## NATIONAL QUALITY FORUM

# Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

## Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 0113	NQF Project: Surgery Endorsement Maintenance 2010
MEA	SURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Participation in a System	ematic Database for Cardiac Surgery
De.2 Brief description of measure: Participrovides benchmarking relative to peers an	ipation in a multicenter data collection and feedback program that d uses process and outcome measures
1.1-2 Type of Measure: Structure/manage De.3 If included in a composite or paired	ment with another measure, please identify composite or paired measure
De.4 National Priority Partners Priority Ar De.5 IOM Quality Domain: Safety	rea: Safety
De.6 Consumer Care Need: Getting better	r

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission  A.4 Measure Steward Agreement attached: STS Measure Steward Agreement. Fully Executed.pdf	A Y N
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least	B Y

every 3 years. Yes, information provided in contact section	N
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  Purpose: Public reporting, Internal quality improvement	C Y□ N□
<ul> <li>D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.</li> <li>D.1Testing: Yes, fully developed and tested</li> <li>D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?</li> </ul>	D Y   N
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	Eval Rating
(for NQF staff use) Specific NPP goal:	
1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, High resource use, Patient/societal consequences of poor quality 1a.2	
<b>1a.3 Summary of Evidence of High Impact:</b> The STS Adult Cardiac Surgery Database captures detailed clinical data on adults undergoing cardiac surgical procedures performed by participants throughout the United States. The collection and analysis of data over a 20-year period has been shown to improve patient outcomes, primarily through feedback provided by center-specific reports that allow participants to evaluate critically their own local results and to compare their own local results with contemporary national risk-adjusted benchmarks.	
In fact, the very act of participation in a systematic database for cardiac surgery has been shown to increase compliance with process measures (Ferguson [1]). Furthermore, the increase in compliance with these process measures will improve outcome (Peterson [2]). Thus, outcomes can be improved by participation in a multicenter data collection and feedback program that provides benchmarking relative to peers and uses process and outcome measures.	
Thus, the very act of participation in a multi-institutional database will also facilitate quality improvement.	1a
<b>1a.4 Citations for Evidence of High Impact:</b> 1. 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.	C □ P □ M □ N □

2. Peterson ED, Roe MT, Mulgund J, DeLong ER, Lytle BL, Brindis RG, Smith SC Jr, Pollack CV Jr, Newby LK, Harrington RA, Gibler WB, Ohman EM. Association between hospital process performance and outcomes among patients with acute coronary syndromes. JAMA. 2006 Apr 26;295(16):1912-20	
3. Kiefe CI, Allison JJ, et al. Improving quality improvement using achievable benchmarks for physician feedback: a randomized controlled trial. JAMA. 2001;285:2871-2879.	
4. Welke 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.	
1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: The very act of participation in a systematic database for cardiac surgery has been shown to increase compliance with process measures (Ferguson). Furthermore, the increase in compliance with these process measures will improve outcome (Peterson). Thus, outcomes can be improved by participation in a multicenter data collection and feedback program that provides benchmarking relative to peers and uses process and outcome measures	
Thus, the very act of participation in a multi-institutional database will also facilitate quality improvement.	
The STS Adult Cardiac Surgery Database captures detailed clinical data on adults undergoing cardiac surgical procedures performed by participants throughout the United States. The collection and analysis of data over a 20-year period has been shown to improve patient outcomes, primarily through feedback provided by center-specific reports that allow participants to evaluate critically their own local results and to compare their own local results with contemporary national risk-adjusted benchmarks.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:	
98% (925/942) of participants who actively submitted data for 2008 maintained their activity in 2009.	
Among 942 participants who submitted at least one record with surgery data during 2008, 925 of these also submitted at least one record with a surgery date during 2009. Thus, 98% of participants who actively submitted data for 2008 maintained their activity in 2009.	
The total number participants who submitted at least one record in 2009 is 973.	
Approximately 90% of cardiac surgery centers in the US participate in the STS Adult Cardiac Surgery Database.	
1b.3 Citations for data on performance gap: Dates: January 1, 2008-December 31, 2009	
Count of participants in the STS Adult Cardiac Surgery Database in 2008 vs. 2009.	
1b.4 Summary of Data on disparities by population group: N/A	1b C□
1b.5 Citations for data on Disparities: N/A	]    
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): The desired outcome of compliance with this metric is to increase the number of cardiac surgeons and cardiac surgical programs that participate in multicenter data collection and feedback program that provide benchmarking relative to peers and uses process and outcome measures. Participation in such initiatives has been shown to improve patient outcome.	1c C□ P□
<b>1c.2-3. Type of Evidence:</b> Observational study, Expert opinion, Systematic synthesis of research, Other Clinical results from approximately 90% of cardiac surgery centers in the US	M

1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):  The very act of participation in a systematic database for cardiac surgery has been shown to increase compliance with process measures.  Reference:	
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.	
The increase in compliance with these process measures will improve outcome.  Reference:	
Peterson ED, Roe MT, Mulgund J, DeLong ER, Lytle BL, Brindis RG, Smith SC Jr, Pollack CV Jr, Newby LK, Harrington RA, Gibler WB, Ohman EM. Association between hospital process performance and outcomes among patients with acute coronary syndromes. JAMA. 2006 Apr 26;295(16):1912-20	
1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):	
1c.6 Method for rating evidence:	
1c.7 Summary of Controversy/Contradictory Evidence:	
1c.8 Citations for Evidence (other than guidelines): 1. 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.  2. Peterson ED, Roe MT, Mulgund J, DeLong ER, Lytle BL, Brindis RG, Smith SC Jr, Pollack CV Jr, Newby LK, Harrington RA, Gibler WB, Ohman EM. Association between hospital process performance and outcomes among patients with acute coronary syndromes. JAMA. 2006 Apr 26;295(16):1912-20  3. Kiefe CI, Allison JJ, et al. Improving quality improvement using achievable benchmarks for physician feedback: a randomized controlled trial. JAMA. 2001;285:2871-2879.  4. Welke 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.	
1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): N/A	
1c.10 Clinical Practice Guideline Citation: 1c.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):	
<b>1c.13 Method for rating strength of recommendation</b> (If different from <u>USPSTF system</u> , also describe rating and how it relates to USPSTF):	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y□ N□

2 SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ( <u>evaluation criteria</u> )	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	
2a. Precisely Specified	
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):  Whether or not the facility participates in a multicenter, data collection and feedback program that provides benchmarking relative to peers and uses process and outcome measures	-
2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator): 12 months	
<b>2a.3 Numerator Details</b> (All information required to collect/calculate the numerator, including all codes, logic, and definitions):	
Participation in the STS Adult Cardiac Surgery Database is initiated by the surgeons and/or hospital and requires quarterly data submission via an approved software system to the Duke Clinical Research Institute (DCRI), the data repository for the three STS Databases.	
2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured):  N/A	-
2a.5 Target population gender: Female, Male 2a.6 Target population age range: 18 years or older on date of encounter	
<b>2a.7 Denominator Time Window</b> (The time period in which cases are eligible for inclusion in the denominator):	
<b>2a.8 Denominator Details (</b> All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):	
2a.9 Denominator Exclusions (Brief text description of exclusions from the target population):	-
<b>2a.10 Denominator Exclusion Details</b> (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):	
<b>2a.11 Stratification Details/Variables (</b> All information required to stratify the measure including the stratification variables, all codes, logic, and definitions <b>):</b> N/A	-
2a.12-13 Risk Adjustment Type: No risk adjustment necessary	
<b>2a.14 Risk Adjustment Methodology/Variables</b> (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):  N/A	2a- specs
2a.15-17 Detailed risk model available Web page URL or attachment:	C
2a.18-19 Type of Score: Categorical 2a.20 Interpretation of Score: Passing score defines better quality	M
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<b>2a.21 Calculation Algorithm (</b> Describe the calculation of the measure as a flowchart or series of steps <b>):</b> N/A	
2a.22 Describe the method for discriminating performance (e.g., significance testing):	
<b>2a.23 Sampling (Survey) Methodology</b> If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A	
2a.24 Data Source (Check the source(s) for which the measure is specified and tested) Registry data	
2a.25 Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): STS Adult Cardiac Surgery Database - Version 2.73	
2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL Data Collection Form (an updated version will be made available on the STS Website in mid-December of 2010)	
http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataCollectionForm2_7_Annotated_20101021.pdf	
<b>2a.29-31 Data dictionary/code table web page URL or attachment:</b> URL http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataSpecificationsV2_7_20101021.pdf an updated version will be made available on the STS Website in mid-December of 2010	
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)	
Clinicians: Group, Facility/Agency, Population: national, Population: regional/network, Population: states, Population: counties or cities	
<b>2a.36-37 Care Settings (</b> Check the setting(s) for which the measure is specified and tested) Hospital	
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)	
TESTING/ANALYSIS	
2b. Reliability testing	
<b>2b.1 Data/sample</b> (description of data/sample and size): As of December 31, 2009, the STS Adult Cardiac Surgery Database had 1,004 Participants who represented 1,020 hospitals in the United States. (An STS Database Participant is either a "practice group of cardiothoracic surgeons" or an individual cardiothoracic surgeon.) The 2008 American Hospital Association Annual Survey reported that 1,088 hospitals perform cardiac surgery in adults in the United States; therefore, STS believes that current STS-participating hospitals represent over 90% of hospitals that provide adult cardiac surgery in the United States.	
The STS Adult Cardiac Surgery Database captures detailed clinical data on adults undergoing cardiac surgical procedures performed by participants throughout the United States. The collection and analysis of data over a 20-year period has been shown to improve patient outcomes], primarily through feedback provided by center-specific reports that allow participants to evaluate critically their own local results and to compare their own local results with contemporary national risk-adjusted benchmarks. Using risk-adjusted data from the STS Adult Cardiac Surgery Database, STS has created numerous statistical risk-adjustment models for several common cardiac surgical operations for mortality and a variety of complications. The STS Database has also served as the basis for the development of performance measures that have been endorsed by the National Quality Forum.	2b C□ P□
<b>2b.2</b> Analytic Method (type of reliability & rationale, method for testing):	M

<b>2b.3 Testing Results</b> (reliability statistics, assessment of adequacy in the context of norms for the test conducted):	
2c. Validity testing	
2c.1 Data/sample (description of data/sample and size): STS Adult Cardiac Surgery Database	
Audits conducted in 2010, all cases performed in 2009; N = 40 randomly selected sites participating in the STS Adult Cardiac Surgery Database	
<b>2c.2 Analytic Method</b> (type of validity & rationale, method for testing): Participating sites are randomly selected for participation in STS Adult Cardiac Surgery Database Audit, which is designed to evaluate the accuracy, consistency, and comprehensiveness of data collection and ultimately validate the integrity of the data contained in the database. The lowa Foundation for Medical Care (IFMC), the quality improvement organization for lowa and Illinois, has conducted audits on behalf of STS since 2006.	
Each year, the IFMC conducts audits at randomly selected sites throughout the country and tracks the individual agreement rates by variable and by year. More specifically, for each site, agreement rates are calculated for 73 individual elements. In addition, aggregate agreement rates for each element, variable category (e.g., pre-operative risk factors, previous interventions, etc), and overall for all categories are calculated for all sites. While this is not region specific, it is data point specific and comparison agreement rates confirm the improvement over time as well as the consistency.	
In addition, validity was confirmed and is regularly assessed by an expert panel of thoracic surgeons assembled by the STS Adult Cardiac Surgery Database Task Force, the STS Task Force on Quality Initiatives and the STS Workforce on National Databases.	2c C□
<b>2c.3 Testing Results</b> (statistical results, assessment of adequacy in the context of norms for the test conducted):	P N
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s):	
2d.2 Citations for Evidence:	
2d.3 Data/sample (description of data/sample and size):	2.1
2d.4 Analytic Method (type analysis & rationale):	2d C□ P□
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):	M   N   NA   NA
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): N/A	
2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):	2e C□
2e.3 Testing Results (risk model performance metrics):	P M N

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	
2f. Identification of Meaningful Differences in Performance	
2f.1 Data/sample from Testing or Current Use (description of data/sample and size): Among 942 participants who submitted at least one record with surgery data during 2008, 925 of these also submitted at least one record with a surgery date during 2009. Thus, 98% of participants who actively submitted data for 2008 maintained their activity in 2009.	
The total number participants who submitted at least one record in 2009 is 973.	
Approximately 90% of cardiac surgery centers in the US participate in the STS Adult Cardiac Surgery Database.	
<b>2f.2</b> Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):	
2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  The evidence connecting improved quality with participation in a systematic national database is inferred from published accounts of improved quality following participation in the STS Adult Cardiac Surgery Database and other national databases. "It appears that the routine feedback of risk-adjusted data on local performance provided by these programs heightens awareness and leads to self-examination and self-assessment, which in turn improves quality and outcomes. This general quality improvement template should be considered for application in other settings beyond cardiac surgery." [1]	
"The Society of Thoracic Surgeons National Cardiac Surgery Database allows subscribing institutions to perform sophisticated patient risk assessment using traditional statistical tools and a newly developed risk model of operative mortalityThe risk model has proven to be a reliable tool for predicting the probability of operative death in an individual patient and may be valuable in both patient counseling and medical decision making. Large multi-institutional databases of this type are key ingredients of modern operative risk assessment. A database containing a broad national experience of this type can represent an aggregate experience that may well approximate a universally accepted standard of care." [2]	
1. Grover FL, Shroyer AL, Hammermeister K, Edwards FH, Ferguson TB, Jr., Dziuban SW, Jr., Cleveland JC, Jr., Clark RE, McDonald G. A decade's experience with quality improvement in cardiac surgery using the Veterans Affairs and Society of Thoracic Surgeons national databases. Ann Surg. 2001 Oct; 234 (4): 464-x472; discussion 472-464.	2f C□ P□
2. Edwards FH, Clark RE, Schwartz M. Impact of internal mammary artery conduits on operative mortality in coronary revascularization. Ann Thorac Surg. 1994 Jan; 57 (1): 27-32	M   N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): N/A	2
2g.2 Analytic Method (type of analysis & rationale):	2g C   P   M
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	N NA
2h. Disparities in Care	2h
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A	C   P   M
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	N NA

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:	2 C P M N
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information	
3a.1 Current Use: In use	
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  Currently being considered for NQF endorsement, the STS CABG Composite Score is a multidimensional performance measure comprised of four domains consisting of 11 individual NQF-endorsed cardiac surgery metrics: (1) Operative Careuse of the internal mammary artery; (2) Perioperative Medical Care (use of preoperative beta blockade; discharge beta blockade, antiplatelet agents, and lipid-lowering agents—an "all-or-none" measure); (3) Risk-adjusted Operative Mortality; and (4) Risk-Adjusted Postoperative Morbidity (occurrence of postoperative stroke, renal failure, prolonged ventilation, re-exploration, or deep sternal wound infectionan "any-or-none" measure). Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org	
Participation in a systematic database is implicitly met, as only participants in the STS database are eligible for a composite score.	
Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily participate in this initiative.	
<b>3a.3 If used in other programs/initiatives</b> (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u> , state the plans to achieve use for QI within 3 years):	
Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement) 3a.4 Data/sample (description of data/sample and size): See 3a.6 below	
3a.5 Methods (e.g., focus group, survey, Ql project):	3a C□
3a.6 Results (qualitative and/or quantitative results and conclusions): Please see attached file	P
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures: N/A	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
<b>3b. Harmonization</b> If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population):	3b C P

3b.2 Are the measure specifications harmonized? If not, why?  N/A; however, data definitions and key elements have been established by a multi-societal writing committee called the "ACCF/AHA Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards" with representatives from each of the following organizations:  Agency for Healthcare Research and Quality American College of Cardiology American College of Chest Physicians American College of Emergency Physicians American College of Physicians American College of Preventative Medicine American Heart Association American Medical Association Centers for Disease Control and Prevention Emergency Nurses Association Food and Drug Administration Joint Commission on Accreditation of Healthcare Organizations National Association of EMS Physicians National Association of EMS Physicians National Heart, Lung, and Blood Institute Preventive Cardiovascular Nurses Association Society for Academic Emergency Medicine Society of Chest Pain Centers and Providers Society of General Internal Medicine Society of Thoracic Surgeons	M NO NA
<ul> <li>3c. Distinctive or Additive Value</li> <li>3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:</li> <li>5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:</li> </ul>	3c C P M N N N N N N N N N N N N N N N N N N
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i> ?	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C   P   M   N
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. ( <a href="evaluation criteria">evaluation criteria</a> )	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	
4a.1-2 How are the data elements that are needed to compute measure scores generated?  Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C   P   M   N   N   N   M   M   M   M   M   M
4b. Electronic Sources	4b
<b>4b.1 Are all the data elements available electronically?</b> (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) Yes	C

4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	
4c. Exclusions  4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?  No  4c.2 If yes, provide justification.	4c C   P   M   NA
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. This measure may be susceptible to human error (i.e., recording the measure inaccurately or not at all).  When data collection on this measure is done through participation in the STS Adult Cardiac Surgery	
Database, an auditing strategy is in place.	
Both STS and the Duke Clinical Research Institute have a list of database participants making participation in the STS Adult Cardiac Surgery Database easy to track.	
Each participant is responsible for the quality and accuracy of the data they submit to the database. The participant agrees to the following quality control measures in the participation agreement: i) Participant hereby warrants that all data submitted for inclusion in the STS National Database will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the independent data warehouse service provider and agrees to cooperate with and assist STS and its designees in connection with the performance of any independent audit.	
ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the STS National Database, including but not limited to apprising the Director of the STS National Database and the independent data warehouse service provider about any other Participation Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named.	4d C□
STS audited for these potential problems during testing.	M N
4e. Data Collection Strategy/Implementation	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures):  Data Collection:	
There are no direct costs to collect the data for this measure. Costs to develop the measure included volunteer cardiothoracic surgeon time, STS staff time, and DCRI statistician and project management time.	
Other fees: STS Adult Cardiac Surgery Database participants (single cardiothoracic surgeons or a group of surgeons) pay annual participant fees of \$2,950 or \$3,700, depending on whether participants are STS members (or whether the majority of surgeons in a group are STS members). As a benefit of STS membership, STS members are charged the lesser of the two fees.	4e C P M N

4e.3 Evidence for costs:	
4e.4 Business case documentation:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4
rationale.	C
	N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement? Comments:	Y □ □ N □ □
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611  Co.2 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Measure Developer If different from Measure Steward Co.3 Organization Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611	
Co.4 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Co.5 Submitter If different from Measure Steward POC Jane, Han, MSW, jhan@sts.org, 312-202-5856-, Society of Thoracic Surgeons	
Co.6 Additional organizations that sponsored/participated in measure development	
ADDITIONAL INFORMATION	
Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development. Members of the STS Task Force on Quality Initiatives provide surgical expertise as needed. The STS Workford National Databases meets at the STS Annual Meeting and reviews the measures on a yearly basis. Changes or updates to the measure will be at the recommendation of the Workforce.	e on
Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment	
Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 Year the measure was first released: 2004 Ad.7 Month and Year of most recent revision: 12, 2010 Ad.8 What is your frequency for review/update of this measure? annually Ad.9 When is the next scheduled review/update for this measure? 2011	

## Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment Section 3a.6.pdf

Date of Submission (MM/DD/YY): 01/12/2011

#### Section 3a.6

Although formal testing of interpretability has not been performed, this measure has been used and reported for STS Adult Cardiac Surgery database participants since 2007. Current report presentation and interpretation manuals are presented below. These materials are updated as needed based upon feedback from database participants.

## 1) Report Overview and Interpretation Manual:

## **The NQF Measures Report**

## a. Organization

This report section is separated into three areas corresponding to: 1) NQF volume measures, 2) NQF process measures, and 3) NQF outcomes measures, in that order. The header at the top of each page references the report section for that page. Each NQF measure is presented on a single row in the section. Tabular data are on the left-hand side of each page and a standard graphic representation is shown on the right-hand side.

### b. Statistical Calculation and Details – NQF Measures

**Time period:** This report section contains information on the individual STS participant and overall STS performance for the <u>most recent 12 months for volume, process and CABG</u> <u>outcomes measures and the most recent 60 months for Valve and Valve + CABG outcomes. The 5 years (60 months) of performance for outcomes involving Valve procedures is necessary due to smaller sample sizes.</u>

**Volume Measures:** The NQF report provides average annual case volumes data for three surgery categories: i) Isolated CABG, ii) Valve without CABG, and iii) combined CABG + Valve. Definitions of the three surgery categories are provided in Table 2 of this NQF Report Overview. For each type of surgery, the <u>participant's annualized volume</u> is calculated as:

Participant Annualized Volume = 12 x (# of surgeries) / (# of months)

where (# of surgeries) denotes the number of surgeries of the specified type performed by the participant during the specified time period, and (# of months) is the number of months during the specified time period for which the participant submitted at least one cardiac surgery of any type. The intent of calculating "annualized" volumes is to adjust for participants who participated in the database for fewer months than the time period specified. For participants who participated in the database and submitted cases every month during 2006, the annualized volume for 2006 is simply the total number of cases.

The <u>STS Average Annualized Volume</u> is the average value of all of the participant annualized volumes across the entire population of STS participants. The <u>Participant Percentile</u> indicates the percent of STS participants whose annualized volumes are less than, or equal to, your own. Higher percentiles indicate higher volumes in relation to other STS participant sites. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant annualized volumes across all database participants. For example, 90% of participants have annualized volumes less than or equal to the value marked "90<sup>th</sup> percentile."

Confidence intervals are not provided for volume measures, as volume is known with certainty and is not estimated.

Process Measures: The NQF process measures provide data on the frequency of usage of five therapies among subsets of Isolated CABG patients. The therapies are: i) preoperative beta blockade therapy, ii) use of IMA, iii) discharge anti-platelet medication, iv) discharge beta blockade therapy, and v) discharge anti-lipid medication. The patient population for each measure differs, in accordance with the NQF specifications (see Table 2 of this NQF Report Overview for details). The number of Eligible Procedures is the number of cases performed by the participant during the specified time period who meet the eligibility requirements to be included in the calculations when summarizing the participant's data. Beginning with the 2008 Harvest 3 report (covering the procedure time period through 6/30/2008), STS implementation of NQF medication process measures using data version 2.61 excludes records for which the medication was contraindicated/not indicated from the eligible population. The main summary statistic, Participant Usage, is the percent of eligible Isolated CABG cases during the specified time period for which the patient received the specified therapy. The Overall STS Usage is the percent of all eligible patients in the entire STS population during the specified time period who received the specified therapy. In calculating these percentages, missing data are treated as a "No", emphasizing the importance of having complete data in these fields.

The <u>Participant Percentile</u> indicates the percent of STS participants who applied the therapy in their respective populations less frequently than or as frequently as did your institution. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant usage across all participants in the database. For example, 90% of participants use the therapy less frequently than the amount indicated by the "90<sup>th</sup> percentile". A bar identified as "Participant" indicates the point estimate and limits of a 95% Confidence Interval (CI) for the participant's usage of therapy. The underlying parameter being estimated is the long-run usage rate that would be observed in a large sample of patients. The 95% CI indicates the range of usage rates that are consistent with the data in light of sampling variability.

Outcomes Measures: The NQF outcomes data provide risk-adjusted analyses of mortality and morbidity for Isolated CABG surgery as well as risk-adjusted operative mortality for Isolated AVR, Isolated MVR, AVR+CABG, and MVR+CABG. The main summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. The interpretation is similar to that of an O/E ratio (see the Risk-Adjusted Results: Overview portion of the General Report Overview for details on STS risk adjustment). An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. Each measure is calculated among patients undergoing surgery of the type specified during the time period specified who additionally meet certain eligibility requirements. The column labeled Eligible Procedures indicates the number of patients who met the inclusion criteria to be included in the analysis for the indicated measure. The Participant Percentile is the percent of STS participants who have an estimated OR that is greater than or equal to your estimated OR. Note that this is different than performance percentiles for process measures, where the percentile indicates the percentage of STS

participants with performance that is *less than* the specified number. This simply reflects the fact that high process compliance is desirable, whereas a high OR is undesirable.

The <u>Observed Participant Rate</u> is the percent of eligible patients who experienced the specified outcome. Unlike the participant estimated OR, the observed participant rate is not riskadjusted. The estimated OR is the main summary statistic for summarizing the NQF measure in this report.

The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of estimated Odds Ratios across all STS participants. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile." The line that extends to the left and right of the Participant Value indicates the lower and upper limits of a 95% Confidence Interval (CI) surrounding the participant's estimated OR.

