be invited to participate in the early identification of draft consensus standards, either as technical advisors or as Steering Committee members. In addition, the NQF process explicitly recognizes a role for the general public to comment on proposed consensus standards and to appeal healthcare quality consensus standards endorsed by NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted at www.qualityforum.org.

Each project NQF undertakes is guided by a Steering Committee (or Review Committee) composed of individuals from each of the four critical stakeholder perspectives. With the assistance of NQF staff and technical advisory panels and with the ongoing input of NQF Members, a Steering Committee conducts an overall assessment of the state of the field in the particular topic area and recommends a set of

draft measures, indicators, or practices for review, along with the rationale for proposing them. The proposed consensus standards are distributed for review and comment by NQF Members and non-members.

Following the comment period, a revised product is distributed to NQF Members for voting. The vote need not be unanimous, either within or across all Member Councils, for consensus to be achieved. If a majority of Members within each Council do not vote approval, staff attempts to reconcile differences among Members to maximize agreement, and a second round of voting is conducted. Proposed consensus standards that have undergone this process and that have been approved by all four Member Councils on the first ballot or by at least two Member Councils after the second round of voting

are forwarded to the Board of Directors for consideration. All products must be endorsed by a vote of the NQF Board of Directors.

Affected parties may appeal voluntary consensus standards endorsed by the NQF Board of Directors. Once a set of voluntary consensus standards has been approved, the federal government may utilize it for standardization purposes in accordance with the provisions of the National Technology Transfer Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119. Consensus standards are updated as warranted.

For this report, the NQF Consensus Development Process, version 1.6, was in effect. The complete process can be found at www.qualityforum.org.

NATIONAL QUALITY FORUM PUBLICATION INFORMATION

National Voluntary Consensus Standards for Cardiac Surgery— A Consensus Report

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