## c. Technical Notes

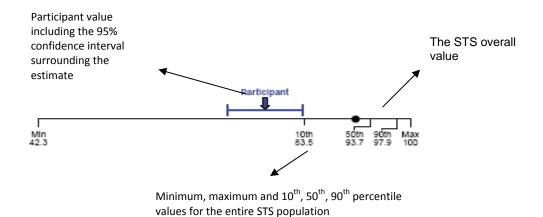
Calculation of Percentiles for the Distribution of Participant Values: The graph provided for each measure contains information about the distribution of the value of the measure across all STS participants, namely the minimum, maximum,  $10^{th}$  percentile,  $50^{th}$  percentile, and 90th percentile. The " $X^{th}$ " percentile, denoted  $P_x$ , is loosely defined as the number having the property that X% of the participant values are less than  $P_x$ , and (100 - X)% of the participant values are greater than  $P_x$ . For process measures, participants with greater than 5% missing data were excluded when calculating percentiles of the STS distribution and do not have a calculated participant percentile. For participants having less than 5% missing data on a process measure, the missing values on the process measure were converted to "No" before calculating percentiles. For outcomes measures, all participants submitting at least one eligible case were included when calculating percentiles of the STS distribution. Missing data on outcomes variables were treated as "No."

NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion criteria, and rules for handling missing data in the NQF section versus the rest of the report. Definitions used in the NQF report were designed to match current NQF specifications as closely as possible. It is expected that these differences will eventually disappear as the NQF measures are refined. Some important differences are:

Case Volumes – The NQF report section presents "annualized" volumes. These are case volumes that have been adjusted for the number of months that a participant was an active contributor to the database. Elsewhere in the STS report, total case volumes are presented without adjustment for the length of participation.

Eligible Cases - The NQF report also presents the number of "eligible cases" for each measure. Separate inclusion criteria are applied to each measure, and these inclusion criteria do not always match the definitions used elsewhere in the STS report. Please refer to the footnotes in each section for specific details.

In addition to the statistics provided for each of the STS Composite Quality Domains and NQF measures, a figure representing the distribution of values for the entire STS population is provided.



The figure allows participants to quickly judge their performance relative to the overall STS. The scale of the figure is set up such that the right side of the distribution represents the most favorable performance and the left side represents the least favorable performance (Note that in some cases smaller numbers will be on the left; in other instances, smaller numbers will be on the right. For example, for the Pre-operative Beta Blockade Therapy measure, the far left side of the distribution will contain the *lowest* percentage Beta Blockade Therapy for an STS participant – this corresponds to least favorable performance. Alternatively, for the Operative Mortality Measure, the far left side of the distribution will contain the *highest* Estimated Odds Ratio – this also corresponds to least favorable performance). If a participant's value for a given measure is to the left of the STS overall value, the participant is performing worse on that measure than the overall STS. Conversely, if the participant's value for a given measure is located to the right of the overall STS value, the participant is performing better than the overall STS.

**NOTE!** Care should be given to reading these figures. In some instances, the various percentiles presented cluster very close together in the data. In such cases, the label for the percentile is not necessarily located immediately at the point on the distribution where the percentile occurs. An example of this is apparent in the figure above: The 50<sup>th</sup> percentile corresponds to a value of 93.7 and looks to align fairly closely with the STS overall value as represented by the large black dot. However, the expandable figure marking actually points to a place somewhere to the right of the STS overall value for the 50<sup>th</sup> percentile marking. So the STS overall value would be some amount less than 93.7.

Also, please note that in some cases, small sample sizes preclude valid comparisons between the participant and the STS overall. Such instances are clearly noted in the report output.

## a. NQF Measures Interpretation Example

Sample CABG Operative Mortality results – tabular and figure representation.

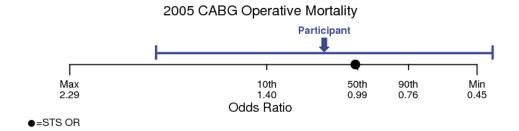
NQF	Eligible	Participant	Participant	Participant
Measure	Procedures	Estimated OR	Percentile	Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

Eligible Procedures: 74 patients met the inclusion criteria for the indicated measure.

Participant Estimated OR (Odds Ratio): The main summary statistic measuring the impact that a participant's performance has on a patient's probability of experiencing an adverse outcome has a value of 1.14 indicating worse than expected performance.

Participant Percentile: 26.3% of STS participants had an estimated OR greater than or equal to your estimated OR. In other words, 26.3% had the same or worse performance.

Participant Observed Rate: 5.4% of the 74 eligible patients experienced the specified outcome.



The highest OR among all STS participants = 2.29

The lowest OR among all STS participants = 0.45

The STS average OR is 1.00

The 95% confidence interval for the participant's OR spans from <0.45 to ~1.90

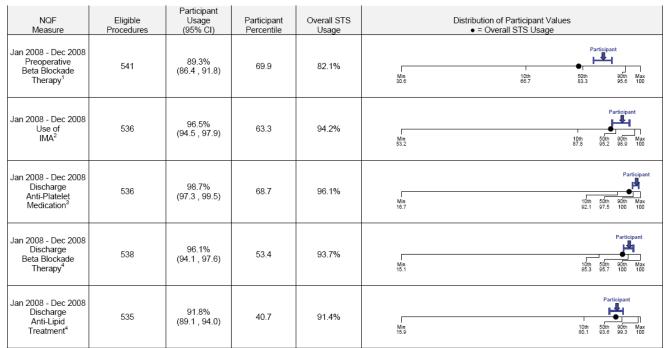
## 2) Sample page from section of the report that contains NQF measure results:



## NQF Measures Process Measures

## Duke Clinical Research Institute

## Participant 99999 STS Period Ending 12/31/2008



Excludes v2.61 contranindicated / not indicated records.

Excludes patients with prior CABG surgery

Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

Excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

## NATIONAL QUALITY FORUM

# Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

## Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 0114	NQF Project: Surgery Endorsement Maintenance 2010
MEA	SURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Risk-Adjusted Post-ope	erative Renal Failure
De.2 Brief description of measure: Percer failure) who develop post-operative renal fa	nt of patients undergoing isolated CABG (without pre-existing renal ailure or require dialysis
1.1-2 Type of Measure: Outcome De.3 If included in a composite or paired of OT1-013-09 - The STS CABG Composite Score	with another measure, please identify composite or paired measure
De.4 National Priority Partners Priority Ar De.5 IOM Quality Domain: Safety De.6 Consumer Care Need: Getting better	

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission  A.4 Measure Steward Agreement attached: STS Measure Steward Agreement. Fully Executed-634267260048541475.pdf	A Y N

<b>B.</b> The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y□ N□
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  ▶ Purpose: Public reporting, Internal quality improvement	C Y□ N□
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.  D.1Testing: Yes, fully developed and tested  D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?  Yes	D Y   N
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
1. IMPORTANCE TO MEASURE AND REPORT  Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	Eval Rating
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality	

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.  - Karthik S, Musleh G, Grayson AD, Keenan DJ, Hasan R, Pullan DM, Dihmis WC, Fabri BM. Effect of avoiding cardiopulmonary bypass in non-elective coronary artery bypass surgery: a propensity score analysis. Eur J Cardiothorac Surg. 2003;24(1):66-71.  - Mangano CM, Diamondstone LS, Ramsay JG, et al. Renal dysfunction after myocardial revascularization: risk factors, adverse outcomes, and hospital resource utilization: the Multicenter Study of Perioperative Ischemia Research Group. Ann Intern Med. 1998;128(3):194-203.  - Mangano DT. Aspirin and mortality from coronary bypass surgery. N Engl J Med. 2002;347(17):1309-1317.  - Sabik JF, Gillinov AM, Blackstone EH, et al. Does off-pump coronary surgery reduce morbidity and mortality? J Thorac Cardiovasc Surg. 2002;124(4):698-707.  - Shroyer AL, 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.  - Stallwood MI, Grayson AD, Mills K, et al. Acute renal failure in coronary artery bypass surgery: independent effect of cardiopulmonary bypass. Ann Thorac Surg. 2004;77(3):968-972.  - Tang AT, Alexiou C, Hsu J, Sheppard SV, Haw MP, Ohri SK. Leukodepletion reduces renal injury in coronary revascularization: a prospective randomized study. Ann Thorac Surg. 2002;74(2):372-327; discussion 377.  - Tang AT, Knott J, Nanson J, et al. A prospective randomized study to evaluate the renoprotective action of beating heart coronary surgery in low risk patients. Eur J Cardiothorac Surg. 2002;22(1):118-123.  - Welke 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.	
1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: Identification of clinical precursors of post-op renal insufficiency and improvement in peri-operative treatment of this high-risk group will improve the long-term survival of our patients. By implementing known recommendations (delay heart surgery at least 3 days after cardiac catheterization, maintain mean CPB perfusion pressure at 80% of pre-op BP, etc), post-op kidney injury should be significantly reduced.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: Please see attachment	
1b.3 Citations for data on performance gap: Dates: January 1, 2009-December 31, 2009	
Analysis includes 608 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data (not restricted to this measure) to the STS Adult Cardiac Surgery Database for all 12 months.	
1b.4 Summary of Data on disparities by population group: N/A	1b C□
1b.5 Citations for data on Disparities: N/A	 
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Post-op renal failure is relevant to the target population because it is a complication of both cardiopulmonary bypass and off-pump CABG. The occurrence of post-op renal failure then becomes an independent factor that reduces the patient's life expectancy.	
<b>1c.2-3. Type of Evidence:</b> Observational study, Expert opinion, Systematic synthesis of research, Other Clinical results from approximately 90% of cardiac surgery centers in the US	1c C□ P□ M□
1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that	

healthcare services/care processes influence the outcome):

To the best of our current knowledge, the primary clinical determinants of post-op renal insufficiency in the "susceptible" subset of patients who undergo CABG are timing of procedure, maintenance of mean perfusion pressure and post-op hydration/avoidance of nephrotoxins. These measures have been defined primarily by retrospective clinical reviews. Prospective, randomized studies of adjuvant drugs and protocols have been inconclusive. Year-to-year comparisons of incidence of renal failure in this population will ultimately validate the efficacy of these new processes of care.

1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):

Evidence for the utility of measuring renal failure post-CABG is strong. Measures to maintain adequate renal function post-CPB are based on theory and historical case reviews.

## 1c.6 Method for rating evidence:

- **1c.7 Summary of Controversy/Contradictory Evidence:** There is little basis for contradictory evidence because only a few clinical correlates have been identified.
- **1c.8 Citations for Evidence (***other than guidelines***):** Boldt J, Brenner T, Lehmann A, Suttner SW, Kumle B, Isgro F. Is kidney function altered by the duration of cardiopulmonary bypass? Ann Thorac Surg. 2003;75(3):906-912.
- Chertow GM, Levy EM, Hammermeister KE, et al. Independent association between acute renal failure and mortality following cardiac surgery. Am J Med. 1998;104(4):343-348
- Conlon PJ, Stafford-Smith M, White WD, Newman MF, King S, Winn MP, Landolfo K. Acute renal failure following cardiac surgery. Nephrol Dial Transplant. 1999;14(5):1158-1162.
- Eagle KA, Guyton RA, Davidoff R, Ewy GA, Fonger J, Gardner TJ, Gott JP, Hermann HC, Marlow RA, Nugent W, O'Connor GT, Orszulak TA, Rieselbach RE, Winters WL, Yusuf S. 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.
- Karthik S, Musleh G, Grayson AD, Keenan DJ, Hasan R, Pullan DM, Dihmis WC, Fabri BM. Effect of avoiding cardiopulmonary bypass in non-elective coronary artery bypass surgery: a propensity score analysis. Eur J Cardiothorac Surg. 2003;24(1):66-71.
- Mangano CM, Diamondstone LS, Ramsay JG, et al. Renal dysfunction after myocardial revascularization: risk factors, adverse outcomes, and hospital resource utilization: the Multicenter Study of Perioperative Ischemia Research Group. Ann Intern Med. 1998;128(3):194-203.
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- Sabik JF, Gillinov AM, Blackstone EH, et al. Does off-pump coronary surgery reduce morbidity and mortality? J Thorac Cardiovasc Surg. 2002;124(4):698-707.
- Shroyer AL, 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.
- Stallwood MI, Grayson AD, Mills K, et al. Acute renal failure in coronary artery bypass surgery: independent effect of cardiopulmonary bypass. Ann Thorac Surg. 2004;77(3):968-972.
- Tang AT, Alexiou C, Hsu J, Sheppard SV, Haw MP, Ohri SK. Leukodepletion reduces renal injury in coronary revascularization: a prospective randomized study. Ann Thorac Surg. 2002;74(2):372-327; discussion 377.
- Tang AT, Knott J, Nanson J, et al. A prospective randomized study to evaluate the renoprotective action of beating heart coronary surgery in low risk patients. Eur J Cardiothorac Surg. 2002;22(1):118-123.
- Welke 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.
- Del Duca D, Iqbal S, Rahme E et al. Renal Failure after cardiac surgery: timing of cardiac catheterization and other risk factors. Ann Thorac Surg; 2007; 84: 1264 71.
- Coca sg, Yusuf B, Shiipak MG et al; Long-term risk of mortality and other adverse outcomes after acute kidney injur: a systematic review and meta-analysis; Am J Kidney Dis; 2009: 53: 928 31.
- 1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):

1c.10 Clinical Practice Guideline Citation: 1c.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):	
1c.13 <b>Method for rating strength of recommendation</b> ( <i>If different from <u>USPSTF system</u></i> , also describe rating and how it relates to USPSTF):	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y□ N□
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ( <u>evaluation criteria</u> )	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	
2a. Precisely Specified	
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):  Number of patients undergoing isolated CABG who develop post-operative renal failure or require dialysis	
2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):	
2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):	
Definition of renal failure/dialysis requirement - Patients with acute renal failure or worsening renal function resulting in one or both of the following:  1. Increase of serum creatinine to > 2.0 and two times the most recent preoperative creatinine level  2. New requirement for dialysis postoperatively	
Number of isolated CABG procedures in which post-operative renal failure [CRenFail (STS Adult Cardiac Surgery Database Version 2.73] is marked as "yes"	
2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured): All patients undergoing isolated CABG	
2a.5 Target population gender: Female, Male 2a.6 Target population age range: 18 and older	2a- specs C P
<b>2a.7 Denominator Time Window</b> (The time period in which cases are eligible for inclusion in the denominator):	M D

#### 12 months

**2a.8 Denominator Details** (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):

Number of isolated CABG procedures

Isolated CABG is determined as a procedure for which all of the following apply:

- OpCAB is marked "Yes"
- VADProc is marked "No" or "Missing") or (VADProc is marked "Yes, Implanted" and UnplVAD is marked "yes")
- OCarASDTy is marked "PFO" or "missing"
- OCarAFibAProc is marked "primarily epicardial" or "missing" and
- OpValve, VSAV, VSAVPr, ResectSubA, VSMV, VSMVPr, OpTricus, OpPulm, OpONCard, OCarLVA, OCarVSD, OCarSVR, OCarCong, OCarTrma, OCarCrTx, OCAoProcType, EndoProc, OCTumor, OCPulThromDis, OCarOthr are all marked "no" or "missing"
- **2a.9 Denominator Exclusions** (*Brief text description of exclusions from the target population*): 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
- **2a.10 Denominator Exclusion Details** (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
  (Dialysis) is marked yes; Last Creatinine Level (CreatLst) > 2
- **2a.11 Stratification Details/Variables** (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):

  N/A
- 2a.12-13 Risk Adjustment Type: Case-mix adjustment
- **2a.14 Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

  Please see attachment
- 2a.15-17 Detailed risk model available Web page URL or attachment: Attachment 2a.15 Detailed Risk Model.pdf
- 2a.18-19 Type of Score: Rate/proportion
- 2a.20 Interpretation of Score: Better quality = Lower score
- **2a.21 Calculation Algorithm** (Describe the calculation of the measure as a flowchart or series of steps): N/A
- 2a.22 Describe the method for discriminating performance (e.g., significance testing):

Participant specific OR and their 95% CI were estimated in the hierarchical model. These model-based estimates were used to control variation due to random statistical fluctuations while estimating true signal variation. A 95% CI excluding zero indicates the participant's performance is significantly lower or higher than an "average" STS participant.

- **2a.23 Sampling (Survey) Methodology** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A
- **2a.24 Data Source** (Check the source(s) for which the measure is specified and tested) Registry data
- **2a.25** Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): STS Adult Cardiac Surgery Database Version 2.73
- **2a.26-28** Data source/data collection instrument reference web page URL or attachment: URL Data Collection Form (an updated version will be made available on the STS Website in mid-December of 2010)---http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataCollectionForm2\_7\_Annotated\_20101021.pdf

	1
<b>2a.29-31 Data dictionary/code table web page URL or attachment:</b> URL http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataSpecificationsV2_7_20101021.pdf an updated version will be made available on the STS Website in mid-December of 2010	
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested) Clinicians: Group, Facility/Agency, Population: national, Population: regional/network, Population: states, Population: counties or cities	
2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested) Hospital	
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)	
TESTING/ANALYSIS	
2b. Reliability testing	
<b>2b.1 Data/sample</b> (description of data/sample and size): STS Adult Cardiac Surgery Database - Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009.	
<b>2b.2 Analytic Method</b> (type of reliability & rationale, method for testing):  Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009. Excluded from analysis are participants that did not submit results for both time periods. Because database participants can change their underlying care processes at any time, we would not expect perfect correlation between two sets of results from even proximate time periods.	2b C□
<b>2b.3 Testing Results</b> (reliability statistics, assessment of adequacy in the context of norms for the test conducted):  Please see attachment	P   M   N
2c. Validity testing	
2c.1 Data/sample (description of data/sample and size): STS Adult Cardiac Surgery Database	
Audits conducted in 2010, all cases performed in 2009; N = 40 randomly selected sites participating in the STS Adult Cardiac Surgery Database	
<b>2c.2 Analytic Method</b> (type of validity & rationale, method for testing):  Participating sites are randomly selected for participation in STS Adult Cardiac Surgery Database Audit, which is designed to evaluate the accuracy, consistency, and comprehensiveness of data collection and ultimately validate the integrity of the data contained in the database. The lowa Foundation for Medical Care (IFMC), the quality improvement organization for lowa and Illinois, has conducted audits on behalf of STS since 2006.	
Each year, the IFMC conducts audits at randomly selected sites throughout the country and tracks the individual agreement rates by variable and by year. More specifically, for each site, agreement rates are calculated for 73 individual elements. In addition, aggregate agreement rates for each element, variable category (e.g., pre-operative risk factors, previous interventions, etc), and overall for all categories are calculated for all sites. While this is not region specific, it is data point specific and comparison agreement rates confirm the improvement over time as well as the consistency.	2c C□
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): Complications - Renal Failure: 98.5% agreement rate	P   M   N
2d Exclusions Justified	2d

2d.1 Summary of Evidence supporting exclusion(s):	C   P   M   N
2d.2 Citations for Evidence:	NA 🗌
<b>2d.3 Data/sample</b> (description of data/sample and size): Dates: January 1, 2009-December 31, 2009; 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure (before the exclusion is applied). Patients who were on dialysis or had creatinine >2 pre-operatively are excluded from this NQF measure.	
2d.4 Analytic Method (type analysis & rationale):	
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): Please see attachment	
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): Please see Risk Adjustment Type section above	
<b>2e.2 Analytic Method</b> (type of risk adjustment, analysis, & rationale):  Detailed information regarding the risk adjustment model can be found in the attachment:	
Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, Normand SL, DeLong ER, Shewan CM, Dokholyan RS, Peterson ED, Edwards FH, Anderson RP. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1coronary artery bypass grafting surgery. Ann Thorac Surg. 2009 Jul;88(1 Suppl):S2-22.	2e
2e.3 Testing Results (risk model performance metrics):	C   P   M   N
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	NA.
2f. Identification of Meaningful Differences in Performance	
<b>2f.1 Data/sample from Testing or Current Use</b> (description of data/sample and size): 608 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months; January 1, 2009-December 31, 2009	
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):	
We calculated the risk adjusted event rate with the participant's Odds Ratio (OR) estimate and the overall STS event rate. Therefore, the risk adjusted rate is closely related to OR estimate. If OR > 1, then the participant's risk adjusted rate will be greater than the overall STS event rate; if OR < 1, then the participant's risk adjusted rate will be smaller than the overall STS event rate. The statistical significance is defined by the 95% confidence interval (CI) or the OR estimate. If the 95% CI for a participant's OR includes the null value 1.0, then we cannot distinguish this participant's performance from the STS average - either the participant's performance was close to average or else the participant's sample size was too small to make a reliable inference. Otherwise, if the 95% CI falls to the right of 1.0, then the participant's performance is considered significantly lower than the average STS results; if the 95% CI falls to the left of 1.0, then the participant's performance is considered significantly higher than the average STS results.	2f
<b>2f.3 Provide Measure Scores from Testing or Current Use</b> (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  Please see attachment	C   P   M   N

	т
2g.1 Data/sample (description of data/sample and size): N/A	C P M
2g.2 Analytic Method (type of analysis & rationale):	N   NA
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	
2h. Disparities in Care	
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A	2h C□ P□
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	M NO
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met?	2 C□
Rationale:	P□
	M
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information	
3a.1 Current Use: In use	
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org	
Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily participate in this initiative.	
<b>3a.3 If used in other programs/initiatives</b> (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u> , state the plans to achieve use for QI within 3 years):  CMS Physician Quality Reporting Initiative (PQRI), www.cms.hhs.gov/pqri	
Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)  3a.4 Data/sample (description of data/sample and size): Please see 3a.6	
3a.5 Methods (e.g., focus group, survey, Ql project):	3a C□
3a.6 Results (qualitative and/or quantitative results and conclusions): Please see attachment	P   M   N
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures;	

OT1-013-09 - The STS CABG Composite Score; Component measures: 0114 Risk-Adjusted Post-Operative Renal Failure, 0115 Risk-Adjusted Surgical Re-exploration, 0116 Anti-Platelet Medication at Discharge, 0117 Beta Blockade at Discharge, 0118 Anti-Lipid Treatment at Discharge, 0119 Risk-Adjusted Operative Mortality for CABG, 0127 Pre-Operative Beta Blockade, 0129 Risk-Adjusted Prolonged Intubation (ventilation), 0130 Risk-Adjusted Deep Sternal Wound Infection Rate, 0131 Risk-Adjusted Stroke/Cerebrovascular Accident, 0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why? N/A; however, data definitions and key elements have been established by a multi-societal writing committee called the "ACCF/AHA Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards" with representatives from each of the following organizations:	
Agency for Healthcare Research and Quality American College of Cardiology American College of Chest Physicians American College of Emergency Physicians American College of Physicians American College of Preventative Medicine American Heart Association American Medical Association Centers for Disease Control and Prevention Emergency Nurses Association Food and Drug Administration Joint Commission on Accreditation of Healthcare Organizations National Association of Emergency Medical Technicians National Association of EMS Physicians National Heart, Lung, and Blood Institute Preventive Cardiovascular Nurses Association Society for Academic Emergency Medicine Society of Chest Pain Centers and Providers Society of General Internal Medicine Society of Thoracic Surgeons	3b C P N N N N N N N N N N N N N N N N N N
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF- endorsed measures: N/A  5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:	3c C P N N
same sarger population,, posserize with the same of enterene way to incurate quantity.	NA 🗆
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C   P   M   N
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. ( <a href="evaluation criteria">evaluation criteria</a> )	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	4a

NQF #0114

4a.1-2 How are the data elements that are needed to compute measure scores generated?  Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	C   P   M   N
4b. Electronic Sources	
<b>4b.1</b> Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) Yes	4b C□ P□
4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	M_ N_
4c. Exclusions	4-
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?	4c C   P   M   N
4c.2 If yes, provide justification.	NA.
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. This measure may be susceptible to human error (i.e., recording the measure inaccurately or not at all).  When data collection on this measure is done through participation in the STS Adult Cardiac Surgery	
Database, an auditing strategy is in place.	
Both STS and the Duke Clinical Research Institute have a list of database participants making participation in the STS Adult Cardiac Surgery Database easy to track.	
Each participant is responsible for the quality and accuracy of the data they submit to the database. The participant agrees to the following quality control measures in the participation agreement: i) Participant hereby warrants that all data submitted for inclusion in the STS National Database will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the independent data warehouse service provider and agrees to cooperate with and assist STS and its designees in connection with the performance of any independent audit.	
ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the STS National Database, including but not limited to apprising the Director of the STS National Database and the independent data warehouse service provider about any other Participation Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named.	4d C□ P□
STS audited for these potential problems during testing. Please see IFMC audit results.	M D
4e. Data Collection Strategy/Implementation	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:	4e C   P   M   N

<b>4e.2 Costs to implement the measure</b> (costs of data collection, fees associated with proprietary measures):  Data Collection:	
There are no direct costs to collect the data for this measure. Costs to develop the measure included volunteer cardiothoracic surgeon time, STS staff time, and DCRI statistician and project management time.	
Other fees: STS Adult Cardiac Surgery Database participants (single cardiothoracic surgeons or a group of surgeons) pay annual participant fees of \$2,950 or \$3,700, depending on whether participants are STS members (or whether the majority of surgeons in a group are STS members). As a benefit of STS membership, STS members are charged the lesser of the two fees.	
4e.3 Evidence for costs:	
4e.4 Business case documentation:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i> ?	4
Steering Committee: Overall, to what extent was the criterion, Feasibility, met?	4
Rationale:	C∐   P∏
	l M⊟
	N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time-
	limited
Steering Committee: Do you recommend for endorsement? Comments:	Y
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner)	
Co.1 <u>Organization</u>	
Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611	
Co.2 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Measure Developer If different from Measure Steward	
Co.3 <u>Organization</u> Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611	
Co.4 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Co.5 Submitter If different from Measure Steward POC Jane, Han, MSW, jhan@sts.org, 312-202-5856-, Society of Thoracic Surgeons	
Co.6 Additional organizations that sponsored/participated in measure development	
ADDITIONAL INFORMATION	
Workgroup/Expert Panel involved in measure development	
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations.	

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Describe the members' role in measure development.

Members of the STS Task Force on Quality Initiatives provide surgical expertise as needed. The STS Workforce on National Databases meets at the STS Annual Meeting and reviews the measures on a yearly basis. Changes or updates to the measure will be at the recommendation of the Workforce.

Ad.2 If adapted, provide name of original measure:

Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released: 2004

Ad.7 Month and Year of most recent revision: 12, 2010

Ad.8 What is your frequency for review/update of this measure? annually

Ad.9 When is the next scheduled review/update for this measure? 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment 0114 Sections 2a.14, 1b.2, 2b.3, 2d.5, 2f.3, 3a.6.pdf

Date of Submission (MM/DD/YY): 01/12/2011

# The Society of Thoracic Surgeons 2008 Cardiac Surgery Risk Models: Part 1—Coronary Artery Bypass Grafting Surgery

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Background. The first version of The Society of Thoracic Surgeons National Adult Cardiac Surgery Database (STS NCD) was developed nearly 2 decades ago. Since its inception, the number of participants has grown dramatically, patient acuity has increased, and overall outcomes have consistently improved. To adjust for these and other changes, all STS risk models have undergone periodic revisions. This report provides a detailed description of the 2008 STS risk model for coronary artery bypass grafting surgery (CABG).

Methods. The study population consisted of 774,881 isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2002, and December 31, 2006, at 819 STS NCD participating centers. This cohort was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. The validation sample was used to assess model calibration and discrimination. Model outcomes included operative mortality, renal failure, stroke, reoperation for any cause, prolonged ventilation, deep sternal wound infection, composite major morbidity or mortality, prolonged length of stay (> 14 days), and short length of stay (< 6 days and alive). Candidate predictor variables were selected based on their availability in versions 2.35, 2.41, and 2.52.1 of the STS NCD and their presence in (or ability to be mapped to) version 2.61. Potential predictor

variables were screened for overall prevalence in the study population, missing data frequency, coding concerns, bivariate relationships with outcomes, and their presence in previous STS or other CABG risk models. Supervised backwards selection was then performed with input from an expert panel of cardiac surgeons and biostatisticians. After successfully validating the fit of the models, the development and validation samples were subsequently combined, and the final regression coefficients were estimated using the overall combined (development plus validation) sample.

Results. The c-index for the mortality model was 0.812, and the c-indices for other endpoints ranged from 0.653 for reoperation to 0.793 for renal failure in the validation sample. Plots of observed versus predicted event rates revealed acceptable calibration in the overall population and in numerous subgroups. When patients were grouped into categories of predicted risk, the absolute difference between the observed and expected event rates was less than 1.5% for each endpoint. The final model intercept and coefficients are provided.

Conclusions. New STS risk models have been developed for CABG mortality and eight other endpoints. Detailed descriptions of model development and testing are provided, together with the final algorithm. Overall model performance is excellent.

(Ann Thorac Surg 2009;88:S2-22) © 2009 by The Society of Thoracic Surgeons

In 1986, The Society of Thoracic Surgeons (STS) convened an Ad Hoc Committee on Risk Factors for Coronary Artery Bypass Graft Surgery (CABG) [1] and an

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Ad Hoc Committee to Develop a National Database for Cardiothoracic Surgery [2]. This was prompted by the

Drs Shahian, O'Brien, Filardo, Ferraris, Haan, Rich, Normand, DeLong, Shewan, Peterson, Edwards, Anderson, and Ms Dokholyan have no conflicts of interest to declare regarding this work.

#### Abbreviations and Acronyms

BSA = body surface area

CABG = coronary artery bypass graft surgery

CHF = congestive heart failure

EF = ejection fraction

GFR = glomerular filtration rate

HCFA = Health Care Financing Administration

IABP = intra-aortic balloon pump NYHA = New York Heart Association NCD = National Adult Cardiac Surgery Database

O/E = observed to expected ratio

QMTF = Quality Measurement Task Force STS = The Society of Thoracic Surgeons

release earlier that year of inadequately risk-adjusted hospital mortality data by the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services. Although the HCFA analytical methodology was widely criticized, STS leadership recognized that the underlying principle of collecting and analyzing data to improve patient outcomes was valid, particularly for complex and costly procedures such as coronary artery bypass grafting surgery (CABG). They believed that it was the responsibility of professional organizations to develop credible clinical data registries for their own specialties, and that risk models derived from such registries would circumvent many of the concerns resulting from the use of unadjusted administrative data. Such clinical registries would be used as credible data sources for quality assessment and improvement activities as well as for research.

These early activities ultimately led to the development of the STS National Adult Cardiac Surgery Database (NCD) [3, 4]. Since its release to members in 1990, the STS NCD has evolved to become one of the largest specialty-specific clinical data registries in the world. It currently has more than 950 participants enrolled, representing just under 90% of the cardiac surgery providers in the United States, with data on more than 3.6 million procedures. Similar STS data registries have now been developed for congenital heart surgery and general thoracic surgery, and future plans include the development of specialty modules (eg, quality metrics, atrial fibrillation surgery, thoracic aortic surgery). Recent enhancements, including the addition of unique physician and patient identifiers, will facilitate linkages with other registries and greatly expand the potential of the STS NCD for longitudinal follow-up, comparative effectiveness, and cost efficiency studies.

In addition to the development of the STS NCD as a comprehensive, nationally representative data registry, the second major goal of the STS was to assure that analyses derived from this registry would be appropriately adjusted for preoperative patient severity, a major deficiency of the HCFA reports that were initially published in 1986. This was accomplished by first identifying

risk factors for specific procedures and outcomes, beginning with isolated CABG, then using these predictor variables to develop risk models. With statistical risk models, which are most often based on logistic regression, the expected outcome for a patient with a given set of risk factors can be determined, and that can be compared with the observed outcome. The observed (O) and expected (E) outcomes are summed over all patients of a particular surgeon or hospital to yield the risk-standardized mortality ratio (O/E), which can then be multiplied by the average rate in the reference population to calculate risk-standardized mortality rates [5–7].

STS CABG risk models have undergone periodic updates and revisions, the most recent of which was based upon 2000 to 2002 STS NCD data. In 2007, the STS Database Modernization Task Force completed a major specification upgrade of the STS NCD data collection instrument from version 2.52.1 to version 2.61. This included refinement, modification, consolidation, or elimination of some data elements, as well as an attempt to harmonize definitions with those of the American College of Cardiology National Cardiovascular Data Registry whenever possible. Given these changes, as well as the number of years since the last risk model update, the STS Quality Measurement Task Force (QMTF) was asked to develop new risk models for isolated CABG, isolated valve repair or replacement, and combined CABG plus valve procedures. The authors of this report include the QMTF members who participated in this initiative.

Implementation of these new models in January 2008 coincided with the release of STS NCD version 2.61. This report, Part 1 of 3, describes the development of the new mortality and morbidity models for isolated CABG surgery.

## **Study Purpose**

The primary goal of this study was to develop risk-prediction algorithms for patients undergoing isolated CABG surgery. As the major intended use of these algorithms was to compare participant outcomes to the overall STS national experience, risk factors were generally restricted to patient and clinical characteristics present preoperatively.

## Risk Model Development and Transparency

The availability of user-friendly statistical software programs and the exponential increase in computing speed have greatly facilitated statistical analyses such as logistic regression, the basis for many risk models. However, despite these technological advances, clinical judgment, experience, intuition, and practicality still play a critical role in risk model development. There are many points in model development at which legitimate differences in approach may lead to substantial differences in the resulting statistical models and the inferences derived from them [8].

We believe the degree of transparency provided in this report regarding the development of the STS CABG risk models is essential in today's health care environment. In an era when society demands full transparency regarding health care performance, the methodologies used to evaluate that performance should be just as transparent [9, 10]. This fundamental principle is among the standards established by the American Heart Association and American College of Cardiology for statistical models used for public reporting [11].

## Study Population and Endpoints

All isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2000, and December 31, 2006, were initially considered for inclusion, although the final development and validation samples were derived from 2002 to 2006 data. Patients missing data on sex (n = 195) were excluded, as these patients are not included in STS performance feedback reports to database participants. That left a study population of 774,881 surgical procedures from 819 database participants. Patients on dialysis preoperatively (n = 12,415) were excluded when developing the risk model for postoperative renal failure.

## Training and Validation Samples

The study population was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. Data from the validation sample were used to assess model fit, discrimination, and calibration. After choosing variables and assessing model fit, the development and validation samples were subsequently combined, and the final model coefficients were estimated using the combined (development plus validation) data.

## **Endpoints**

Risk models were developed for the nine endpoints listed below. Only mortality was recorded beyond the index hospitalization. Morbidity data included only in-hospital complications, although beginning in STS NCD version 2.61, sternal infections will be recorded for up to 30 days postoperatively. The nine endpoints are as follows: (1) operative mortality: death during the same hospitalization as surgery, regardless of timing, or within 30 days of surgery regardless of venue; (2) permanent stroke (cerebrovascular accident): a central neurologic deficit persisting longer than 72 hours; (3) renal failure: a new requirement for dialysis or an increase of the serum creatinine to more than 2.0 mg/dL and double the most recent preoperative creatinine level; (4) prolonged ventilation (longer than 24 hours); (5) deep sternal wound infection; (6) reoperation for any reason; (7) major morbidity or mortality: a composite defined as the occurrence of any of the above endpoints; (8) prolonged postoperative length of stay (PLOS): length of stay (LOS) more than 14 days (alive or dead); and (9) short postoperative LOS (SLOS): LOS less than 6 days and patient alive at discharge (this SLOS definition differs from the previous STS risk models, which did not exclude patients who died in-hospital; patients who died within 5 days of surgery are

included in the new models but are treated as not having a short stay).

Table 1 summarizes the frequencies of these endpoints in the study population for each predictor variable category (ie, the bivariate relationships).

## Selection of Candidate Predictor Variables

Initial Data Screening of Candidate Predictor Variables

We began by considering all possible candidate variables from the development set (Table 2). Because the primary goal of the STS risk models is to adjust surgical outcomes, in general only preoperative patient variables are included. However, because these models are also used for other purposes such as individual patient prediction and counseling, there were a few modifications (which are discussed in the relevant sections) in the application of this general principle.

As there were a large number of procedures and endpoints available, we were not statistically constrained to highly parsimonious models, nor is such an approach generally favored in regression modeling [12–14]. Discarding valid data elements can waste valuable information that has been collected at substantial effort and cost. Furthermore, although much of the discrimination of a predictive model may be contained in a relatively small number of variables [15, 16], some predictor variables that add only modestly to discrimination may still be important predictors of outcomes at the patient level [17, 18].

# Expert Panel Review for Clinical Relevance and Face Validity

All candidate variables available in version 2.61 were individually discussed by a panel of cardiac surgeons and health policy experts to assure that clinical relevance as well as multiple aspects of validity (face, construct, and content) had been considered.

## Data Version for Model Development

Although these new risk models were to be introduced in conjunction with the release of STS NCD version 2.61, they were developed with data collected under the three previous data versions (2.35, 2.41, and 2.52.1) because no 2.61 data were yet available. The QMTF began its predictor selection process with two caveats. First, any candidate variable had to be collected consistently across the three previous data versions. Second, it had to also be available in version 2.61 or have the ability to be mapped to this new version. For example, history of smoking and renal failure were not candidate variables as they were either not included in, or were unable to be mapped to, version 2.61. Renal function is now assessed by the last preoperative serum creatinine value, which is collected in all data versions. Because the definition of hypercholesterolemia has changed substantially over successive STS data versions, and because counterintuitive results have been observed in some previous analyses of hyper-

Table 1. Distribution of Risk Factors and Frequency of Adverse Outcomes in Overall Study Population, Isolated Coronary Artery Bypass Graft Surgery (2002–2006)

Variable	Number of Patients		Percent of Patients Experiencing Endpoint								
	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Overall											
Total	774,881	100.0	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Age, years											
< 55	137,318	17.72	1.0	0.5	1.7	7.1	0.3	3.7	10.0	2.7	67.1
55–64	221,697	28.61	1.3	0.9	2.4	7.8	0.4	4.2	11.4	3.8	59.4
65–74	245,132	31.63	2.4	1.6	3.9	10.0	0.5	5.5	14.9	5.9	47.7
≥ 75	170,734	22.03	4.7	2.3	6.4	13.9	0.5	7.5	20.9	9.6	33.0
Sex											
Male	560,006	72.27	2.0	1.2	3.4	8.7	0.4	5.1	13.4	4.9	55.0
Female	214,875	27.73	3.4	1.9	4.1	12.2	0.5	5.6	17.0	7.2	41.5
Race											
Caucasian	665,941	85.94	2.3	1.3	3.5	9.3	0.4	5.1	13.9	5.3	52.2
Black	44,405	5.73	2.7	2.0	5.2	13.5	0.7	6.3	19.0	8.2	41.3
Hispanic	25,103	3.24	2.6	1.5	4.3	11.3	0.5	5.6	16.1	6.1	48.4
Asian	12,509	1.61	2.7	1.9	3.8	12.6	0.3	7.2	17.4	7.0	45.2
Other	21,222	2.74	2.3	1.3	3.6	10.4	0.5	5.5	14.8	6.0	48.7
Missing	5,701	0.74	2.3	1.4	4.1	9.4	0.4	5.2	14.5	6.1	48.9
Body surface area (m <sup>2</sup> )	-,						**-				
< 1.50	14,339	1.85	6.2	2.4	4.6	16.2	0.3	8.3	22.1	9.8	36.5
1.50–1.74	111,458	14.38	3.8	2.0	4.0	12.6	0.3	6.5	17.7	7.4	42.5
1.75–1.99	280,677	36.22	2.4	1.5	3.5	9.6	0.4	5.4	14.4	5.6	50.7
≥ 2.00	363,817	46.95	1.7	1.0	3.6	8.6	0.5	4.6	13.1	4.8	55.0
Missing	4,590	0.59	3.7	1.4	4.0	7.6	0.3	4.7	13.9	6.8	46.0
Body mass index (kg/m²)	4,070	0.07	0.7	1.1	1.0	7.0	0.5	1.7	10.7	0.0	10.0
< 25	169,091	21.82	3.3	1.7	3.5	11.0	0.3	6.7	16.3	6.7	47.6
25–29	303,371	39.15	2.1	1.3	3.1	8.6	0.3	4.9	13.1	4.8	54.2
30–34	186,148	24.02	1.8	1.2	3.6	9.0	0.5	4.5	13.4	5.0	53.1
≥ 35	110,213	14.22	2.3	1.2	5.2	12.0	0.8	4.9	16.8	6.8	45.7
Missing	6,058	0.78	3.7	1.4	4.2	8.6	0.3	4.8	14.5	6.7	47.2
Diabetes mellitus	0,030	0.70	0.7	1.1	1,4	0.0	0.5	1.0	14.5	0.7	17.2
No diabetes	492,800	63.60	2.1	1.2	2.8	8.8	0.3	5.0	13.0	4.7	54.8
Diabetes-noninsulin	195,421	25.22	2.3	1.6	4.3	10.1	0.5	5.2	15.2	6.0	48.2
Diabetes-insulin	84,406	10.89	3.6	1.8	7.1	13.9	1.0	6.5	20.6	9.7	37.5
Diabetes-missing treatment	1,439	0.19	3.1	2.2	4.6	11.1	0.7	4.6	15.7	8.8	41.9
Missing	815	0.13	3.8	0.7	2.6	8.8	0.5	4.5	12.3	6.9	43.7
Hypertension	013	0.11	3.0	0.7	2.0	0.0	0.5	1.0	12.5	0.7	10.7
No	167,260	21.59	1.9	0.9	2.2	8.1	0.3	4.6	11.7	4.2	58.2
Yes	606,813	78.31	2.5	1.5	4.0	10.1	0.5	5.4	15.1	5.9	49.3
Missing	808	0.10	3.8	0.7	2.4	9.3	0.5	5.2	12.7	6.7	43.9
Hypercholesterolemia	808	0.10	3.0	0.7	2.4	9.3	0.5	3.2	12.7	0.7	43.9
No	199,894	25.80	3.0	1.6	3.9	11.0	0.5	5.8	16.1	6.5	48.7
Yes	573,257	73.98	2.1	1.3	3.5	9.2	0.3	5.0	13.8	5.2	52.1
Missing	1,730	0.22	4.1	1.6	3.5	10.3	0.3	4.7	13.9	7.3	47.5
•	1,730	0.22	4.1	1.0	3.3	10.3	0.3	4.7	13.9	7.3	47.3
Past or present smoker	205 000	20.20	2.4	1.4	2.7	0.0	0.4	E 1	12.0	E 2	E0 1
No Yes	295,999 477 911	38.20	2.4	1.4 1.3	3.7 3.6	9.0	$0.4 \\ 0.5$	5.1 5.3	13.9 14.7	5.3 5.7	50.1 51.9
	477,911	61.68	2.3			10.1				5.7	
Missing Chronic lung disease	971	0.13	3.4	0.7	3.1	9.9	0.4	5.3	13.5	9.1	41.0
Chronic lung disease	610 011	70.01	2.0	1.0	2.2	0.4	0.2	4.0	12.0	4.7	E2 F
None	612,211	79.01	2.0	1.3	3.3	8.4	0.3	4.9	13.0	4.7	53.7
Mild	85,005	10.97	2.8	1.5	4.2	12.0	0.6	5.8	16.9	7.0	45.7
Moderate	47,745	6.16	3.8	1.6	5.3	15.8	0.8	6.8	20.8	9.6	39.5
Severe	22,302	2.88	7.0	2.0	7.7	22.8	1.1	9.5	29.0	15.3	29.2
Missing	7,618	0.98	2.6	1.4	3.2	8.2	0.2	3.9	12.6	5.7	53.4

Table 1. Continued

	Numb Patie				Percer	nt of Pat	t of Patients Experiencing Endpoint						
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS		
Peripheral vascular disease													
No	653,260	84.30	2.0	1.2	3.2	8.8	0.4	4.8	13.1	4.8	53.5		
Yes	120,480	15.55	4.4	2.3	6.1	14.4	0.7	7.5	21.2	9.6	38.7		
Missing	1,141	0.15	3.9	1.1	3.1	11.8	0.3	5.5	14.4	7.4	43.9		
Cerebrovascular disease													
No	668,073	86.22	2.1	1.1	3.3	9.0	0.4	4.9	13.4	5.0	53.4		
Yes	105,792	13.65	4.0	2.9	5.8	14.0	0.6	7.2	20.7	9.3	37.7		
Missing	1,016	0.13	3.2	0.6	2.4	8.9	0.3	4.2	11.4	6.8	43.2		
CVA													
No CVA	717,721	92.62	2.2	1.2	3.4	9.3	0.4	5.1	13.8	5.2	52.5		
Remote CVA (> 2 weeks)	53,341	6.88	4.2	3.1	6.1	15.3	0.7	7.4	22.0	10.3	35.5		
Recent CVA ( $\leq$ 2 weeks)	1,763	0.23	5.0	4.9	6.5	18.8	0.9	8.7	25.4	13.0	32.5		
CVA-missing timing	745	0.10	3.8	3.5	6.9	14.0	0.5	5.9	21.7	10.7	34.2		
Missing	1,311	0.17	3.3	1.0	2.6	7.4	0.2	4.3	11.4	5.9	47.8		
Endocarditis													
No endocarditis	773,002	99.76	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2		
Treated endocarditis	472	0.06	4.4	0.8	5.3	15.3	0.6	8.5	19.9	8.9	33.7		
Active endocarditis	110	0.01	2.7	1.8	6.3	20.0	1.8	11.8	24.5	20.0	41.8		
Endocarditis-missing type	90	0.01	4.4	4.4	5.8	11.1	1.1	3.3	15.6	2.2	55.6		
Missing	1,207	0.16	4.1	1.0	3.5	9.0	0.2	4.6	12.8	7.0	46.2		
Renal failure													
No	731,626	94.42	2.1	1.3	3.2	9.0	0.4	5.0	13.4	5.0	52.8		
Yes	42,153	5.44	7.2	2.7	14.7	22.5	1.0	9.9	31.9	15.8	23.4		
Missing	1,102	0.14	3.1	0.8	2.8	7.4	0.3	3.4	10.8	6.4	46.6		
Renal function													
Creatinine < 1.00 mg/dL	274,197	35.39	1.6	1.1	1.5	8.0	0.3	4.4	11.2	4.0	55.6		
Creatinine 1-1.49 mg/dL	398,833	51.47	2.0	1.3	3.4	8.9	0.4	5.0	13.5	4.9	53.1		
Creatinine 1.5-1.99 mg/dL	57,779	7.46	4.5	2.3	10.8	16.1	0.7	7.8	25.2	10.6	34.5		
Creatinine 2.0-2.49 mg/dL	12,463	1.61	6.9	2.9	14.3	21.3	0.9	9.4	31.5	15.3	24.7		
Creatinine $\geq 2.5 \text{ mg/dL}$	7,906	1.02	8.2	3.2	20.4	23.4	0.9	11.1	37.9	18.6	20.4		
Dialysis	12,415	1.60	8.4	2.7	*NA	25.3	1.2	10.5	31.5	16.4	19.6		
Missing	11,288	1.46	3.3	1.2	3.1	7.6	0.3	4.3	12.9	5.9	50.1		
Immunosuppressive treatment													
No	758,368	97.87	2.3	1.4	3.6	9.6	0.4	5.2	14.2	5.4	51.5		
Yes	14,976	1.93	5.4	1.8	6.3	15.6	0.8	8.7	22.5	10.8	37.0		
Missing	1,537	0.20	3.3	0.8	2.8	6.5	0.4	4.6	11.4	6.1	46.8		
Prior CABG Surgery													
No	735,033	94.86	2.2	1.4	3.5	9.4	0.4	5.1	14.1	5.4	51.7		
Yes	36,693	4.74	5.3	1.6	5.8	14.7	0.5	7.5	20.9	7.8	42.6		
Missing	3,155	0.41	2.7	1.1	3.3	8.9	0.5	4.8	12.9	6.8	48.9		
Prior valve surgery													
No	769,434	99.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.3		
Yes	2,280	0.29	5.9	1.9	6.8	15.3	0.7	8.6	22.5	11.1	32.0		
Missing	3,167	0.41	2.9	1.2	3.5	8.6	0.5	4.4	12.7	6.3	50.0		
Prior other cardiac surgery													
No	755,653	97.52	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.3		
Yes	15,218	1.96	3.9	1.5	4.9	13.1	0.6	6.6	18.6	7.6	45.5		
Missing	4,010	0.52	2.8	1.0	2.9	8.5	0.4	4.4	12.2	5.9	50.5		
Number of previous CV surgeries													
No previous CV surgery	723,623	93.39	2.2	1.4	3.5	9.4	0.4	5.1	14.0	5.4	51.7		
One prior CV surgery	40,474	5.22	4.7	1.6	5.4	13.8	0.5	7.3	19.9	7.7	44.1		
Two or more prior CV Surgeries	4,840	0.62	6.2	1.4	5.6	14.7	0.6	8.0	22.0	8.4	41.5		
Missing	5,944	0.77	2.9	1.1	3.2	9.8	0.6	5.5	14.3	6.1	51.2		

Table 1. Continued

	Numb Patie				Percer	t of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Prior PCI											
No PCI	606,824	78.31	2.3	1.4	3.6	9.5	0.4	5.1	14.2	5.6	51.1
$PCI \le 6 \text{ hours}$	7,373	0.95	8.9	2.1	7.4	25.8	0.6	10.5	32.6	11.3	35.5
PCI > 6 hours	155,161	20.02	2.3	1.2	3.5	9.6	0.4	5.4	14.3	5.1	52.4
PCI-missing timing	2,456	0.32	3.0	0.6	3.3	8.0	0.8	5.1	13.4	6.8	48.9
Missing	3,067	0.40	3.3	1.0	3.0	9.8	0.5	4.7	13.7	6.2	47.3
Acuity status											
Elective	381,116	49.18	1.5	1.1	2.9	6.6	0.4	4.3	11.1	4.1	55.6
Urgent	356,287	45.98	2.4	1.5	3.9	10.8	0.5	5.6	15.7	6.2	48.5
Emergent	34,513	4.45	8.1	2.6	8.3	29.6	0.7	10.4	34.1	13.3	33.2
Emergent salvage	1,967	0.25	38.6	4.9	17.4	52.7	0.7	18.4	70.0	23.5	12.6
Missing	998	0.13	3.2	1.3	3.6	9.2	0.5	4.8	13.7	6.5	43.6
MI											
No prior MI	424,599	54.80	1.5	1.1	2.8	6.9	0.3	4.5	11.3	4.1	55.4
MI > 21  days	137,522	17.75	2.1	1.3	3.5	8.9	0.5	5.2	13.9	5.4	50.4
MI 8–21 days	26,205	3.38	4.0	1.8	6.0	14.4	0.8	7.5	20.7	10.2	38.1
MI 1–7 days	148,659	19.18	3.4	1.8	4.8	14.0	0.5	6.1	18.9	7.5	45.7
MI > 6 and < 24 hours	21,044	2.72	6.0	2.4	6.7	23.6	0.5	8.1	28.1	10.4	39.1
$MI \le 6 \text{ hours}$	11,539	1.49	10.4	2.6	8.6	31.2	0.6	10.6	36.8	13.3	33.5
MI-missing timing	4,064	0.52	3.6	1.6	4.6	11.3	0.5	5.6	17.5	7.2	43.9
Missing	1,249	0.16	2.1	1.1	2.4	6.6	0.2	3.8	10.2	6.7	49.4
Angina											
No	130,143	16.80	2.5	1.4	3.8	9.5	0.4	5.6	14.7	6.2	48.5
Yes	643,815	83.09	2.3	1.3	3.6	9.7	0.4	5.2	14.3	5.4	51.8
Missing	923	0.12	2.3	1.0	2.6	8.8	0.5	4.0	11.2	8.2	43.9
Cardiogenic shock											
No	758,766	97.92	2.0	1.3	3.4	8.9	0.4	5.0	13.6	5.2	51.9
Yes	14,919	1.93	18.0	3.6	14.6	49.6	1.0	15.3	55.7	23.1	18.3
Missing	1,196	0.15	2.7	1.1	3.2	8.0	0.4	4.4	12.0	7.4	44.7
Resuscitation	,										
No	766,674	98.94	2.2	1.3	3.5	9.4	0.4	5.1	14.1	5.4	51.5
Yes	6,939	0.90	17.1	3.0	11.4	37.5	0.9	14.0	46.1	18.2	24.3
Missing	1,268	0.16	2.2	0.8	3.4	8.0	0.6	3.9	11.5	7.3	45.0
Arrhythmia	,										
No arrhythmia	706,709	91.20	2.0	1.3	3.3	8.9	0.4	4.9	13.4	5.0	53.1
AFib/flutter	39,125	5.05	5.4	2.3	7.1	16.4	0.7	8.5	23.8	11.9	29.4
Heart block	10,026	1.29	5.8	1.9	6.8	16.8	0.6	9.2	24.2	9.4	36.4
Sustained VT/VF	14,336	1.85	8.2	2.0	6.8	23.8	0.6	11.1	31.5	12.0	33.0
Arrhythmia–other	1,853	0.24	3.8	1.6	5.3	12.9	0.6	6.5	19.1	7.3	39.2
Arrhythmia–missing type	1,344	0.17	3.9	1.7	4.4	11.9	0.7	7.3	17.5	8.3	37.9
Missing	1,488	0.19	2.7	1.0	3.0	7.1	0.5	3.8	11.1	6.5	45.5
Preoperative IABP	1,100	0.13	,	110	0.0	,,,	0.0	0.0	1111	0.0	10.0
No	714,824	92.25	2.0	1.3	3.3	8.0	0.4	4.9	12.8	4.9	52.8
Yes	58,134	7.50	6.9	2.2	7.7	30.8	0.6	9.6	34.4	12.9	32.0
Missing	1,923	0.25	4.2	1.7	4.3	10.9	0.6	5.8	16.0	7.2	45.7
NYHA class	1,720	0.20	1.2	1.7	1.0	10.7	0.0	3.0	10.0	7.2	10.7
I	97,812	12.62	1.5	1.1	2.5	6.3	0.3	4.4	10.6	3.9	57.0
II	187,947	24.25	1.3	1.1	2.6	6.5	0.3	4.2	10.7	3.8	56.5
III	287,760	37.14	2.0	1.3	3.6	9.0	0.3	5.0	13.9	5.4	51.3
IV	165,325	21.34	4.5	1.9	5.5	16.6	0.4	7.1	21.9	8.8	42.5
Missing	36,037	4.65	4.5 2.4	1.9	3.6	8.9	0.6	5.3	13.6	5.8	42.5 47.7
9	30,037	4.03	4.4	1.4	3.0	0.7	0.3	5.5	13.0	5.0	4/./
Congestive heart failure	666 E00	86.02	10	1.2	2.0	7.0	0.2	47	12.2	4.2	E4 7
No Voc	666,592 106,700	86.03	1.8	1.2	2.9	7.9	0.3	4.7	12.2	4.3	54.7
Yes	106,700	13.77	5.9	2.4	8.5	21.0	0.9	8.7	28.0	13.2	29.5
Missing	1,589	0.21	3.3	1.4	3.1	9.2	0.4	4.5	13.0	7.4	49.6

Table 1. Continued

	Numb Patie				Percer	nt of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Number of diseased coronary vessels											
None	2,012	0.26	2.3	0.4	2.8	8.9	0.4	4.6	12.6	5.5	53.1
One	32,311	4.17	1.5	0.6	1.9	6.1	0.2	4.4	9.8	3.1	66.3
Two	150,881	19.47	1.8	1.0	2.7	8.0	0.4	4.5	12.0	4.5	56.3
Three	586,658	75.71	2.5	1.5	4.0	10.4	0.4	5.5	15.3	6.0	49.1
Missing	3,019	0.39	2.6	0.6	1.8	5.5	0.2	4.5	10.8	5.9	54.2
Left main disease $\geq 50\%$											
No	554,355	71.54	2.1	1.3	3.4	8.8	0.4	5.0	13.5	5.1	52.7
Yes	217,548	28.08	3.0	1.5	4.3	11.9	0.5	5.9	16.8	6.6	47.6
Missing	2,978	0.38	2.3	1.4	2.7	6.3	0.3	5.5	11.9	5.9	45.4
Ejection fraction (%)											
< 25	25,323	3.27	7.2	2.2	8.0	25.2	0.8	10.5	31.9	13.7	27.8
25–34	57,460	7.42	4.6	2.1	6.1	17.6	0.6	7.6	23.8	10.3	36.8
35–44	108,623	14.02	3.0	1.7	4.7	12.4	0.6	6.0	17.5	7.2	45.7
45–54	189,478	24.45	1.9	1.3	3.4	8.7	0.4	4.8	13.2	5.0	53.1
≥ 55	351,455	45.36	1.5	1.1	2.7	6.8	0.3	4.4	11.1	3.9	56.1
Missing	42,542	5.49	3.4	1.4	4.1	10.8	0.4	5.6	16.0	6.1	50.0
Mitral stenosis											
No	756,609	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Yes	2,703	0.35	5.5	2.4	6.4	17.0	0.7	7.5	22.9	10.5	35.7
Missing	15,569	2.01	2.1	1.3	3.4	8.3	0.4	4.6	13.1	5.0	53.1
Aortic stenosis	,										
No	750,185	96.81	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.4
Yes	11,386	1.47	4.7	2.1	6.5	14.8	0.7	7.9	21.5	9.7	36.6
Missing	13,310	1.72	2.3	1.3	3.3	8.5	0.4	4.7	13.1	5.0	52.5
Tricuspid stenosis	,										
No	756,574	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	597	0.08	3.4	2.3	6.6	14.9	0.7	6.0	20.9	10.1	43.6
Missing	17,710	2.29	2.1	1.3	3.6	8.5	0.4	4.7	13.4	5.0	53.2
Pulmonic stenosis	,										
No	753,975	97.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	445	0.06	3.4	2.2	3.9	12.6	0.0	6.3	20.2	6.3	49.4
Missing	20,461	2.64	2.2	1.4	3.8	8.7	0.4	5.0	13.9	5.3	52.5
Mitral insufficiency	,										
None	622,173	80.29	2.1	1.2	3.3	8.9	0.4	4.9	13.4	5.0	53.2
Trivial	49,152	6.34	2.4	1.6	4.2	10.5	0.4	5.7	15.7	6.2	47.9
Mild	60,811	7.85	3.7	2.0	5.7	14.3	0.5	6.9	20.3	8.6	40.3
Moderate	16,723	2.16	6.7	2.7	7.9	20.1	0.7	9.6	28.0	12.5	30.3
Severe	2,143	0.28	8.7	3.1	8.9	24.1	0.6	11.0	32.6	15.1	28.2
Missing	23,879	3.08	2.1	1.2	3.0	7.5	0.4	4.7	12.0	5.2	51.5
Aortic insufficiency	20,017	0.00			0.0	7.0	0.1	2.,,	12.0	J	01.0
None	705,771	91.08	2.3	1.3	3.5	9.5	0.4	5.1	14.1	5.4	51.9
Trivial	17,988	2.32	3.6	2.1	5.6	13.4	0.5	7.0	19.4	8.3	40.9
Mild	18,571	2.40	4.1	2.2	5.9	14.3	0.4	7.3	20.8	9.0	37.9
Moderate	3,576	0.46	5.3	2.6	7.0	16.2	0.5	7.9	23.2	10.2	32.8
Severe	411	0.05	7.1	1.9	6.7	15.6	0.7	9.5	25.8	10.9	37.2
Missing	28,564	3.69	2.1	1.2	3.2	7.9	0.4	4.6	12.5	5.3	51.4
Tricuspid insufficiency	_0,004	0.07	4.1	1.4	0.2	1.7	01	4.0	12.0	0.0	01.7
None	675,778	87.21	2.2	1.3	3.4	9.4	0.4	5.1	13.9	5.3	52.1
Trivial	32,856	4.24	2.5	1.6	4.5	9. <del>4</del> 11.1	0.4	6.1	16.6	6.7	47.4
Mild	29,611	3.82	3.9	2.2	5.9	14.7	0.4	7.4	21.0	9.1	39.3
Moderate	5,753	0.74	7.6	3.0	9.0	22.7	0.5	9.8	30.2	13.7	26.9
Severe	728	0.09	9.1	2.9	10.5	24.2	0.4	10.9	33.0	17.2	26.2
Missing	30,155	3.89	2.2	1.2	3.2	7.9	0.4	4.6	12.6	5.2	51.7

Table 1. Continued

	Numb Patie				Percer	nt of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Pulmonic insufficiency											
None	724,258	93.47	2.3	1.4	3.6	9.7	0.4	5.2	14.3	5.5	51.4
Trivial	10,726	1.38	2.8	1.5	4.3	12.3	0.5	6.5	17.3	7.3	44.8
Mild	4,867	0.63	3.8	2.1	5.6	14.1	0.4	7.4	21.0	9.1	39.7
Moderate	546	0.07	6.6	3.1	7.8	17.6	0.2	7.9	24.4	11.5	29.7
Severe	217	0.03	5.1	0.5	5.1	9.7	0.5	6.5	15.7	8.8	50.7
Missing	34,267	4.42	2.2	1.3	3.5	8.3	0.4	4.8	13.2	5.5	50.7

CABG = coronary artery bypass graft surgery; Comp = composite adverse outcome (any); DSWI = deep sternal wound infection; IABP = intra-aortic balloon pump; CVA = cerebrovascular accident (stroke); MI = mvocardial Mort = mortality; Na = not applicable; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; Reop = reoperation; RF = renal failure; PLOS = prolonged length of stay; SLOS = short length of stay; Vent = prolonged ventila-VT = ventricular tachycardia. VF = ventricular fibrillation;

cholesterolemia, a decision was made not to include this variable in the new models.

### Predictor Frequency

For each variable, the QMTF explored the overall prevalence and missing data frequency per year. Predictor variables that are rarely present in the development sample are difficult to model. For this reason, mitral (0.35%), tricuspid (0.08%), and pulmonic stenosis (0.06%), pulmonic insufficiency (0.10%), and endocarditis (0.09%) were not considered as variables in the new isolated CABG models.

### Inconsistently Coded Variables

A few variables have been collected inconsistently or with questionable reliability, often for clinically unavoidable reasons. For example, pulmonary artery mean pressure data were missing for 70% of patients during 2002 to 2006. Furthermore, the value of this continuous variable may vary substantially depending on the clinical state and volume-loading status of the patient when the measurement is obtained. Because of these concerns, pulmonary artery pressure was not included in the models.

### Derived or Redundant Variables

Several derived variables were considered for inclusion in the models. For example, body mass index (BMI) is a useful measure of overall body habitus. However, because BMI is highly correlated with body surface area (BSA), the more commonly used anthropometric measure in most previous STS models, the latter was retained in the new models. Similarly, there is a theoretical superiority to inclusion of glomerular filtration rate (GFR) rather than serum creatinine as a measure of renal function. However, the Modification of Diet in Renal Disease formula for estimating GFR is a complex function of creatinine, race, sex, and age, and not all laboratories perform this calculation automatically. Furthermore, as age, sex, and race are already model covariates, using GFR would complicate the interpretation of their regression coefficients. Some of the prognostic value of GFR

comes from these variables that are already included in the model. Finally, previous studies suggest that various measures of renal function used in CABG mortality risk models have similar performance [19]. For all these reasons, serum creatinine was retained as the measure of renal function.

### Controversial Variables

RACE. Several variables raised particular clinical, statistical, or health policy issues. For example, race was an obvious candidate variable because it was a significant predictor (p < 0.001) of each endpoint except mortality and because the proportion of nonwhite patients varied substantially across institutions. In exploratory analyses, the association between race and outcomes persisted after adjusting for hospital identity, suggesting that this association is not explained by differences in hospital quality.

However, general principles of risk model development complicated the decision as to whether or not to include race in the models. When the dominant purpose of a risk model is adjustment of provider results, it is advisable to include only biological and clinical patient variables that are present before a patient's first contact with the provider. In this context, race is clearly a fixed biological characteristic, but its impact on patient outcomes may be mediated through other mechanisms. It is possible that certain racial and ethnic groups have worse outcomes not because of inherent biological characteristics but because of differences in the quality of care delivered to them. In this case, including race and ethnicity in a risk model could essentially select out or obscure the very disparity issues that society wishes to identify and correct. Inclusion of race and ethnicity in a risk model would say, in effect, that we expect nonwhites to have inferior results and would make an allowance for providers who care for such patients, just as we would for providers who care for patients in cardiogenic shock.

After deliberation regarding the pros and cons, the QMTF ultimately elected to retain race and ethnicity in the new models because of their impact on outcomes,

### Table 2. Initial List of Potential Candidate Variables

### Demographics

- 1. Age
- 2. Sex
- 3. Race (black, Caucasian, Hispanic, Asian, Native American, other)

Note: Data collection changed in v2.61. New version allows for multiple races (check all that apply). Added Hawaiian/Pacific Islander category. Hispanic ethnicity is a separate variable.

### Anthropometric

- 4. Height
- 5. Weight

### Status

- 6. Status (elective, urgent, emergent, salvage)
- 7. Shock
- 8. Resuscitation

### Cardiac variables

9. Angina, angina type (STS categories are unstable, stable, no angina)

Note: Angina was removed on v2.61 data collection form. The new form has a variable called "cardiac presentation on admission." Angina is one of possible response categories to that field.

10. New York Heart Association functional class

Note: In v2.61, NYHA class is only collected if patient has congestive heart failure.

- 11. Arrhythmia and arrhythmia type (sustained VT/VF; heart block; AFib/flutter, None)
- 12. Myocardial infarction timing: ( $\leq 6$ , > 6 and < 24 hours; 1–7, 8–21, > 21 days)

### Hemodynamic/catheterization variables

- 13. Ejection fraction
- 14. Number of diseased vessels (0, 1, 2, 3)
- 15. Left main disease
- 16. Pulmonary artery mean pressure
- 17. Mitral stenosis
- 18. Aortic stenosis
- 19. Tricuspid stenosis
- 20. Pulmonic stenosis
- 21. Mitral insufficiency (none, trivial, mild, moderate, severe)
- 22. Aortic insufficiency (none, trivial, mild, moderate, severe)
- 23. Tricuspid insufficiency (none, trivial, mild, moderate, severe)
- 24. Pulmonic insufficiency (none, trivial, mild, moderate, severe)

### Comorbidities

- 25. Serum creatinine
- 26. Dialysis
- 27. Renal failure

Note: This variable was removed in v2.61.

- 28. Endocarditis (active, treated, none)
- 29. Diabetes and treatment (insulin, oral, diet, untreated, no diabetes)
- 30. Chronic lung disease (none, mild, moderate, severe)
- 31. Congestive heart failure
- 32. Peripheral vascular disease
- 33. Cerebrovascular disease
- 34. CVA and CVA timing (recent, remote, none)

Note: CVA is a child field of cerebrovascular disease in v2.61.

35. Hypercholesterolemia (v2.35, v2.41) and Dyslipidemia (v2.52)

Note: Data from all 3 versions were merged and analyzed under the variable name "hypercholesterolemia."

- 36. Hypertension
- 37. Smoker

Note: Major definition change in v2.61.

### Preoperative interventions

- 38. Preoperative intra-aortic balloon pump
- 39. Preoperative inotropes
- 40. Immunosuppressive treatment
- 41. Prior percutaneous coronary intervention and timing ( $\leq$  6 hours, > 6 hours, none)

### **Previous Interventions**

- 42. Prior coronary artery bypass graft surgery
- 43. Prior valve surgery
- 44. Prior other cardiac surgery
- 45. Number of previous cardiovascular surgeries

while recognizing the potential limitations of this decision.

PREOPERATIVE INTRA-AORTIC BALLOON PUMP. Preoperative intra-aortic balloon pump (IABP) is a proxy for more serious preoperative status of the patient (eg, unstable angina, ventricular dysfunction). It captures information that may not be present in other data elements, and it is associated with higher risk of postoperative morbidity and mortality. For these reasons, most CABG risk models include preoperative IABP as a risk predictor. However, placement of an IABP is also a highly discretionary care process the frequency of which varies widely among participating institutions. Indications are subjective and are often dictated by the cardiologist before even referring the patient for cardiac surgery. Based on CABG risk models, an institution that liberally utilizes IABPs will have a higher expected risk of morbidity and mortality (according to the model) compared with another institution with a similar case-mix but a more restrictive IABP policy. That would impact their relative O/E ratios and risk-adjusted outcomes.

Despite its discretionary nature (and the potential for gaming), the QMTF decided to retain IABP use in the models because it is such an important predictor. Ultimately, it was elected to model preoperative IABP as a joint variable with preoperative inotrope use as an overall measure of preoperative acuity/severity.

### Review of External Sources

The QMTF also reviewed multiple external resources to aid in the selection of potential candidate variables [15, 16, 20]. First, all previous versions of the STS CABG risk models were reviewed. The QMTF also examined other CABG risk models including the European System for Cardiac Operative Risk Evaluation (EuroSCORE) [21], the New York Cardiac Surgery Reporting System [22], the Veterans Affairs Administration cardiac surgery models [23, 24], and the Northern New England Cardiovascular Disease Study Group model [25, 26]. We particularly wanted to identify variables that were found in some form across all the risk models. Subject to the constraints of version 2.61 data specifications, we made a special effort to include such variables in the new STS risk models, in some instances requiring us to "force" them into the models, as described in the section on the final variable selection procedure.

### Missing Data

Missing data in the STS NCD are rare, having a frequency of less than 1% for most variables. Candidate predictor variables missing most commonly were ejection fraction (5.5%), New York Heart Association (NYHA) class (4.7%), tricuspid insufficiency (3.9%), aortic insufficiency (3.7%), mitral insufficiency (3.1%), aortic stenosis (1.7%), and creatinine/dialysis (1.5%).

Missing predictor values in the STS NCD were managed using imputation. Multiple imputation is the generally preferred statistical method [27], but single imputation was also considered based on the following

practical considerations: (a) the fraction of missing data in the STS NCD was small and, hence, single and multiple imputation would likely give similar point estimates; (b) a slight adjustment to the standard errors would not impact the study conclusions or the published risk algorithms; (c) the large sample size would make multiple imputation less practical to implement because of long computational times.

Prior to selecting an imputation strategy, exploratory analyses were performed using CABG data from 2002 to 2003 to compare single versus multiple imputation results for predicting mortality. These analyses confirmed that the choice between single versus multiple imputation would have only a slight impact on regression coefficients. For example, the estimated odds ratio for a 5-unit increase in ejection fraction was 0.90 (with a 95% confidence interval extending from 0.83 to 0.97) under single imputation and was 0.92 (with a confidence interval extending from 0.85 to 0.99) under multiple imputation. Other variables were missing less frequently than ejection fraction and were even less sensitive to the choice between single versus multiple imputation. Additional analyses of missing data consisted of reestimating the final model coefficients using single versus multiple imputation and comparing results. A summary of these investigations, as well as model coefficients and covariance matrices, are available at www.sts.org/riskmodels. For most patients, if risk were calculated using the multiple imputation model instead of single imputation, the relative change in their risk estimate would only be 1% to 2% (eg, 5% to 5.1% is a 2% change).

Based on the considerations described above, single imputation was used with the following specific rules: (1) binary (yes/no) risk factors were modeled as yes versus no or missing. Missing data for such variables usually implies their absence, and for most binary variables the composite event rates were similar for "no" and "missing" categories; (2) missing data on categorical predictor variables were imputed to the lowest risk value, which, in most instances, was the mode. In most instances, composite event rates for patients with missing data were among the lowest. It is the policy of the STS Data Warehouse and Analysis Center to discourage missing data through this default coding practice; and (3) missing data on continuous predictor variables were imputed to the conditional median. For ejection fraction, we conditioned on congestive heart failure (CHF) and sex. For BSA, we conditioned on sex. For serum creatinine, we conditioned on renal failure (although this approach will be modified when the model is ultimately applied to version 2.61 data, as renal failure has been removed).

For model endpoints (eg, mortality), missing data were handled by modeling yes versus no or missing. Thus, cases with missing data for an endpoint were analyzed as if the endpoint did not occur. Complete case analysis was not used because "missing" was not considered to be consistently coded for these variables. For example, some STS data managers have reported that they set complications to "no" unless there is explicit documentation in the medical record that the complication occurred. Other

data managers may leave the field missing unless there is explicit documentation that the complication did not occur. Thus, missing data may reflect differences in coding practices rather than truly unknown or missing data.

# Preliminary Analyses for Ordinal Categorical Variables and Continuous Variables

The QMTF conducted preliminary analyses to determine how best to model ordinal categorical variables and continuous variables. Categorical variables were entered into a logistic regression model by including a separate parameter for each category. Continuous variables were entered as piecewise linear functions (splines) with several changes of slope (knots). Terms were then removed one at a time using backward selection based on the Wald statistic. At each iteration, either two adjacent categories were collapsed into a single category or else two adjacent line segments were collapsed into a single line with no change of slope. The backward selection terminated when all adjacent categories and slopes were statistically different from one another at p < 0.001. This variable selection routine was performed separately for each endpoint. An expert panel determined the final coding based on the results of the backwards selection algorithm, supplemented by their clinical judgment and practical considerations. Table 3 summarizes these coding decisions.

### **Specific Coding Decisions**

RACE AND ETHNICITY. In versions 2.35, 2.41, and 2.52.1, race was collected by choosing one of the following mutually exclusive response categories: Caucasian, black, Hispanic, Asian, Native American, and other. In version 2.61, the data collection form was modified to conform to standards adopted by the US Census Bureau. It allows for selecting one or more races per patient (ie, select all that apply), and treats ethnicity (Hispanic versus non-Hispanic) as a separate variable. Because of these differences, the mapping of race among data versions is not straightforward.

Ultimately, the QMTF decided to model race as black, Asian, Hispanic, and Caucasian/other (collapsed). Initially, these categories will be mapped to version 2.61 as follows: (1) black will include all black patients, regardless of ethnicity or additional races; (2) Hispanic will include all nonblack Hispanic patients; (3) Asian will include all Asian patients who are not also identified as black or Hispanic; and (4) all remaining patients will be placed in the Caucasian/other category. The validity of this mapping will be assessed once 2.61 data become available and future versions could employ race "bridging" methodologies.

BODY SURFACE AREA. Height and weight were replaced by BSA, which was modeled as a quadratic trend to allow for a possible U-shaped relationship with outcomes (eg, extreme obesity and cachexia). This quadratic polynomial was modeled separately for males and females. Any BSA values below 1.4 or above 2.6 were mapped to these

values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

ANGINA. Version 2.61 of the data collection form eliminates angina and substitutes a new variable called "cardiac presentation on admission," within which unstable angina is one of the possible response categories. The QMTF believed that unstable angina would be coded more consistently than any other angina class, and also that this was the most important type of angina presentation to include in the models. Angina coding was therefore restricted in the new risk models to "unstable angina without MI < 7 days (yes/no)." It was necessary to exclude patients with myocardial infarction less than 7 days because the new version 2.61 does not permit simultaneous coding of angina and acute myocardial infarction.

REOPERATIVE STATUS. The most important consideration with regard to reoperative status is the number of prior sternotomies, irrespective of the specific type of procedure performed. The revised models replaced prior CABG, prior valve, and prior "other" cardiac surgery with simply the number of previous cardiovascular surgeries.

ACUITY STATUS. The new models combine resuscitation with salvage status. By definition, all salvage patients should have resuscitation coded "yes."

NUMBER OF DISEASED CORONARY VESSELS. Outcomes are modeled using the number of diseased vessels (grouped as 0 or 1 versus 2 versus 3), as a linear effect across the three categories. This approach is consistent with the previous STS CABG models and was supported by the data.

NYHA CLASS. Version 2.61 uses NYHA class as a subfield of CHF. The grouping of NYHA IV versus less than IV (I–III) classes is consistent with all existing STS models. The final categories were no CHF, CHF not NYHA IV, and CHF plus NYHA IV.

AGE. Age was modeled as a linear spline with knots at ages 50 and 60 years.

EJECTION FRACTION. Ejection fraction (EF) was modeled linearly, and EFs below 10% and above 50% were mapped to these values respectively. Only 0.03% of patients have EFs lower than 10%; such values are considered invalid and are treated like missing data. The coding decision regarding EF values above 50% was based on preliminary analyses in which the data were used to suggest the functional form of continuous variables.

CREATININE. Creatinine was modeled as a linear spline with knots at 1.0 and 1.5. Creatinine levels less than 0.5 or greater than 5.0 were mapped to these values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

MORTALITY AND LENGTH OF STAY. The QMTF changed the previous STS definition of the "short postoperative length of stay (SLOS)" endpoint. The original definition did not specifically exclude early postoperative deaths, and such patients could have been inappropriately included with the remaining SLOS patients who had a particularly short and uncomplicated postoperative course. In the new models, patients who die within 5 days of surgery are included in the analysis but are not counted as a short stay.

Table 3. Final List of Candidate Variables and Coding For STS Risk Models

Candidate Variables	Coding
Continuous variables	
Age <sup>a</sup>	Linear spline with knots at 50 and 60.
Ejection fraction <sup>a</sup>	Linear; values $>$ 50 are mapped to 50. Only 0.03% of patients have ejection fraction $<$ 10, and that is presumed to be a data entry error these values are considered invalid and are treated like missing data. The decision to consolidate values $>$ 50 was based on initial exploratory analyses in which data were used to suggest the functional form of continuous variables.
Body surface area <sup>a</sup>	Quadratic polynomial modeled separately for males and females. Note: body surface areas $< 1.4$ and $> 2.6$ were mapped to these values, respectively. <sup>c</sup>
Creatinine <sup>a</sup>	Linear spline with knots at 1.0 and 1.5. (Only for patients not on dialysis.) Note: Creatinine values < 0.5 and > 5.0 were mapped to these values, respectively. <sup>d</sup>
Time trend <sup>a</sup>	Ordinal categorical variable with separate category for each 6-month harvest interval.
Binary variables	
Dialysis <sup>a</sup>	Yes/no
Preoperative atrial fibrillation <sup>b</sup>	Yes/no
Shock	Yes/no
Female <sup>a</sup>	Yes/no
Hypertension	Yes/no
Immunosuppressive treatment	Yes/no
Percutaneous coronary intervention $\leq$ 6 hours	Yes/no
Preoperative intra-aortic balloon pump or inotropes	Yes/no
Peripheral vascular disease	Yes/no
Unstable angina (no myocardial infarction < 7 days)	Yes/no
Left main disease	Yes/no
Aortic stenosis	Yes/no
Aortic insufficiency	Defined as at least moderate (yes/no)
Mitral insufficiency	Defined as at least moderate (yes/no)
Tricuspid insufficiency	Defined as at least moderate (yes/no)
Categorical variables	· ·
Chronic lung disease	4 groups: (1) none, (2) mild, (3) moderate, (4) severe
CVD/CVA	3 groups: (1) no CVD, (2) CVD no CVA, (3) CVD + CVA
Diabetes mellitus	3 groups: (1) insulin diabetes, (2) noninsulin diabetes, (3) other or no diabetes
Number diseased coronary vessels	3 groups: (1) fewer than 2 diseased vessels, (2) 2 disease vessels, (3) 3 diseased vessels; modeled as linear across the categories.
Myocardial infarction	4 groups: (1) $\leq$ 6 hours, (2) $>$ 6 and $<$ 24 hours, (3) 1 to 21 days, (4) $>$ 21 days or no myocardial infarction.
Race	4 groups: (1) black, (2) Asian, (3) Hispanic, (4) other, including Caucasian
Status	4 groups: (1) elective, (2) urgent, (3) emergent, no resuscitation, (4) salvage or emergent with resuscitation
Previous cardiovascular operations	3 groups: 0 previous, 1 previous, 2 or more previous
CHF and NYHA class	3 groups: no CHF, CHF not NYHA IV, CHF + NYHA IV
Interactions	
Age by reoperation <sup>a</sup>	
Age by emergent status <sup>a</sup>	

<sup>&</sup>lt;sup>a</sup> These variables were forced into each model. <sup>b</sup> Preoperative atrial fibrillation was forced into the model for stroke. <sup>c</sup> These are the approximate 1st and 99th percentiles of the empirical distribution. Values less than 1.4 were mapped to 1.4. Values greater than 2.6 were mapped to 2.6. Estimates in the extreme tails of the body surface area distribution are highly influenced by data from other regions of the body surface area distribution (owing to use of a parametric, quadratic model) and may not be reliable. <sup>d</sup> These are approximately the 1st and 99th percentiles of the empirical distribution. Although we used a flexible spline model, linear splines can have unreliable extreme results in the tails due to the assumption that the effect is linear above the largest knot and below the smallest knot.

Table 4. Discrimination of Models (C-Index)

New STS	models—devel	opment sample	(C-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.810	0.716	0.795	0.756	0.706	0.657	0.724	0.769	0.727
New STS	models—valida	ntion sample (C	-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.812	0.720	0.793	0.754	0.689	0.653	0.725	0.767	0.726
Old STS r	nodels—validat	tion sample (C-	index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.807	0.713	0.750	0.742	0.672	0.645	0.711	0.754	0.713
		outcom a (amy).	CVAt1	DCMI — 1		stion. Most – se	t-lit DI OC	

 $\begin{array}{lll} Comp = composite \ adverse \ outcome \ (any); & CVA = stroke; \\ length \ of \ stay; & Reop = reoperation; & RF = renal \ failure; \\ prolonged \ ventilation. & \end{array}$ 

 $\begin{aligned} DSWI &= \text{deep sternal wound infection;} &\quad Mort &= \text{mortality;} &\quad PLOS &= \text{prolonged} \\ SLOS &= \text{short length of stay;} &\quad STS &= \text{The Society of Thoracic Surgeons;} &\quad Vent &= \end{aligned}$ 

### Final Variable Selection Procedure

### Backward Selection

Using the remaining candidate variables and the coding schemes described previously, a supervised backward selection approach was then performed. Initial variable selection used the Wald  $\chi^2$  statistic with a significance criterion of 0.001. This high level of significance was chosen because of the very large sample size that resulted in quite small p values. An expert panel of cardiothoracic surgeons and biostatisticians then reviewed the selected variables and made several modifications. Measures of model performance (discrimination and calibration) were similar when all variables were retained in the models regardless of statistical significance or expert panel review.

### Forced Variables

Several variables were included in the models regardless of statistical significance. These included all of the continuous variables (age, BSA, date of surgery [in 6-month intervals], creatinine, ejection fraction), plus sex and dialysis. In addition, atrial fibrillation was included a priori in the model for permanent stroke.

The rationale for including surgery date, a nonmodifiable variable of no intrinsic interest, was to adjust for changes in the frequency of adverse outcomes over the 5-year study period. We adjusted for surgery date to reduce potential confounding by time trends when estimating regression coefficients for variables that are of primary interest, such as preoperative clinical characteristics. For example, temporal changes in the frequency of coding for dyslipidemia, if they occur coincidentally with a secular declining trend in mortality rates, may lead to the unwarranted causal inferences unless there is adjustment for surgery date.

Date of surgery was categorized by 6-month intervals (corresponding to STS data harvests) and modeled as a linear trend across the ordinal categories. Surgery date is not included in the final risk algorithm and a patient's predicted risk is not dependent upon it. The intercept

parameter published in the Appendix has been adjusted to incorporate the time trend, and it reflects the baseline risk for a reference period of July to December 2006.

### Interaction Terms

These models focused on main effects, and the final models included only four sets of preselected variable interactions: (1) sex by BSA; (2) sex by BSA squared; (3) age by reoperation; (4) age by emergent status. More extensive investigation for interactions was considered, including nonlinear, machine-learning approaches. However, the incremental value of such approaches remains uncertain [28], and interpretability can also become more problematic with numerous interaction terms.

Although multiple terms were allotted for modeling the main effects of age and reoperation, only a single degree of freedom was allotted for their interaction. The models defined a single variable interaction term for age and reoperation. It was equal to the patient's age minus 50 if the patient was at least 50 years old and had a previous CV surgery; otherwise it was equal to zero. This term represents the difference in the change of the slope of age at age 50 for patients who have had at least one previous CV surgery compared with patients who have not had a previous CV surgery. Similarly, only one degree of freedom was allotted for the interaction between age and status. The interaction represents the difference in the change of the slope of age at age 50 for patients with emergent or salvage status compared with patients with elective or urgent status. Although these interaction terms complicate the interpretation of other model variables, this was considered to be acceptable because the main focus of the analysis was prediction, not effect estimation.

### Results

### Model Performance

Table 4 presents the discrimination of each of the isolated CABG models as well as a comparison with the previous

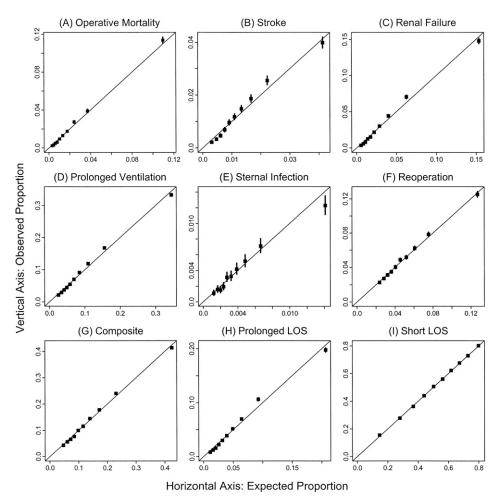


Fig 1. Plots of observed (O) versus expected (E) in validation sample

STS CABG risk models. For the new CABG models, discrimination ranged from 0.657 to 0.810 in the development sample and from 0.653 to 0.812 in the validation sample. The close agreement between c-indices from the development and validation samples reflects the large sample size and suggests that the models did not overfit the data. When the discrimination of the new and previous STS models were compared using the validation sample, the c-index of the new model was larger for each endpoint.

The Hosmer-Lemeshow test is not reported as an overall measure of calibration for these models because of its sensitivity to sample size. With samples as large as those used to develop these models, the null hypothesis will inevitably be proven false, given that all such models are only approximations [29]. As an alternative to such global measures of calibration, Figure 1 shows plots of observed versus expected event proportions within deciles of predicted risk for a variety of endpoints. For each endpoint, the absolute difference between the observed and expected proportions was less than 1.5% in each decile category. Additional analyses of model fit and discrimination are available online at www.sts.org/riskmodels.

### Final Models

After calculating these measures of model performance, the final regression coefficients were estimated from the combined training and validation samples. Odds ratios for each predictor variable and model endpoint are summarized in Table 5. "Not applicable" indicates that the specific predictor was not included in a particular risk model. These final models were estimated using generalized estimating equations with empirical (sandwich) standard error estimates to account for clustering of patients within institutions [30]. An independence working correlation matrix was used to apply the generalized estimating equations method. With this approach, the estimated regression coefficients were identical to those obtained using ordinary logistic regression, but the standard errors were adjusted to account for correlated observations within hospitals.

### Final Model Intercept and Coefficients

The Appendix contains the algorithm, intercept and coefficients for the final STS 2008 CABG risk models. The variance/covariance matrix is available on the web at www.sts.org/riskmodels. An on-line risk calculator is available at http://209.220.160.181/STSWebRiskCalc261/.

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Table 5. Estimated Odds Ratios for CABG Mortality, Morbidity, and Length of Stay Models

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50 (no reoperation, elective)	1.36 (1.24, 1.49)	1.78 (1.58, 1.99)	1.24 (1.16, 1.33)	1.06 (1.02, 1.10)	1.43 (1.23, 1.67)	1.14 (1.09, 1.19)	1.08 (1.05, 1.11)	1.35 (1.27, 1.43)	0.77 (0.75, 0.78)
Age 70 versus 50 (no reoperation, elective)	2.53 (2.31, 2.76)	2.43 (2.19, 2.71)	1.93 (1.81, 2.07)	1.42 (1.37, 1.47)	1.70 (1.47, 1.97)	1.45 (1.39, 1.51)	1.49 (1.44, 1.53)	2.17 (2.05, 2.29)	0.44 (0.43, 0.45)
Age 80 versus 50 (no reoperation, elective)	4.70 (4.29, 5.15)	3.34 (2.99, 3.72)	3.01 (2.80, 3.24)	1.90 (1.82, 1.99)	2.02 (1.73, 2.36)	1.85 (1.76, 1.94)	2.05 (1.98, 2.12)	3.48 (3.28, 3.69)	0.25 (0.24, 0.26)
BSA 1.6 versus 2.0 among females	1.26 (1.19, 1.32)	1.15 (1.08, 1.23)	0.84 (0.80, 0.89)	1.03 (1.00, 1.06)	0.49 (0.43, 0.57)	1.23 (1.18, 1.28)	1.03 (1.01, 1.06)	0.94 (0.90, 0.97)	1.17 (1.14, 1.20)
BSA 1.6 versus 2.0 among males	1.75 (1.64, 1.86)	1.19 (1.08, 1.31)	1.24 (1.17, 1.32)	1.40 (1.34, 1.46)	0.77 (0.63, 0.93)	1.40 (1.33, 1.46)	1.35 (1.30, 1.40)	1.43 (1.36, 1.50)	0.79 (0.77, 0.82)
BSA 1.8 versus 2.0 among females	1.02 (0.99, 1.05)	1.07 (1.03, 1.11)	0.86 (0.84, 0.88)	0.95 (0.94, 0.97)	0.67 (0.63, 0.71)	1.06 (1.04, 1.08)	0.96 (0.94, 0.97)	0.90 (0.88, 0.92)	1.14 (1.13, 1.16)
BSA 1.8 versus 2.0 among males	1.20 (1.17, 1.23)	1.09 (1.05, 1.13)	1.02 (1.00, 1.04)	1.09 (1.07, 1.10)	0.85 (0.79, 0.91)	1.13 (1.11, 1.15)	1.08 (1.07, 1.09)	1.10 (1.08, 1.12)	0.96 (0.95, 0.97)
BSA 2.2 versus 2.0 among females	1.20 (1.14, 1.27)	0.95 (0.88, 1.02)	1.32 (1.27, 1.37)	1.18 (1.15, 1.22)	1.62 (1.51, 1.74)	1.03 (1.00, 1.07)	1.19 (1.16, 1.21)	1.28 (1.24, 1.32)	0.78 (0.77, 0.80)
BSA 2.2 versus 2.0 among males	1.01 (0.99, 1.03)	0.92 (0.90, 0.95)	1.17 (1.15, 1.19)	1.10 (1.08, 1.11)	1.27 (1.22, 1.32)	0.97 (0.96, 0.99)	1.07 (1.06, 1.08)	1.08 (1.07, 1.10)	0.90 (0.89, 0.91)
Creatinine 1.5 versus 1.0	1.66 (1.57, 1.76)	1.39 (1.30, 1.49)	3.36 (3.16, 3.58)	1.56 (1.51, 1.62)	1.44 (1.28, 1.62)	1.33 (1.28, 1.38)	1.76 (1.70, 1.82)	1.65 (1.59, 1.72)	0.69 (0.67, 0.71)
Creatinine 2.0 versus 1.0	1.94 (1.84, 2.04)	1.49 (1.39, 1.58)	4.06 (3.83, 4.31)	1.73 (1.68, 1.79)	1.47 (1.30, 1.65)	1.44 (1.40, 1.49)	2.05 (1.98, 2.11)	1.92 (1.86, 2.00)	0.55 (0.53, 0.57)
Creatinine 2.5 versus 1.0	2.26 (2.14, 2.39)	1.59 (1.47, 1.71)	4.90 (4.61, 5.21)	1.92 (1.85, 1.99)	1.50 (1.30, 1.72)	1.57 (1.51, 1.64)	2.39 (2.30, 2.48)	2.24 (2.15, 2.34)	0.44 (0.42, 0.46)
Dialysis versus no dialysis and creatinine = 1.0	3.84 (3.54, 4.16)	1.67 (1.48, 1.88)	NA	2.85 (2.68, 3.03)	2.13 (1.78, 2.56)	1.86 (1.73, 2.00)	2.46 (2.33, 2.60)	2.80 (2.63, 2.98)	0.27 (0.25, 0.29)
EF per 10-unit decrease	1.19 (1.17, 1.22)	1.14 (1.11, 1.16)	1.08 (1.06, 1.10)	1.18 (1.16, 1.20)	1.11 (1.07, 1.16)	1.11 (1.09, 1.13)	1.16 (1.15, 1.18)	1.17 (1.15, 1.19)	0.84 (0.83, 0.85)
Preoperative atrial fibrillation	1.36 (1.28, 1.44)	1.21 (1.12, 1.30)	1.24 (1.18, 1.30)	1.20 (1.16, 1.24)	NA	1.26 (1.21, 1.31)	1.24 (1.21, 1.28)	1.42 (1.37, 1.48)	0.61 (0.59, 0.63)
CHF not NYHA IV	1.21 (1.15, 1.28)	NA	1.36 (1.30, 1.43)	1.31 (1.26, 1.35)	1.33 (1.19, 1.48)	1.16 (1.11, 1.21)	1.27 (1.23, 1.31)	1.43 (1.38, 1.48)	0.72 (0.70, 0.75)
CHF NYHA IV	1.39 (1.31, 1.47)	NA	1.35 (1.28, 1.42)	1.52 (1.45, 1.59)	1.45 (1.25, 1.67)	1.26 (1.20, 1.32)	1.48 (1.42, 1.54)	1.50 (1.44, 1.57)	0.65 (0.61, 0.68)
Chronic lung disease, mild	1.22 (1.16, 1.29)	NA	1.14 (1.08, 1.21)	1.36 (1.31, 1.41)	1.56 (1.40, 1.73)	1.11 (1.07, 1.15)	1.23 (1.19, 1.27)	1.34 (1.29, 1.39)	0.79 (0.76, 0.82)
Chronic lung disease, moderate	1.40 (1.32, 1.49)	NA	1.25 (1.18, 1.33)	1.65 (1.57, 1.73)	1.80 (1.58, 2.06)	1.20 (1.14, 1.26)	1.42 (1.36, 1.47)	1.65 (1.58, 1.73)	0.68 (0.65, 0.71)
Chronic lung disease, severe	2.35 (2.19, 2.52)	NA	1.66 (1.54, 1.79)	2.37 (2.24, 2.51)	2.40 (2.06, 2.79)	1.54 (1.44, 1.64)	1.98 (1.90, 2.07)	2.46 (2.34, 2.60)	0.48 (0.45, 0.51)
CVD with CVA	1.31 (1.24, 1.38)	2.09 (1.96, 2.22)	1.18 (1.12, 1.23)	1.35 (1.31, 1.39)	NA	1.21 (1.17, 1.26)	1.32 (1.29, 1.36)	1.45 (1.40, 1.51)	0.70 (0.68, 0.72)

Table 5. Continued

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
CVD without CVA	1.14 (1.08, 1.20)	1.65 (1.54, 1.75)	1.11 (1.06, 1.17)	1.15 (1.11, 1.18)	NA	1.12 (1.08, 1.17)	1.17 (1.14, 1.20)	1.14 (1.10, 1.18)	0.85 (0.81, 0.89)
Diabetes, insulin dependent	1.30 (1.24, 1.37)	1.19 (1.12, 1.27)	1.80 (1.72, 1.87)	1.22 (1.18, 1.26)	2.24 (2.02, 2.48)	1.14 (1.10, 1.18)	1.30 (1.27, 1.34)	1.59 (1.53, 1.64)	0.64 (0.62, 0.66)
Diabetes, noninsulin dependent	1.01 (0.97, 1.06)	1.16 (1.11, 1.22)	1.32 (1.28, 1.36)	1.04 (1.02, 1.07)	1.38 (1.27, 1.49)	0.98 (0.96, 1.01)	1.08 (1.06, 1.10)	1.15 (1.12, 1.17)	0.87 (0.86, 0.88)
Diseased vessels (2 versus 1, or 3 versus 2)	1.17 (1.12, 1.23)	1.35 (1.29, 1.42)	1.23 (1.19, 1.27)	1.19 (1.16, 1.22)	1.15 (1.07, 1.24)	1.07 (1.05, 1.10)	1.16 (1.14, 1.18)	1.15 (1.11, 1.18)	0.81 (0.80, 0.82)
Preoperative IABP/ inotropes	1.41 (1.33, 1.49)	NA	1.43 (1.36, 1.51)	2.56 (2.42, 2.72)	NA	1.37 (1.31, 1.43)	1.96 (1.86, 2.06)	1.60 (1.53, 1.67)	0.60 (0.57, 0.63)
Shock	2.29 (2.12, 2.47)	1.38 (1.23, 1.55)	1.65 (1.54, 1.77)	2.08 (1.96, 2.21)	NA	1.43 (1.34, 1.52)	2.10 (1.99, 2.23)	1.73 (1.62, 1.84)	0.58 (0.54, 0.62)
Female versus male (at BSA = 1.8)	1.31 (1.25, 1.36)	1.32 (1.24, 1.39)	1.25 (1.21, 1.31)	1.33 (1.29, 1.36)	1.19 (1.06, 1.35)	0.90 (0.87, 0.93)	1.18 (1.15, 1.21)	1.24 (1.20, 1.28)	0.65 (0.63, 0.66)
Hypertension	NA	1.29 (1.22, 1.37)	1.25 (1.20, 1.30)	1.10 (1.08, 1.13)	NA	NA	1.12 (1.10, 1.15)	1.07 (1.04, 1.11)	0.92 (0.90, 0.94)
Immunosuppressive treatment	1.48 (1.37, 1.60)	NA	1.21 (1.12, 1.31)	1.11 (1.05, 1.18)	NA	1.32 (1.24, 1.41)	1.20 (1.14, 1.26)	1.28 (1.20, 1.37)	0.80 (0.76, 0.84)
Aortic insufficiency, moderate/severe	NA	0.82 (0.75, 0.89)							
Mitral insufficiency, moderate/severe	1.31 (1.21, 1.41)	NA	NA	1.12 (1.06, 1.18)	NA	1.24 (1.16, 1.32)	1.20 (1.15, 1.26)	1.15 (1.09, 1.22)	0.85 (0.80, 0.91)
Tricuspid insufficiency, moderate/severe	NA	NA	1.31 (1.17, 1.45)	1.28 (1.18, 1.39)	NA	NA	1.24 (1.16, 1.33)	NA	0.78 (0.71, 0.87)
$PCI \le 6 \text{ hours}$	1.37 (1.24, 1.50)	NA	1.29 (1.16, 1.43)	1.21 (1.13, 1.29)	NA	1.30 (1.19, 1.42)	1.31 (1.23, 1.39)	1.17 (1.07, 1.27)	0.79 (0.74, 0.84)
Peripheral vascular disease	1.42 (1.36, 1.48)	1.32 (1.26, 1.39)	1.21 (1.17, 1.26)	1.22 (1.19, 1.26)	1.36 (1.24, 1.48)	1.24 (1.20, 1.28)	1.25 (1.22, 1.28)	1.31 (1.28, 1.35)	0.82 (0.81, 0.84)
Aortic stenosis	NA	NA	NA	1.18 (1.11, 1.26)	NA	NA	1.16 (1.10, 1.22)	1.15 (1.07, 1.23)	0.87 (0.82, 0.92)
Left main disease	NA	NA	NA	1.07 (1.04, 1.09)	NA	NA	1.04 (1.02, 1.06)	NA	NA
MI 1–21 days	1.37 (1.32, 1.44)	1.31 (1.25, 1.37)	1.27 (1.22, 1.32)	1.34 (1.29, 1.38)	NA	NA	1.23 (1.20, 1.25)	1.22 (1.18, 1.25)	0.88 (0.86, 0.90)
MI > 6 and < 24 hours	1.59 (1.46, 1.74)	1.59 (1.43, 1.76)	1.48 (1.36, 1.60)	1.59 (1.49, 1.68)	NA	NA	1.43 (1.37, 1.50)	1.31 (1.24, 1.39)	0.80 (0.76, 0.84)
$MI \leq 6 \text{ hours}$	1.70 (1.53, 1.89)	1.49 (1.31, 1.68)	1.43 (1.29, 1.57)	1.56 (1.45, 1.67)	NA	NA	1.44 (1.35, 1.53)	1.30 (1.21, 1.40)	0.82 (0.77, 0.87)
Time trend, per 6- month harvest interval	0.97 (0.97, 0.98)	0.97 (0.96, 0.98)	1.01 (1.00, 1.02)	1.01 (1.01, 1.02)	0.97 (0.95, 0.99)	0.99 (0.99, 1.00)	1.00 (1.00, 1.01)	1.00 (0.99, 1.01)	0.99 (0.98, 1.00)
Race Asian	NA	1.33 (1.14, 1.55)	1.08 (0.96, 1.22)	1.33 (1.21, 1.47)	1.00 (0.66, 1.51)	1.31 (1.17, 1.46)	1.23 (1.15, 1.31)	1.26 (1.13, 1.40)	0.70 (0.61, 0.81)
Race black	NA	1.41 (1.30, 1.54)	1.24 (1.16, 1.33)	1.37 (1.27, 1.48)	1.30 (1.13, 1.51)	1.21 (1.14, 1.30)	1.31 (1.24, 1.38)	1.43 (1.34, 1.51)	0.69 (0.65, 0.73)
Race Hispanic	NA	1.12 (0.98, 1.27)	1.24 (1.11, 1.39)	1.16 (1.07, 1.26)	1.30 (1.07, 1.58)	1.05 (0.97, 1.13)	1.12 (1.05, 1.19)	1.09 (0.99, 1.20)	0.85 (0.77, 0.94)

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SCIS
Reoperation, 1 previous operation <sup>a</sup>	3.13 (2.74, 3.57)	NA	1.52 (1.35, 1.71)	.52 (1.35, 1.71) 1.72 (1.58, 1.86)	NA	1.57 (1.43, 1.74)	1.57 (1.43, 1.74) 1.61 (1.50, 1.72) 1.62 (1.47, 1.80) 0.72 (0.67, 0.78)	1.62 (1.47, 1.80)	0.72 (0.67, 0.78)
Reoperation, $\geq 2$ previous operations <sup>a</sup>	4.19 (3.45, 5.09)	NA	1.58 (1.33, 1.87)	.58 (1.33, 1.87) 1.86 (1.62, 2.14)	NA	1.71 (1.44, 2.03)	1.71 (1.44, 2.03) 1.84 (1.65, 2.05)	1.79 (1.53, 2.08)	0.64 (0.56, 0.73)
Status urgent <sup>a</sup>	1.16 (1.10, 1.22)	1.11 (1.06, 1.17)	1.12 (1.05, 1.19)	1.24 (1.18, 1.31)	1.20 (1.10, 1.32)	1.18 (1.13, 1.23)	1.18 (1.14, 1.22)	1.20 (1.15, 1.25)	0.86 (0.83, 0.90)
Status emergent, no resuscitation <sup>a</sup>	2.83 (2.52, 3.18)	2.12 (1.82, 2.48)	1.68 (1.49, 1.89)	2.14 (1.96, 2.34)	1.87 (1.46, 2.40)	1.83 (1.68, 1.99)	1.77 (1.64, 1.91)	2.12 (1.93, 2.32)	0.62 (0.58, 0.67)
Status emergent with resuscitation or salvage <sup>a</sup>	8.00 (6.91, 9.26)	8.00 (6.91, 9.26) 2.51 (1.98, 3.18)	2.16 (1.82, 2.55)	3.01 (2.68, 3.38)	2.09 (1.45, 3.01)	2.34 (2.06, 2.65) 3.65 (3.26, 4.09)	3.65 (3.26, 4.09)	2.39 (2.10, 2.72) 0.34 (0.30, 0.38)	0.34 (0.30, 0.38)
Unstable angina	1.12 (1.07, 1.17)	NA	1.11 (1.05, 1.17)	.11 (1.05, 1.17) 1.05 (1.01, 1.10)	NA	NA	NA	NA	NA

<sup>a</sup> Variable interacts with age. Reported odds ratio represents effect of risk factor for patients aged 50 years old.

CVD = cerebrovascular disease; = renal failure; NA = not applicable; = cerebrovascular accident, or stroke; Mort = mortality; = peripheral vascular disease; Comp = composite adverse outcome (any); .BP = intra-aortic balloon pump; MI = r = intra-aortic balloon pump; N PLOS = prolonged length of stay; BSA = body surface area; CH = deep sternal wound infection; Heart Association; short length of stay; Previously, the STS risk models were completely upgraded every 3 years, with annual recalibration in the interim to assure that the benchmark O/E ratio is always 1. In the near future, annual upgrades of the models are planned.

### Limitations

Regardless of sample size or degree of statistical sophistication, all risk models are imperfect representations of reality. Although the STS risk models are based upon excellent clinical data and large sample sizes, there are some risk factors that are rare in the overall population but, when present, may be important predictors of outcome for specific patients. Some such variables, such as liver disease, are not included in the risk models, and the mortality risk for patients with these risk factors may be underestimated. Addition of a number of such variables will be considered at the next major specification upgrade.

There are other variables whose specifications undergo small but important changes over time, often in response to comments from STS database participants. These refinements are discussed on regular biweekly conference calls open to database participants, and suggested changes are regularly communicated to participants through a variety of means including FAQ's. With each major specification upgrade, they are incorporated into the new software specifications.

Audit is extremely important to assure the accuracy of any data registry. For the STS database and the risk models derived from it, robust audit is particularly critical as this registry is increasingly used for public reporting of outcomes and pay for performance. Studies suggest that the accuracy of the STS database is high for most important variables [31-35], although these audits are currently restricted to a limited number of sites annually because of budgetary constraints. In these audits, one of the most problematic variables has been 30-day mortality status (as opposed to in-hospital mortality). This is often a difficult endpoint to ascertain and may require more substantial investment of time and effort by participants, particularly for patients referred from outside their own institutions. Analysis of STS data suggests that approximately 90% of 30-day deaths occur in-hospital. Thus, if some patients recorded as being alive at 30 days have actually had their status ascertained only during the index hospitalization, the impact of this misclassification on the risk models should be negligible. This hypothesis was confirmed by comparing the odds ratios of all model variables for in-hospital versus 30-day mortality. Differences between the two were quite small, and these data are available on the web at www. sts.org/riskmodels. A new risk model for in-hospital mortality has been developed and placed on the same STS website. Furthermore, an aggressive program is in place to further enhance the accuracy of 30-day follow-up. In 2009, STS instituted a requirement that participants maintain documentation of the method by which they ascertained 30-day status, and that has become part of our routine audit. Linkage of the STS database with external death registries, such as the Social Security Death Master File, will

further support this capability. Finally, plans are being developed to expand the audit of certain key variables such as 30-day mortality to a significantly greater number of sites annually.

### **Conclusions**

Risk-adjustment models account for the effect of patient comorbidities on outcomes. STS risk models are based upon clinical data from the STS NCD, one of the oldest and largest of all specialty registries. The value of such clinical registries is particularly evident in today's health care environment, where accreditation, regulatory compliance, reimbursement, and referrals are increasingly based upon objective data. Organizations such as the AQA and the National Quality Forum that evaluate and endorse performance measures strongly advocate the use of risk-adjusted outcomes measures.

STS believes that clinical data are superior to those derived from administrative sources. Furthermore, given the substantial implications of risk-adjusted outcomes, we believe that all risk models used for profiling quality of care should be transparent to permit comprehensive peer review and to foster credibility among stakeholders.

We present a detailed exposition of the development and validation of the 2008 STS CABG risk model. This describes not only the statistical considerations but, just as importantly, the many clinical and pragmatic judgments that are always necessary in risk model development.

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### **Appendix**

Regression Coefficients and Variable Definitions for STS 2008 CABG Models

For each endpoint, the formula for calculating a patient's predicted risk of the endpoint has the form:

Predicted Risk = 
$$\frac{e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}{1+e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}$$

where  $x_1, x_2, \ldots, x_n$  denote patient preoperative risk factors (eg, quantitative variables such as age, and comorbidities coded as 1 = present, 0 = absent), and  $\beta_0, \beta_1, \ldots, \beta_n$  denote regression coefficients (numerical constants). Regression coefficients for each endpoint are presented in Appendix Table 1. The variables  $x_1, x_2, \ldots, x_n$  are the same for each endpoint and are defined in Appendix Table 2. The regression coefficient for the time trend is not presented. Instead, the intercept has been adjusted to incorporate the time trend. This adjusted intercept reflects the baseline risk for a reference period of July to December 2006.

Appendix Table 1. Regression Coefficients

-47	33								
Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Intercept	-6.34090	-7.18174	-7.94605	-4.15175	-6.75378	-3.84861	-3.71671	-5.35975	2.84959
Atrial fibrillation	0.30830	0.18935	0.21351	0.17871	0.00000	0.23031	0.21565	0.35322	-0.49309
Age	-0.00259	0.00996	0.00678	0.00170	-0.00665	-0.00013	0.00247	0.00914	-0.01781
Age function 1	0.03325	0.04742	0.01496	0.00393	0.04270	0.01305	0.00515	0.02085	-0.00895
Age function 2	0.03140	-0.02582	0.02249	0.02366	-0.01895	0.01133	0.02441	0.01734	-0.02904
Age by reoperation function	-0.01714	-0.00098	-0.00291	-0.00459	0.00304	-0.00720	-0.00444	-0.00809	0.00449
Age by status function	-0.01366	-0.01363	-0.00022	-0.00106	-0.00352	-0.00435	0.00270	-0.00833	-0.00266
BSA function 1	-1.39342	-0.44041	-0.53672	-0.83950	0.65513	-0.83758	-0.75006	-0.89037	0.57952
BSA function 2	2.41303	0.06122	2.19879	2.15647	0.90025	1.16543	1.81770	2.15270	-1.83776
CHF but not NYHA IV	0.19229	0.00000	0.30971	0.26853	0.28272	0.14692	0.23695	0.35623	-0.32350
CHF and NYHA IV	0.32663	0.00000	0.30013	0.41599	0.36909	0.22846	0.39005	0.40757	-0.43827
Chronic lung disease mild	0.20273	0.00000	0.13488	0.30473	0.44371	0.10432	0.20878	0.29051	-0.23600
Chronic lung disease moderate	0.33843	0.00000	0.22530	0.50235	0.59021	0.18071	0.34720	0.50246	-0.39085
Chronic lung disease severe	0.85513	0.00000	0.50645	0.86175	0.87366	0.43034	0.68538	0.90211	-0.73862
Creatinine function 1	0.19353	0.02822	1.91934	-0.02712	-0.37465	0.01583	0.13361	-0.09060	0.00773
Creatinine function 2	0.82140	0.63174	0.50685	0.92120	1.09976	0.55107	0.99190	1.09571	-0.75781
Creatinine function 3	-0.70646	-0.52856	-2.04970	-0.68907	-0.68466	-0.39956	-0.81791	-0.70069	0.30449
CVD without prior CVA	0.13177	0.49807	0.10637	0.13792	0.00000	0.11403	0.15561	0.13271	-0.16385
CVD and prior CVA	0.26877	0.73600	0.16135	0.29946	0.00000	0.19208	0.28099	0.37248	-0.35706
Diabetes noninsulin dependent	0.01375	0.14992	0.27443	0.04283	0.31888	-0.01929	0.07453	0.13541	-0.13813
Diabetes insulin dependent	0.26312	0.14332	0.58581	0.19735	0.80627	0.12930	0.26525	0.46226	-0.44725
Dialysis	1.53777	0.54158	0.00000	1.01943	0.38312	0.63691	1.03466	0.93792	-1.30294
Ejection fraction function	0.01765	0.01274	0.00754	0.01669	0.01081	0.03091	0.01496	0.93792	-0.01756
Female	0.26801	0.01274	0.00754	0.28338	0.01081	-0.10270	0.01436	0.01342	-0.01750 $-0.43658$
Female by BSA function 1	0.82285	0.08974	0.96428	0.76954	1.11546	0.31901	0.66663	1.05623	-0.96846
Female by BSA function 2	0.05606	0.06490	-0.61086	-0.62558	0.17399	-0.02390	-0.25077	-0.35160	0.46088
Hypertension	0.00000	0.25718	0.22126	0.09930	0.00000	0.00000	0.11674	0.07200	-0.08155
IABP or inotropes	0.34193	0.00000	0.36023	0.94050	0.00000	0.31326	0.67253	0.47092	-0.51444
Immunosuppressive treatment	0.39159	0.00000	0.18881	0.10686	0.00000	0.27802	0.18030	0.24833	-0.22718
Insufficiency, aortic	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.19889
Insufficiency, mitral	0.26631	0.00000	0.00000	0.11169	0.00000	0.21170	0.18225	0.14174	-0.15962
Insufficiency, tricuspid	0.00000	0.00000	0.26729	0.24834	0.00000	0.00000	0.21893	0.00000	-0.24548
Left main disease	0.00000	0.00000	0.00000	0.06629	0.00000	0.00000	0.03570	0.00000	0.00000
MI 1 to 21 days	0.31810	0.27134	0.23962	0.28925	0.00000	0.00000	0.20524	0.19517	-0.12752
MI > 6 and < 24 hours	0.46614	0.46063	0.38917	0.46158	0.00000	0.00000	0.35859	0.27109	-0.22557
$MI \le 6 \text{ hours}$	0.53242	0.39601	0.35421	0.44230	0.00000	0.00000	0.36337	0.26311	-0.19946
No. diseased vessel function	0.16120	0.30339	0.20729	0.17622	0.13869	0.06895	0.15075	0.13589	-0.21043
PCI ≤ 6 hours	0.31149	0.00000	0.25189	0.18695	0.00000	0.26256	0.26774	0.15633	-0.23860
Peripheral vascular disease	0.34951	0.27985	0.19308	0.20240	0.30529	0.21306	0.22277	0.27380	-0.19321
Race black	0.00000	0.34423	0.21696	0.31563	0.26572	0.19456	0.26634	0.35426	-0.37515
Race Hispanic	0.00000	0.11002	0.21645	0.14802	0.26330	0.04798	0.11289	0.08968	-0.16091
Race Asian	0.00000	0.28567	0.07579	0.28561	-0.00145	0.26855	0.20484	0.23064	-0.35049
Reop, 1 previous operation	1.13997	0.00000	0.41962	0.53987	0.00000	0.45372	0.47614	0.48534	-0.32375
Reop, $\geq$ 2 previous operations	1.43250	0.00000	0.45592	0.62211	0.00000	0.53695	0.61014	0.57945	-0.44745
Shock	0.82667	0.32434	0.50003	0.73290	0.00000	0.35800	0.74320	0.54575	-0.54475
Status urgent	0.14608	0.10671	0.11226	0.21738	0.18496	0.16500	0.16492	0.18202	-0.14608
Status emergent	1.04010	0.75216	0.51857	0.76090	0.62665	0.60549	0.56983	0.75083	-0.47745
Status salvage	2.07934	0.91950	0.76808	1.10085	0.73651	0.84873	1.29422	0.87072	-1.08265
Stenosis aortic	0.00000	0.00000	0.00000	0.16529	0.00000	0.00000	0.14706	0.13988	-0.14173
Unstable angina	0.11217	0.00000	0.10287	0.05060	0.00000	0.00000	0.00000	0.00000	0.00000

 $BSA = body \ surface \ area; \ CHF = congestive \ heart \ failure; \ Comp = composite \ adverse \ event \ (any); \ CVA = cerebrovascular \ accident \ (stroke); \ CVD = cerebrovascular \ disease; \ DSWI = deep \ sternal \ wound \ infection; \ IABP = intra-aortic \ balloon \ pump; \ MI = myocardial \ infarction; \ Mort = mortality; \ NYHA = New \ York \ Heart \ Association; \ PCI = percutaneous \ coronary \ intervention; \ PLOS = prolonged \ length \ of \ stay; \ Reop = reoperation; \ RF = renal \ failure; \ SLOS = short \ length \ of \ stay; \ Vent = prolonged \ ventilation.$ 

### Appendix Table 2. Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	$= \max(age-50, 0)$
Age function 2	$= \max(age-60, 0)$
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	$= (BSA \text{ function } 1)^2$
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
<del>-</del>	
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral Insufficiency, tricuspid	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
, I	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI > 6 and <24 hours prior to surgery, = 0 otherwise
$MI \le 6 \text{ hours}$	= 1 if history of MI $\leq$ 6 hours prior to surgery, = 0 otherwise
No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
$PCI \leq 6 \text{ hours}$	= 1 if patient had $PCI \le 6$ hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, ≥ 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwis

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

# **2a.14. Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method)

The risk adjusted model is a hierarchical logistic regression model with participant level intercept. logit(outcome)  $\sim X\beta + (\gamma | participant)$ 

where X is the patient's risk factors,  $\theta$  is the regression coefficients of patient-level risk factors and  $\gamma$  is the participant level regression coefficient.

### **Inclusion Criteria**

The patient level risk adjusted model was developed using a population of patients undergoing isolated CABG procedure in the time period January 2002 – December 2006. For this measurement we re-fit the patient-level model using the latest two and a half years of data (January 2008 – June 2010) from the STS Adult Cardiac Surgery Database.

### Variable Definitions and Selection

All variables for consideration are listed in the table below.

### Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition			
Intercept	= 1 for all patients			
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise			
Age	= Patient age in years			
Age function 1	= max (age–50, 0)			
Age function 2	= max (age-60, 0)			
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise			
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise			
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8			
BSA function 2	= (BSA function 1) <sup>2</sup>			
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise			
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise			
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise			
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise			
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise			
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise			
Creatinine function 2	$= \max ([\text{creatinine}, \text{sloj}, \text{in patients in the six diarysis}) = \max ([\text{creatinine}, \text{function 1}] - 1.0, 0)$			
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)			
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise			
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise			
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise			
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise			
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise			
Ejection fraction function	= max (50 – ejection fraction, 0)			
Female	= 1 if patient is female, = 0 otherwise			
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise			
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise			
Hypertension	= 1 if patient has hypertension, = 0 otherwise			
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise			
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise			
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise			
Insufficiency, mitral	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise			
Insufficiency, tricuspid	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise			
Left main disease	= 1 if patient has left main disease, = 0 otherwise			
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise			
MI > 6 and < 24 hours	= 1 if history of MI >6 and <24 hours prior to surgery, = 0 otherwise			
MI ≤ 6 hours = 1 if history of MI ≤ 6 hours prior to surgery, = 0 otherwise				

No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise		
PCI ≤ 6 hours	= 1 if patient had PCI ≤ 6 hours prior to surgery, = 0 otherwise		
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise		
Race black	= 1 if patient is black, = 0 otherwise		
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise		
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise		
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise		
Reop, 2 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise		
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise		
Status urgent	= 1 if status is urgent, = 0 otherwise		
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise		
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise		
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise		
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwise		
•			

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

The final patient-level model was built by backward selection method with several variables forced into the model. For the final patient-level model, please see the attachment.

# **1b.2.** Summary of Measure Results Demonstrating Performance Gap (Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.)

The summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. A high OR is undesirable and we define the percentiles with decreasing OR. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile" below.

Measurement	Postoperative Renal Insufficiency
N	608
Mean	1.1
1 <sup>st</sup>	3.0
5 <sup>th</sup>	2.2
10 <sup>th</sup>	1.8
25 <sup>th</sup>	1.3
Median	1.0
75 <sup>th</sup>	0.7
90 <sup>th</sup>	0.6
95 <sup>th</sup>	0.5
99 <sup>th</sup>	0.4
Outlier	100 (16.4)
High	27
Low	73

Also provided is the distribution of the risk adjusted event rate (see below). The risk adjusted rate is an estimate of the participant's event rate if, hypothetically, the case-mix of the patients treated by the participants is the same as the overall STS case-mix. It is calculated by the OR of the participant, other patient level parameter estimates from the hierarchical logistic model, and the overall STS event rate, by:

STS event rate \* (Participant's Expected Event Rate) / (Participant's Expected Event Rate Assuming Its Performance = STS Average Performance)

In the above equation, "Participant's Expected Event Rate" is calculated with the participant's actual OR, and "Participant's Expected Event Rate Assuming Its Performance = STS Average Performance" is calculated by assuming the participant's OR = 1 (i.e. no difference in performance from the STS average).

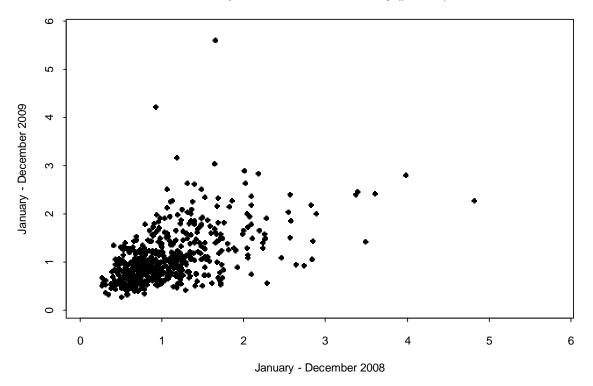
Measurement	Postoperative Renal Insufficiency
N	608
Mean	3.6
1 <sup>st</sup>	1.4
5 <sup>th</sup>	1.7

Measurement	Postoperative Renal Insufficiency
10 <sup>th</sup>	2.0
25 <sup>th</sup>	2.5
Median	3.3
75 <sup>th</sup>	4.4
90 <sup>th</sup>	5.7
95 <sup>th</sup>	6.7
99 <sup>th</sup>	9.2
Outlier	100 (16.4)
High	27
Low	73

**2b.3. Testing Results** (Reliability statistics, assessment of adequacy in the context of norms for the test conducted)

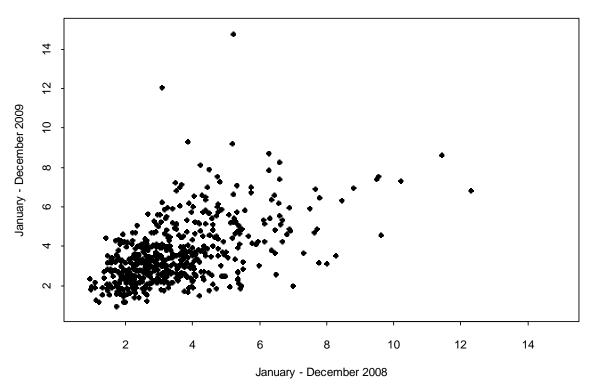
Testing results:  $\rho = 0.51$ 





Risk Adjusted Rate:

### Postoperative Renal Insufficiency ( $\rho$ =0.51)

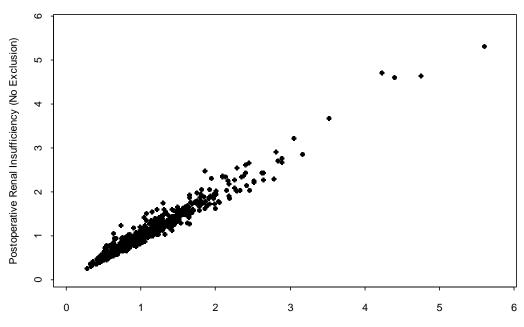


### **2d.5. Testing Results** (E.g., frequency, variability, sensitivity analyses)

Postoperative Renal Insufficiency		
# of Patients	144060	
# excluded	6100	
% excluded	0.04	

### **Odds Ratios:**

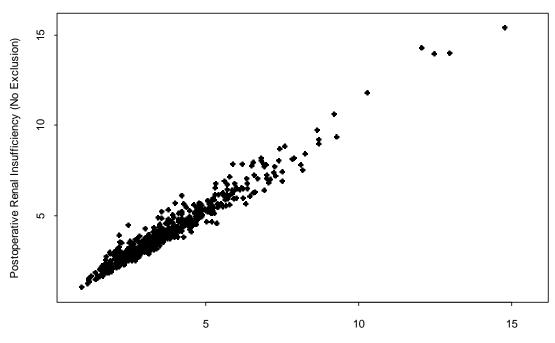
### Postoperative Renal Insufficiency (ρ=0.97)



Postoperative Renal Insufficiency (Exclusion = Pre-operative Renal Failure)

### Risk adjusted rate:

### Postoperative Renal Insufficiency (ρ=0.97)



Postoperative Renal Insufficiency (Exclusion = Pre-operative Renal Failure)

# **2f.3. Measure Scores from Testing or Current Use** (Description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)

Results below are from January 1, 2009-December 31, 2009. The sample contains 608 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months.

Measurement	Postoperative Renal Insufficiency
N	608
Mean	1.1
1 <sup>st</sup>	3.0
5 <sup>th</sup>	2.2
10 <sup>th</sup>	1.8
25 <sup>th</sup>	1.3
Median	1.0
75 <sup>th</sup>	0.7
90 <sup>th</sup>	0.6
95 <sup>th</sup>	0.5
99 <sup>th</sup>	0.4
Outlier†	100 (16.4)
High	27
Low	73

### Risk Adjusted Rate:

Measurement	Postoperative Renal Insufficiency			
N	608			
Mean	3.6			
1 <sup>st</sup>	1.4			
5 <sup>th</sup>	1.7			
10 <sup>th</sup>	2.0			
25 <sup>th</sup>	2.5			
Median	3.3			
75 <sup>th</sup>	4.4			
90 <sup>th</sup>	5.7			
95 <sup>th</sup>	6.7			
99 <sup>th</sup>	9.2			
Outlier†	100 (16.4)			
High	27			
Low	73			

†Represents the number of participants that are outliers according to two-sided 95% confidence interval of odds ratio.

### **3a.6. Results** (Qualitative or quantitative results and conclusions)

Although formal testing of interpretability has not been performed, this measure has been used and reported for STS Adult Cardiac Surgery database participants since 2007. Current report presentation and interpretation manuals are presented below. These materials are updated as needed based upon feedback from database participants.

### 1) Report Overview and Interpretation Manual:

### **The NQF Measures Report**

### a. Organization

This report section is separated into three areas corresponding to: 1) NQF volume measures, 2) NQF process measures, and 3) NQF outcomes measures, in that order. The header at the top of each page references the report section for that page. Each NQF measure is presented on a single row in the section. Tabular data are on the left-hand side of each page and a standard graphic representation is shown on the right-hand side.

### b. Statistical Calculation and Details – NQF Measures

**Time period:** This report section contains information on the individual STS participant and overall STS performance for the <u>most recent 12 months for volume</u>, <u>process and CABG outcomes measures and the most recent 60 months for Valve and Valve + CABG outcomes</u>. The 5 years (60 months) of <u>performance for outcomes involving Valve procedures is necessary due to smaller sample sizes</u>.

**Volume Measures:** The NQF report provides average annual case volumes data for three surgery categories: i) Isolated CABG, ii) Valve without CABG, and iii) combined CABG + Valve. Definitions of the three surgery categories are provided in Table 2 of this NQF Report Overview. For each type of surgery, the <u>participant's annualized volume</u> is calculated as:

Participant Annualized Volume = 12 x (# of surgeries) / (# of months)

where (# of surgeries) denotes the number of surgeries of the specified type performed by the participant during the specified time period, and (# of months) is the number of months during the specified time period for which the participant submitted at least one cardiac surgery of any type. The intent of calculating "annualized" volumes is to adjust for participants who participated in the database for fewer months than the time period specified. For participants who participated in the database and submitted cases every month during 2006, the annualized volume for 2006 is simply the total number of cases.

The <u>STS</u> Average Annualized Volume is the average value of all of the participant annualized volumes across the entire population of STS participants. The <u>Participant Percentile</u> indicates the percent of STS participants whose annualized volumes are less than, or equal to, your own. Higher percentiles indicate higher volumes in relation to other STS participant sites. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant annualized volumes across all database participants. For example, 90% of participants have annualized volumes less than or equal to the value marked "90<sup>th</sup> percentile." Confidence intervals are not provided for volume measures, as volume is known with certainty and is not estimated.

**Process Measures:** The NQF process measures provide data on the frequency of usage of five therapies among subsets of Isolated CABG patients. The therapies are: i) preoperative beta blockade therapy, ii) use of IMA, iii) discharge anti-platelet medication, iv) discharge beta blockade therapy, and v) discharge anti-lipid medication. The patient population for each measure differs, in accordance with the NQF specifications (see Table 2 of this NQF Report Overview for details). The number of <u>Eligible</u>

Procedures is the number of cases performed by the participant during the specified time period who meet the eligibility requirements to be included in the calculations when summarizing the participant's data. Beginning with the 2008 Harvest 3 report (covering the procedure time period through 6/30/2008), STS implementation of NQF medication process measures using data version 2.61 excludes records for which the medication was contraindicated/not indicated from the eligible population. The main summary statistic, Participant Usage, is the percent of eligible Isolated CABG cases during the specified time period for which the patient received the specified therapy. The Overall STS Usage is the percent of all eligible patients in the entire STS population during the specified time period who received the specified therapy. In calculating these percentages, missing data are treated as a "No", emphasizing the importance of having complete data in these fields.

The <u>Participant Percentile</u> indicates the percent of STS participants who applied the therapy in their respective populations less frequently than or as frequently as did your institution. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant usage across all participants in the database. For example, 90% of participants use the therapy less frequently than the amount indicated by the "90<sup>th</sup> percentile". A bar identified as "Participant" indicates the point estimate and limits of a 95% Confidence Interval (CI) for the participant's usage of therapy. The underlying parameter being estimated is the long-run usage rate that would be observed in a large sample of patients. The 95% CI indicates the range of usage rates that are consistent with the data in light of sampling variability.

Outcomes Measures: The NQF outcomes data provide risk-adjusted analyses of mortality and morbidity for Isolated CABG surgery as well as risk-adjusted operative mortality for Isolated AVR, Isolated MVR, AVR+CABG, and MVR+CABG. The main summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. The interpretation is similar to that of an O/E ratio (see the Risk-Adjusted Results: Overview portion of the General Report Overview for details on STS risk adjustment). An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. Each measure is calculated among patients undergoing surgery of the type specified during the time period specified who additionally meet certain eligibility requirements. The column labeled Eligible Procedures indicates the number of patients who met the inclusion criteria to be included in the analysis for the indicated measure. The Participant Percentile is the percent of STS participants who have an estimated OR that is greater than or equal to your estimated OR. Note that this is different than performance percentiles for process measures, where the percentile indicates the percentage of STS participants with performance that is less than the specified number. This simply reflects the fact that high process compliance is desirable, whereas a high OR is undesirable.

The <u>Observed Participant Rate</u> is the percent of eligible patients who experienced the specified outcome. Unlike the participant estimated OR, the observed participant rate is not risk-adjusted. The estimated OR is the main summary statistic for summarizing the NQF measure in this report.

The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of estimated Odds Ratios across all STS participants. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile." The line that extends to the left and right of the Participant Value indicates the lower and upper limits of a 95% Confidence Interval (CI) surrounding the participant's estimated OR.

### c. Technical Notes

**Calculation of Percentiles for the Distribution of Participant Values:** The graph provided for each measure contains information about the distribution of the value of the measure across all STS

participants, namely the minimum, maximum,  $10^{th}$  percentile,  $50^{th}$  percentile, and 90th percentile. The " $X^{th}$ " percentile, denoted  $P_x$ , is loosely defined as the number having the property that X% of the participant values are less than  $P_x$ , and (100 - X)% of the participant values are greater than  $P_x$ . For process measures, participants with greater than 5% missing data were excluded when calculating percentiles of the STS distribution and do not have a calculated participant percentile. For participants having less than 5% missing data on a process measure, the missing values on the process measure were converted to "No" before calculating percentiles. For outcomes measures, all participants submitting at least one eligible case were included when calculating percentiles of the STS distribution. Missing data on outcomes variables were treated as "No."

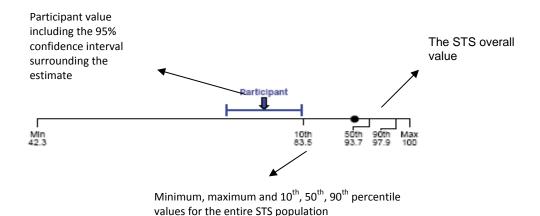
NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion criteria, and rules for handling missing data in the NQF section versus the rest of the report. Definitions used in the NQF report were designed to match current NQF specifications as closely as possible. It is expected that these differences will eventually disappear as the NQF measures are refined. Some important differences are:

Case Volumes – The NQF report section presents "annualized" volumes. These are case volumes that have been adjusted for the number of months that a participant was an active contributor to the database. Elsewhere in the STS report, total case volumes are presented without adjustment for the length of participation.

Eligible Cases - The NQF report also presents the number of "eligible cases" for each measure. Separate inclusion criteria are applied to each measure, and these inclusion criteria do not always match the definitions used elsewhere in the STS report. Please refer to the footnotes in each section for specific details.

### **Interpretation Manual**

In addition to the statistics provided for each of the STS Composite Quality Domains and NQF measures, a figure representing the distribution of values for the entire STS population is provided.



The figure allows participants to quickly judge their performance relative to the overall STS. The scale of the figure is set up such that the right side of the distribution represents the <u>most</u> favorable performance and the left side represents the <u>least</u> favorable performance (Note that in some cases smaller numbers will be on the left; in other instances, smaller numbers will be on the right. For example, for the Pre-operative Beta Blockade Therapy measure, the far left side of the distribution will contain the *lowest* percentage Beta Blockade Therapy for an STS participant – this corresponds to least

favorable performance. Alternatively, for the Operative Mortality Measure, the far left side of the distribution will contain the *highest* Estimated Odds Ratio – this also corresponds to least favorable performance). If a participant's value for a given measure is to the left of the STS overall value, the participant is performing worse on that measure than the overall STS. Conversely, if the participant's value for a given measure is located to the right of the overall STS value, the participant is performing better than the overall STS.

**NOTE!** Care should be given to reading these figures. In some instances, the various percentiles presented cluster very close together in the data. In such cases, the label for the percentile is not necessarily located immediately at the point on the distribution where the percentile occurs. An example of this is apparent in the figure above: The 50<sup>th</sup> percentile corresponds to a value of 93.7 and looks to align fairly closely with the STS overall value as represented by the large black dot. However, the expandable figure marking actually points to a place somewhere to the right of the STS overall value for the 50<sup>th</sup> percentile marking. So the STS overall value would be some amount less than 93.7.

Also, please note that in some cases, small sample sizes preclude valid comparisons between the participant and the STS overall. Such instances are clearly noted in the report output.

### a. NQF Measures Interpretation Example

Sample CABG Operative Mortality results – tabular and figure representation.

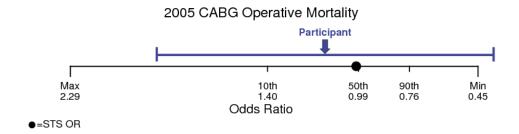
NQF	Eligible	Participant	Participant	Participant
Measure	Procedures	Estimated OR	Percentile	Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

Eligible Procedures: 74 patients met the inclusion criteria for the indicated measure.

Participant Estimated OR (Odds Ratio): The main summary statistic measuring the impact that a participant's performance has on a patient's probability of experiencing an adverse outcome has a value of 1.14 indicating worse than expected performance.

Participant Percentile: 26.3% of STS participants had an estimated OR greater than or equal to your estimated OR. In other words, 26.3% had the same or worse performance.

Participant Observed Rate: 5.4% of the 74 eligible patients experienced the specified outcome.



The highest OR among all STS participants = 2.29 The lowest OR among all STS participants = 0.45 The STS average OR is 1.00

### 2) Sample page from section of the report that contains NQF measure results:



### NQF Measures Process Measures Participant 99999 STS Period Ending 12/31/2008



NQF Measure	Eligible Procedures	Participant Usage (95% CI)	Participant Percentile	Overall STS Usage	Distribution of Participant Values
Jan 2008 - Dec 2008 Preoperative Beta Blockade Therapy <sup>1</sup>	541	89.3% (86.4 , 91.8)	69.9	82.1%	Participant    Min   10th   50th   90th   Max   95.6   100
Jan 2008 - Dec 2008 Use of IMA <sup>2</sup>	536	96.5% (94.5 , 97.9)	63.3	94.2%	Participant  Min 10th 50th 90th Max 53.2 87.8 85.2 98.9 100
Jan 2008 - Dec 2008 Discharge Anti-Platelet Medication <sup>3</sup>	536	98.7% (97.3 , 99.5)	68.7	96.1%	Participant  Min 10th 50th 90th Max 18.7 92.1 97.5 100 100
Jan 2008 - Dec 2008 Discharge Beta Blockade Therapy <sup>4</sup>	538	96.1% (94.1 , 97.6)	53.4	93.7%	Participant  Min 10th 50th 80th Max 15.1 85.3 85.7 100 100
Jan 2008 - Dec 2008 Discharge Anti-Lipid Treatment⁴	535	91.8% (89.1 , 94.0)	40.7	91.4%	Participant

Excludes v2.61 contranindicated / not indicated records.

Excludes patients with prior CABG surgery

Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

Excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

### NATIONAL QUALITY FORUM

## Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

### Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 0115	NQF Project: Surgery Endorsement Maintenance 2010			
MEASURE DESCRIPTIVE INFORMATION				
De.1 Measure Title: Risk-Adjusted Surgical	Re-exploration			
	nt of patients aged 18 years and older undergoing isolated CABG who bleeding with or without tamponade, graft occlusion, valve dysfunction,			
1.1-2 Type of Measure: Outcome De.3 If included in a composite or paired of OT1-013-09 - The STS CABG Composite Score	with another measure, please identify composite or paired measure			
De.4 National Priority Partners Priority Area: Safety De.5 IOM Quality Domain: Safety De.6 Consumer Care Need: Getting better				

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission  A.4 Measure Steward Agreement attached: STS Measure Steward Agreement. Fully Executed-634267284737152750.pdf	A Y N

<b>B.</b> The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y N
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  ▶ Purpose: Public reporting, Internal quality improvement	C Y□ N□
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.  D.1Testing: Yes, fully developed and tested  D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y N
(for NQF staff use) Have all conditions for consideration been met?  Staff Notes to Steward (if submission returned):	Met Y_ N_
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
1. IMPORTANCE TO MEASURE AND REPORT  Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	Eval Rating
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  **Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2  1a.3 Summary of Evidence of High Impact: Surgical re-exploration for bleeding remains a known complication following cardiac surgery. Coronary artery surgery remains a frequently performed procedure that affects large numbers of patients. The literature (see Heinand Karthik below) documents that bleeding following coronary artery bypass surgery confers greater ICU stay and therefore greater resource consumption. It remains unknown and controversial whether long-term outcomes are worse for the isolated re-exploration for bleeding patients. However, Hein documents that patients with ICU stay > 3 days (with bleeding as multivariate risk factor for this outcome), have a long-term survival which is inferior to patients with ICU stay < 3 days. The patient consequences of this complication relates to the physiological stress of	

- Hein OV, Birnbaum J, Wernecke K, England M, Knoertz W, Spies C. Prolonged Intensive Care Unit Stay in Cardiac Surgery: Risk Factors and Long-Term Survival. Ann Thor Surg 2006;81:880-85 Karthik S, Grayson AD, McCarron EE, Pullan DM, Desmond MJ. Reexploration for bleeding after coronary artery bypass surgery: risk factors, outcomes, and the effect of time delay. Ann Thor Surg 2004;78:527-34.	
1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: It is believed that by providing participants with rates of surgical re-exploration that greater attention will be focused upon efforts to reduce the rate of re-exploration through established processes and structures of care.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:  Please see attachment	
1b.3 Citations for data on performance gap: Dates: January 1, 2009-December 31, 2009	
Analysis includes 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data (not restricted to this measure) to the STS Adult Cardiac Surgery Database for all 12 months.	
1b.4 Summary of Data on disparities by population group: N/A	1b C□
1b.5 Citations for data on Disparities: N/A	P
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): It still remains unproven through level I evidence that surgical rates of re-exploration confer a direct effect on outcome. Several indirect measures suggest that surgical re-exploration confers worse outcomes. As cited above, surgical re-exploration is a risk factor for an ICU stay of > 3 days. A length of stay of greater than 3 days in the ICU is associated with worse long term survival (retrospective, single center data).	
<b>1c.2-3. Type of Evidence:</b> Observational study, Expert opinion, Systematic synthesis of research, Other Clinical results from approximately 90% of cardiac surgery centers in the US	
1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):  The summary of evidence is gathered from retrospective, observational data. These data do not establish a clear link between poor outcomes and surgical re-exploration. Expert thought and leader opinion, however, generally agrees that surgical re-exploration for bleeding is associated with worse outcomes and increased resources (length of stay).	
1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):	
1c.6 Method for rating evidence:	
<b>1c.7 Summary of Controversy/Contradictory Evidence:</b> Stamou and colleagues (citation below) instituted a Continuous Quality Improvement (CQI) program at their center. They found that CQI did not emerge as an independent factor to reduce surgical re-exploration. While their data did not reach statistical significance, the Odds Ratio of the CQI for re-exploration was 0.8 (95% CI 0.5-1.2), suggesting some reduction by the CQI	1c C□ P□
1c.8 Citations for Evidence (other than guidelines): -Shrover AL. Coombs LP. Peterson ED. et al. The	M∐ N□

Society of Thoracic Surgeons: 30-day operative mortality and morbidity risk models. Ann Thorac Surg. 2003;75:1856-1865.  -Welke 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.  -Hein OV, Birnbaum J, Wernecke K, England M, Knoertz W, Spies C. Prolonged Intensive Care Unit Stay in Cardiac Surgery: Risk Factors and Long-Term Survival. Ann Thor Surg 2006;81:880-85.  -Karthik S, Grayson AD, McCarron EE, Pullan DM, Desmond MJ. Reexploration for bleeding after coronary	
artery bypass surgery: risk factors, outcomes, and the effect of time delay. Ann Thor Surg 2004;78:527-34Stamou SC, Camp SL, Reames MK, et al. Continuous Quality Improvement Program and Major Morbidity and Cardiac Surgery. Am J Cardiol 2008;102:772-777	
1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):	
1c.10 Clinical Practice Guideline Citation: 1c.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):	
1c.13 <b>Method for rating strength of recommendation</b> (If different from <u>USPSTF system</u> , also describe rating and how it relates to USPSTF):	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y_ N_
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ( <u>evaluation criteria</u> )	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	
2a. Precisely Specified	
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):  Number of patients undergoing isolated CABG who require return to the operating room for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason	
<b>2a.2 Numerator Time Window</b> (The time period in which cases are eligible for inclusion in the numerator):	
2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):  Number of isolated CABG procedures in which any of the following are marked "yes":  ReOp for Bleeding [COpReBld (STS Adult Cardiac Surgery Database Version 2.73)], Reintervention for Graft Occlusion (COpReGft), ReOp for Valve Dysfunction (COpReVIV), ReOp for Other Cardiac Reason (COpReOth)	za- specs C P M

**2a.4 Denominator Statement** (Brief, text description of the denominator - target population being measured):

All patients undergoing isolated CABG

2a.5 Target population gender: Female, Male 2a.6 Target population age range: 18 and older

**2a.7 Denominator Time Window** (The time period in which cases are eligible for inclusion in the denominator):

12 months

**2a.8 Denominator Details** (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):

Number of isolated CABG procedures

Isolated CABG is determined as a procedure for which all of the following apply:

- OpCAB is marked "Yes"
- (VADProc is marked "No" or "Missing") or (VADProc is marked "Yes, Implanted" and UnplVAD is marked "yes")
- OCarASDTy is marked "PFO" or "missing"
- OCarAFibAProc is marked "primarily epicardial" or "missing" and
- OpValve, VSAV, VSAVPr, ResectSubA, VSMV, VSMVPr, OpTricus, OpPulm, OpONCard, OCarLVA, OCarVSD, OCarSVR, OCarCong, OCarTrma, OCarCrTx, OCAoProcType, EndoProc, OCTumor, OCPulThromDis, OCarOthr are all marked "no" or "missing"
- 2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): N/A
- **2a.10 Denominator Exclusion Details** (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):

  N/A
- **2a.11 Stratification Details/Variables (**All information required to stratify the measure including the stratification variables, all codes, logic, and definitions**):** N/A
- 2a.12-13 Risk Adjustment Type: Case-mix adjustment
- **2a.14 Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

  Please see attachment
- 2a.15-17 Detailed risk model available Web page URL or attachment: Attachment 2a.15 Detailed Risk Model-634267294901293682.pdf

2a.18-19 Type of Score: Rate/proportion

2a.20 Interpretation of Score: Better quality = Lower score

**2a.21 Calculation Algorithm** (Describe the calculation of the measure as a flowchart or series of steps): N/A

**2a.22 Describe the method for discriminating performance** (e.g., significance testing):

Participant specific odd ratios and its 95% CI were estimated in the hierarchical model. These model-based estimates were used to control variation due to random statistical fluctuations while estimating true signal variation. A 95% CI excluding zero indicates the participant's performance is significantly lower or higher than an "average" STS participant.

**2a.23 Sampling (Survey) Methodology** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A

**2a.24 Data Source** (Check the source(s) for which the measure is specified and tested) Registry data

2a.25 Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): STS Adult Cardiac Surgery Database - Version 2.73	
<b>2a.26-28 Data source/data collection instrument reference web page URL or attachment:</b> URL Data Collection Form (an updated version will be made available on the STS Website in mid-December of 2010)http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataCollectionForm2_7_Annotated_20101021.pdf	
2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataSpecificationsV2_7_20101021.pdf an updated version will be made available on the STS Website in mid-December of 2010	
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and	
tested) Clinicians: Group, Facility/Agency, Population: national, Population: regional/network, Population: states, Population: counties or cities	
<b>2a.36-37 Care Settings (</b> Check the setting(s) for which the measure is specified and tested) Hospital	
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)	
TESTING/ANALYSIS	
2b. Reliability testing	
<b>2b.1 Data/sample</b> <i>(description of data/sample and size)</i> : STS Adult Cardiac Surgery Database - Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009.	
<b>2b.2 Analytic Method</b> (type of reliability & rationale, method for testing): Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009. Excluded from analysis are participants that did not submit results for both time periods. Because database participants can change their underlying care processes at any time, we would not expect perfect correlation between two sets of results from even proximate time periods.	2b
<b>2b.3 Testing Results</b> (reliability statistics, assessment of adequacy in the context of norms for the test conducted):  Please see attachment	P   M   N
2c. Validity testing	
2c.1 Data/sample (description of data/sample and size): STS Adult Cardiac Surgery Database	
Audits conducted in 2010, all cases performed in 2009; N = 40 randomly selected sites participating in the STS Adult Cardiac Surgery Database	
<b>2c.2 Analytic Method</b> (type of validity & rationale, method for testing):  Participating sites are randomly selected for participation in STS Adult Cardiac Surgery Database Audit, which is designed to evaluate the accuracy, consistency, and comprehensiveness of data collection and ultimately validate the integrity of the data contained in the database. The lowa Foundation for Medical Care (IFMC), the quality improvement organization for lowa and Illinois, has conducted audits on behalf of STS since 2006.	20
Each year, the IFMC conducts audits at randomly selected sites throughout the country and tracks the individual agreement rates by variable and by year. More specifically, for each site, agreement rates are calculated for 73 individual elements. In addition, aggregate agreement rates for each element, variable category (e.g., pre-operative risk factors, previous interventions, etc.), and overall for all categories are	2c C P M N

calculated for all sites. While this is not region specific, it is data point specific and comparison agreement rates confirm the improvement over time as well as the consistency.	
<b>2c.3 Testing Results</b> (statistical results, assessment of adequacy in the context of norms for the test conducted):	
ReOp for Bleeding: 99.9% agreement rate ReOp for Graft Occlusion: 100.0% agreement rate ReOp for Valve Dysfunction: 99.9% agreement rate ReOp for Other Cardiac Reason: 99.5% agreement rate	
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s):	
2d.2 Citations for Evidence:	
2d.3 Data/sample (description of data/sample and size):	2d
2d.4 Analytic Method (type analysis & rationale):	C D
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):	M_ N_ NA_
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): Please see Risk Adjustment Type section above	
<b>2e.2 Analytic Method</b> (type of risk adjustment, analysis, & rationale): Detailed information regarding the risk adjustment model can be found in the attachment:	
Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, Normand SL, DeLong ER, Shewan CM, Dokholyan RS, Peterson ED, Edwards FH, Anderson RP. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1coronary artery bypass grafting surgery. Ann Thorac Surg. 2009 Jul;88(1 Suppl):S2-22.	2e
2e.3 Testing Results (risk model performance metrics):	C   P   M   N
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	NA 🗌
2f. Identification of Meaningful Differences in Performance	
<b>2f.1 Data/sample from Testing or Current Use</b> (description of data/sample and size): 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months; January 1, 2009-December 31, 2009	
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):	
We calculated the risk adjusted event rate with the participant's Odds Ratio (OR) estimate and the overall STS event rate. Therefore, the risk adjusted rate is closely related to OR estimate. If OR > 1, then the	
participant's risk adjusted rate will be greater than the overall STS event rate; if OR < 1, then the	
participant's risk adjusted rate will be smaller than the overall STS event rate. The statistical significance is defined by the 95% confidence interval (CI) or the OR estimate. If the 95% CI for a participant's OR	2f
includes the null value 1.0, then we cannot distinguish this participant's performance from the STS average - either the participant's performance was close to average or else the participant's sample size was too	C □ P □
small to make a reliable inference. Otherwise, if the 95% CI falls to the right of 1.0, then the participant's performance is considered significantly lower than the average STS results; if the 95% CI falls to the left of	M

1.0, then the participant's performance is considered significantly higher than the average STS results.	
<b>2f.3 Provide Measure Scores from Testing or Current Use</b> (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  Please see attachment	
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): N/A	
2g.2 Analytic Method (type of analysis & rationale):	2g C P
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	M N
2h. Disparities in Care	2h
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A	C□
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	P   M   N   NA   NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:	2 C□ P□
	M□   N□
3. USABILITY	
3. USABILITY  Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand	N_ Eval
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	N_ Eval
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)  3a. Meaningful, Understandable, and Useful Information	N_ Eval
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)  3a. Meaningful, Understandable, and Useful Information  3a.1 Current Use: In use  3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website,	N_ Eval
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)  3a. Meaningful, Understandable, and Useful Information  3a.1 Current Use: In use  3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org  Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily	N_ Eval
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)  3a. Meaningful, Understandable, and Useful Information  3a.1 Current Use: In use  3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org  Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily participate in this initiative.  3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):	N_ Eval

3a.6 Results (qualitative and/or quantitative results and conclusions):	
Please see attachment	
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures:	
OT1-013-09 - The STS CABG Composite Score; Component measures: 0114 Risk-Adjusted Post-operative	
Renal Failure, 0115 Risk-Adjusted Surgical Re-exploration, 0116 Anti-Platelet Medication at Discharge, 0117	
Beta Blockade at Discharge, 0118 Anti-Lipid Treatment at Discharge, 0119 Risk-Adjusted Operative Mortality for CABG, 0127 Pre-Operative Beta Blockade, 0129 Risk-Adjusted Prolonged Intubation (ventilation), 0130	
Risk-Adjusted Deep Sternal Wound Infection Rate, 0131 Risk-Adjusted Stroke/Cerebrovascular Accident,	
0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)	
	l
(for NQF staff use) Notes on similar/related <u>endorsed</u> or submitted measures:	
3b. Harmonization	
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target	
population/setting/data source or different topic but same target population):	
3b.2 Are the measure specifications harmonized? If not, why?	
N/A; however, data definitions and key elements have been established by a multi-societal writing	
committee called the "ACCF/AHA Writing Committee to Develop Acute Coronary Syndromes and Coronary	
Artery Disease Clinical Data Standards" with representatives from each of the following organizations:	
Agency for Healthcare Research and Quality	
American College of Cardiology	
American College of Chest Physicians	
American College of Emergency Physicians	
American College of Physicians American College of Preventative Medicine	
American Heart Association	
American Medical Association	
Centers for Disease Control and Prevention	
Emergency Nurses Association	
Food and Drug Administration	
Joint Commission on Accreditation of Healthcare Organizations	
National Association of Emergency Medical Technicians	
National Association of EMS Physicians	
National Heart, Lung, and Blood Institute	3b
Preventive Cardiovascular Nurses Association	C□
Society for Academic Emergency Medicine	P
Society of Chest Pain Centers and Providers	M_
Society of General Internal Medicine	N
Society of Thoracic Surgeons	NA.
3c. Distinctive or Additive Value	
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-	
endorsed measures:	3c
N/A	C□
	P_
5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the	M
same target population), Describe why it is a more valid or efficient way to measure quality:	N
N/A	NA 🗌
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Usability?	
	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met?	3
Rationale:	C
	P□

	M_ N_
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. ( <a href="evaluation criteria">evaluation criteria</a> )	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	
4a.1-2 How are the data elements that are needed to compute measure scores generated?  Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C P M N
4b. Electronic Sources	
<ul> <li>4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims)</li> <li>Yes</li> <li>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</li> </ul>	4b C   P   M   N
4c. Exclusions	- \
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?  No  4c.2 If yes, provide justification.	4c C   P   M   N   NA
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. This measure may be susceptible to human error (i.e., recording the measure inaccurately or not at all).  When data collection on this measure is done through participation in the STS Adult Cardiac Surgery	
Database, an auditing strategy is in place.	
Both STS and the Duke Clinical Research Institute have a list of database participants making participation in the STS Adult Cardiac Surgery Database easy to track.	
Each participant is responsible for the quality and accuracy of the data they submit to the database. The participant agrees to the following quality control measures in the participation agreement: i) Participant hereby warrants that all data submitted for inclusion in the STS National Database will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the independent data warehouse service provider and agrees to cooperate with and assist STS and its designees in connection with the performance of any independent audit.	
ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the STS National Database, including but not limited to apprising the Director of the STS National Database and the independent data warehouse service provider about any other Participation Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named.	4d C□ P□
STS audited for these potential problems during testing. Please see IFMC audit results.	N D

4e. Data Collection Strategy/Implementation	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): Data Collection: There are no direct costs to collect the data for this measure. Costs to develop the measure included volunteer cardiothoracic surgeon time, STS staff time, and DCRI statistician and project management time.	
Other fees: STS Adult Cardiac Surgery Database participants (single cardiothoracic surgeons or a group of surgeons) pay annual participant fees of \$2,950 or \$3,700, depending on whether participants are STS members (or whether the majority of surgeons in a group are STS members). As a benefit of STS membership, STS members are charged the lesser of the two fees.	
4e.3 Evidence for costs:	4e C□ P□ M□
4e.4 Business case documentation:	N
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C   P   M   N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement? Comments:	Y □ N □ A □
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) Co.1 <u>Organization</u> Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611	
Co.2 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Measure Developer If different from Measure Steward  Co.3 Organization  Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611	
Co.4 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Co.5 Submitter If different from Measure Steward POC  Jane, Han, MSW, jhan@sts.org, 312-202-5856-, Society of Thoracic Surgeons	

Co.6 Additional organizations that sponsored/participated in measure development

#### **ADDITIONAL INFORMATION**

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Members of the STS Task Force on Quality Initiatives provide clinical expertise as needed. The STS Workforce on National Databases meets at the STS Annual Meeting and reviews the measures on a yearly basis. Changes or updates to the measure will be at the recommendation of the Workforce.

Ad.2 If adapted, provide name of original measure:

Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released: 2004

Ad.7 Month and Year of most recent revision: 12, 2010

Ad.8 What is your frequency for review/update of this measure? annually

Ad.9 When is the next scheduled review/update for this measure? 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment 0115 Sections 2a.14, 1b.2, 2b.3, 2f.3, 3a.6.pdf

Date of Submission (MM/DD/YY): 01/12/2011

# The Society of Thoracic Surgeons 2008 Cardiac Surgery Risk Models: Part 1—Coronary Artery Bypass Grafting Surgery

David M. Shahian, MD,<sup>a</sup> Sean M. O'Brien, PhD,<sup>b</sup> Giovanni Filardo, PhD, MPH,<sup>c</sup> Victor A. Ferraris, MD,<sup>d</sup> Constance K. Haan, MD,<sup>e</sup> Jeffrey B. Rich, MD,<sup>f</sup> Sharon-Lise T. Normand, PhD,<sup>g</sup> Elizabeth R. DeLong, PhD,<sup>b</sup> Cynthia M. Shewan, PhD,<sup>h</sup> Rachel S. Dokholyan, MPH,<sup>b</sup> Eric D. Peterson, MD, MPH,<sup>b</sup> Fred H. Edwards, MD,<sup>e</sup> and Richard P. Anderson, MD<sup>i†</sup>

<sup>a</sup>Massachusetts General Hospital, Boston, Massachusetts; <sup>b</sup>Duke Clinical Research Institute, Durham, North Carolina; <sup>c</sup>Institute for Health Care Research and Improvement, Baylor Health Care System, Dallas, Texas; <sup>d</sup>University of Kentucky Chandler Medical Center, Division of Cardiovascular and Thoracic Surgery, Lexington, Kentucky; <sup>e</sup>University of Florida, Division of Cardiothoracic Surgery, Jacksonville, Florida; <sup>f</sup>Sentara Cardiovascular Research Institute, Norfolk, Virginia; <sup>g</sup>Department of Health Care Policy, Harvard Medical School, and Department of Biostatistics, Harvard School of Public Health, Boston, Massachusetts; <sup>h</sup>The Society of Thoracic Surgeons, Chicago, Illinois; and <sup>i</sup>Seattle, Washington

Background. The first version of The Society of Thoracic Surgeons National Adult Cardiac Surgery Database (STS NCD) was developed nearly 2 decades ago. Since its inception, the number of participants has grown dramatically, patient acuity has increased, and overall outcomes have consistently improved. To adjust for these and other changes, all STS risk models have undergone periodic revisions. This report provides a detailed description of the 2008 STS risk model for coronary artery bypass grafting surgery (CABG).

Methods. The study population consisted of 774,881 isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2002, and December 31, 2006, at 819 STS NCD participating centers. This cohort was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. The validation sample was used to assess model calibration and discrimination. Model outcomes included operative mortality, renal failure, stroke, reoperation for any cause, prolonged ventilation, deep sternal wound infection, composite major morbidity or mortality, prolonged length of stay (> 14 days), and short length of stay (< 6 days and alive). Candidate predictor variables were selected based on their availability in versions 2.35, 2.41, and 2.52.1 of the STS NCD and their presence in (or ability to be mapped to) version 2.61. Potential predictor

variables were screened for overall prevalence in the study population, missing data frequency, coding concerns, bivariate relationships with outcomes, and their presence in previous STS or other CABG risk models. Supervised backwards selection was then performed with input from an expert panel of cardiac surgeons and biostatisticians. After successfully validating the fit of the models, the development and validation samples were subsequently combined, and the final regression coefficients were estimated using the overall combined (development plus validation) sample.

Results. The c-index for the mortality model was 0.812, and the c-indices for other endpoints ranged from 0.653 for reoperation to 0.793 for renal failure in the validation sample. Plots of observed versus predicted event rates revealed acceptable calibration in the overall population and in numerous subgroups. When patients were grouped into categories of predicted risk, the absolute difference between the observed and expected event rates was less than 1.5% for each endpoint. The final model intercept and coefficients are provided.

Conclusions. New STS risk models have been developed for CABG mortality and eight other endpoints. Detailed descriptions of model development and testing are provided, together with the final algorithm. Overall model performance is excellent.

(Ann Thorac Surg 2009;88:S2-22) © 2009 by The Society of Thoracic Surgeons

In 1986, The Society of Thoracic Surgeons (STS) convened an Ad Hoc Committee on Risk Factors for Coronary Artery Bypass Graft Surgery (CABG) [1] and an

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Ad Hoc Committee to Develop a National Database for Cardiothoracic Surgery [2]. This was prompted by the

Drs Shahian, O'Brien, Filardo, Ferraris, Haan, Rich, Normand, DeLong, Shewan, Peterson, Edwards, Anderson, and Ms Dokholyan have no conflicts of interest to declare regarding this work.

#### Abbreviations and Acronyms

BSA = body surface area

CABG = coronary artery bypass graft surgery

CHF = congestive heart failure

EF = ejection fraction

GFR = glomerular filtration rate

HCFA = Health Care Financing Administration

IABP = intra-aortic balloon pump NYHA = New York Heart Association NCD = National Adult Cardiac Surgery Database

O/E = observed to expected ratio

QMTF = Quality Measurement Task Force STS = The Society of Thoracic Surgeons

release earlier that year of inadequately risk-adjusted hospital mortality data by the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services. Although the HCFA analytical methodology was widely criticized, STS leadership recognized that the underlying principle of collecting and analyzing data to improve patient outcomes was valid, particularly for complex and costly procedures such as coronary artery bypass grafting surgery (CABG). They believed that it was the responsibility of professional organizations to develop credible clinical data registries for their own specialties, and that risk models derived from such registries would circumvent many of the concerns resulting from the use of unadjusted administrative data. Such clinical registries would be used as credible data sources for quality assessment and improvement activities as well as for research.

These early activities ultimately led to the development of the STS National Adult Cardiac Surgery Database (NCD) [3, 4]. Since its release to members in 1990, the STS NCD has evolved to become one of the largest specialty-specific clinical data registries in the world. It currently has more than 950 participants enrolled, representing just under 90% of the cardiac surgery providers in the United States, with data on more than 3.6 million procedures. Similar STS data registries have now been developed for congenital heart surgery and general thoracic surgery, and future plans include the development of specialty modules (eg, quality metrics, atrial fibrillation surgery, thoracic aortic surgery). Recent enhancements, including the addition of unique physician and patient identifiers, will facilitate linkages with other registries and greatly expand the potential of the STS NCD for longitudinal follow-up, comparative effectiveness, and cost efficiency studies.

In addition to the development of the STS NCD as a comprehensive, nationally representative data registry, the second major goal of the STS was to assure that analyses derived from this registry would be appropriately adjusted for preoperative patient severity, a major deficiency of the HCFA reports that were initially published in 1986. This was accomplished by first identifying

risk factors for specific procedures and outcomes, beginning with isolated CABG, then using these predictor variables to develop risk models. With statistical risk models, which are most often based on logistic regression, the expected outcome for a patient with a given set of risk factors can be determined, and that can be compared with the observed outcome. The observed (O) and expected (E) outcomes are summed over all patients of a particular surgeon or hospital to yield the risk-standardized mortality ratio (O/E), which can then be multiplied by the average rate in the reference population to calculate risk-standardized mortality rates [5–7].

STS CABG risk models have undergone periodic updates and revisions, the most recent of which was based upon 2000 to 2002 STS NCD data. In 2007, the STS Database Modernization Task Force completed a major specification upgrade of the STS NCD data collection instrument from version 2.52.1 to version 2.61. This included refinement, modification, consolidation, or elimination of some data elements, as well as an attempt to harmonize definitions with those of the American College of Cardiology National Cardiovascular Data Registry whenever possible. Given these changes, as well as the number of years since the last risk model update, the STS Quality Measurement Task Force (QMTF) was asked to develop new risk models for isolated CABG, isolated valve repair or replacement, and combined CABG plus valve procedures. The authors of this report include the QMTF members who participated in this initiative.

Implementation of these new models in January 2008 coincided with the release of STS NCD version 2.61. This report, Part 1 of 3, describes the development of the new mortality and morbidity models for isolated CABG surgery.

#### **Study Purpose**

The primary goal of this study was to develop risk-prediction algorithms for patients undergoing isolated CABG surgery. As the major intended use of these algorithms was to compare participant outcomes to the overall STS national experience, risk factors were generally restricted to patient and clinical characteristics present preoperatively.

#### Risk Model Development and Transparency

The availability of user-friendly statistical software programs and the exponential increase in computing speed have greatly facilitated statistical analyses such as logistic regression, the basis for many risk models. However, despite these technological advances, clinical judgment, experience, intuition, and practicality still play a critical role in risk model development. There are many points in model development at which legitimate differences in approach may lead to substantial differences in the resulting statistical models and the inferences derived from them [8].

We believe the degree of transparency provided in this report regarding the development of the STS CABG risk models is essential in today's health care environment. In an era when society demands full transparency regarding health care performance, the methodologies used to evaluate that performance should be just as transparent [9, 10]. This fundamental principle is among the standards established by the American Heart Association and American College of Cardiology for statistical models used for public reporting [11].

#### Study Population and Endpoints

All isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2000, and December 31, 2006, were initially considered for inclusion, although the final development and validation samples were derived from 2002 to 2006 data. Patients missing data on sex (n = 195) were excluded, as these patients are not included in STS performance feedback reports to database participants. That left a study population of 774,881 surgical procedures from 819 database participants. Patients on dialysis preoperatively (n = 12,415) were excluded when developing the risk model for postoperative renal failure.

#### Training and Validation Samples

The study population was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. Data from the validation sample were used to assess model fit, discrimination, and calibration. After choosing variables and assessing model fit, the development and validation samples were subsequently combined, and the final model coefficients were estimated using the combined (development plus validation) data.

#### **Endpoints**

Risk models were developed for the nine endpoints listed below. Only mortality was recorded beyond the index hospitalization. Morbidity data included only in-hospital complications, although beginning in STS NCD version 2.61, sternal infections will be recorded for up to 30 days postoperatively. The nine endpoints are as follows: (1) operative mortality: death during the same hospitalization as surgery, regardless of timing, or within 30 days of surgery regardless of venue; (2) permanent stroke (cerebrovascular accident): a central neurologic deficit persisting longer than 72 hours; (3) renal failure: a new requirement for dialysis or an increase of the serum creatinine to more than 2.0 mg/dL and double the most recent preoperative creatinine level; (4) prolonged ventilation (longer than 24 hours); (5) deep sternal wound infection; (6) reoperation for any reason; (7) major morbidity or mortality: a composite defined as the occurrence of any of the above endpoints; (8) prolonged postoperative length of stay (PLOS): length of stay (LOS) more than 14 days (alive or dead); and (9) short postoperative LOS (SLOS): LOS less than 6 days and patient alive at discharge (this SLOS definition differs from the previous STS risk models, which did not exclude patients who died in-hospital; patients who died within 5 days of surgery are

included in the new models but are treated as not having a short stay).

Table 1 summarizes the frequencies of these endpoints in the study population for each predictor variable category (ie, the bivariate relationships).

#### Selection of Candidate Predictor Variables

Initial Data Screening of Candidate Predictor Variables

We began by considering all possible candidate variables from the development set (Table 2). Because the primary goal of the STS risk models is to adjust surgical outcomes, in general only preoperative patient variables are included. However, because these models are also used for other purposes such as individual patient prediction and counseling, there were a few modifications (which are discussed in the relevant sections) in the application of this general principle.

As there were a large number of procedures and endpoints available, we were not statistically constrained to highly parsimonious models, nor is such an approach generally favored in regression modeling [12–14]. Discarding valid data elements can waste valuable information that has been collected at substantial effort and cost. Furthermore, although much of the discrimination of a predictive model may be contained in a relatively small number of variables [15, 16], some predictor variables that add only modestly to discrimination may still be important predictors of outcomes at the patient level [17, 18].

### Expert Panel Review for Clinical Relevance and Face Validity

All candidate variables available in version 2.61 were individually discussed by a panel of cardiac surgeons and health policy experts to assure that clinical relevance as well as multiple aspects of validity (face, construct, and content) had been considered.

#### Data Version for Model Development

Although these new risk models were to be introduced in conjunction with the release of STS NCD version 2.61, they were developed with data collected under the three previous data versions (2.35, 2.41, and 2.52.1) because no 2.61 data were yet available. The QMTF began its predictor selection process with two caveats. First, any candidate variable had to be collected consistently across the three previous data versions. Second, it had to also be available in version 2.61 or have the ability to be mapped to this new version. For example, history of smoking and renal failure were not candidate variables as they were either not included in, or were unable to be mapped to, version 2.61. Renal function is now assessed by the last preoperative serum creatinine value, which is collected in all data versions. Because the definition of hypercholesterolemia has changed substantially over successive STS data versions, and because counterintuitive results have been observed in some previous analyses of hyper-

Table 1. Distribution of Risk Factors and Frequency of Adverse Outcomes in Overall Study Population, Isolated Coronary Artery Bypass Graft Surgery (2002–2006)

	Numl Pati		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Overall											
Total	774,881	100.0	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Age, years											
< 55	137,318	17.72	1.0	0.5	1.7	7.1	0.3	3.7	10.0	2.7	67.1
55–64	221,697	28.61	1.3	0.9	2.4	7.8	0.4	4.2	11.4	3.8	59.4
65–74	245,132	31.63	2.4	1.6	3.9	10.0	0.5	5.5	14.9	5.9	47.7
≥ 75	170,734	22.03	4.7	2.3	6.4	13.9	0.5	7.5	20.9	9.6	33.0
Sex											
Male	560,006	72.27	2.0	1.2	3.4	8.7	0.4	5.1	13.4	4.9	55.0
Female	214,875	27.73	3.4	1.9	4.1	12.2	0.5	5.6	17.0	7.2	41.5
Race											
Caucasian	665,941	85.94	2.3	1.3	3.5	9.3	0.4	5.1	13.9	5.3	52.2
Black	44,405	5.73	2.7	2.0	5.2	13.5	0.7	6.3	19.0	8.2	41.3
Hispanic	25,103	3.24	2.6	1.5	4.3	11.3	0.5	5.6	16.1	6.1	48.4
Asian	12,509	1.61	2.7	1.9	3.8	12.6	0.3	7.2	17.4	7.0	45.2
Other	21,222	2.74	2.3	1.3	3.6	10.4	0.5	5.5	14.8	6.0	48.7
Missing	5,701	0.74	2.3	1.4	4.1	9.4	0.4	5.2	14.5	6.1	48.9
Body surface area (m <sup>2</sup> )	-,						**-				
< 1.50	14,339	1.85	6.2	2.4	4.6	16.2	0.3	8.3	22.1	9.8	36.5
1.50–1.74	111,458	14.38	3.8	2.0	4.0	12.6	0.3	6.5	17.7	7.4	42.5
1.75–1.99	280,677	36.22	2.4	1.5	3.5	9.6	0.4	5.4	14.4	5.6	50.7
≥ 2.00	363,817	46.95	1.7	1.0	3.6	8.6	0.5	4.6	13.1	4.8	55.0
Missing	4,590	0.59	3.7	1.4	4.0	7.6	0.3	4.7	13.9	6.8	46.0
Body mass index (kg/m²)	4,070	0.07	0.7	1.1	1.0	7.0	0.0	1.7	10.7	0.0	10.0
< 25	169,091	21.82	3.3	1.7	3.5	11.0	0.3	6.7	16.3	6.7	47.6
25–29	303,371	39.15	2.1	1.3	3.1	8.6	0.3	4.9	13.1	4.8	54.2
30–34	186,148	24.02	1.8	1.2	3.6	9.0	0.5	4.5	13.4	5.0	53.1
≥ 35	110,213	14.22	2.3	1.2	5.2	12.0	0.8	4.9	16.8	6.8	45.7
Missing	6,058	0.78	3.7	1.4	4.2	8.6	0.3	4.8	14.5	6.7	47.2
Diabetes mellitus	0,030	0.70	0.7	1.1	1.4	0.0	0.0	1.0	14.5	0.7	17.2
No diabetes	492,800	63.60	2.1	1.2	2.8	8.8	0.3	5.0	13.0	4.7	54.8
Diabetes–noninsulin	195,421	25.22	2.3	1.6	4.3	10.1	0.5	5.2	15.2	6.0	48.2
Diabetes-insulin	84,406	10.89	3.6	1.8	7.1	13.9	1.0	6.5	20.6	9.7	37.5
Diabetes-missing treatment	1,439	0.19	3.1	2.2	4.6	11.1	0.7	4.6	15.7	8.8	41.9
Missing	815	0.13	3.8	0.7	2.6	8.8	0.5	4.5	12.3	6.9	43.7
Hypertension	013	0.11	3.0	0.7	2.0	0.0	0.5	4.5	12.5	0.9	43.7
No	167,260	21.59	1.9	0.9	2.2	8.1	0.3	4.6	11.7	4.2	58.2
Yes	606,813	78.31	2.5	1.5	4.0	10.1	0.5	5.4	15.1	5.9	49.3
Missing	808	0.10	3.8	0.7	2.4	9.3	0.5	5.2	12.7	6.7	43.9
Hypercholesterolemia	808	0.10	3.0	0.7	2.4	9.3	0.5	3.2	12.7	0.7	43.9
No	199,894	25.80	3.0	1.6	3.9	11.0	0.5	5.8	16.1	6.5	48.7
Yes	573,257	73.98	2.1	1.3	3.5	9.2	0.3	5.0	13.8	5.2	52.1
Missing	1,730	0.22	4.1	1.6	3.5	10.3	0.4	4.7	13.9	7.3	47.5
9	1,730	0.22	4.1	1.0	3.3	10.5	0.3	4.7	13.9	7.3	47.3
Past or present smoker No	295,999	38.20	2.4	1.4	3.7	9.0	0.4	E 1	13.9	E 2	50.1
			2.4	1.4			0.4	5.1		5.3	
Yes	477,911	61.68	2.3	1.3	3.6	10.1	0.5	5.3	14.7	5.7	51.9
Missing	971	0.13	3.4	0.7	3.1	9.9	0.4	5.3	13.5	9.1	41.0
Chronic lung disease	(10.011	70.01	2.0	1.0	2.2	0.4	0.2	4.0	12.0	4 7	F2 F
None	612,211	79.01	2.0	1.3	3.3	8.4	0.3	4.9	13.0	4.7	53.7
Mild	85,005	10.97	2.8	1.5	4.2	12.0	0.6	5.8	16.9	7.0	45.7
Moderate	47,745	6.16	3.8	1.6	5.3	15.8	0.8	6.8	20.8	9.6	39.5
Severe	22,302	2.88	7.0	2.0	7.7	22.8	1.1	9.5	29.0	15.3	29.2
Missing	7,618	0.98	2.6	1.4	3.2	8.2	0.2	3.9	12.6	5.7	53.4

Table 1. Continued

	Numb Patie		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Peripheral vascular disease											
No	653,260	84.30	2.0	1.2	3.2	8.8	0.4	4.8	13.1	4.8	53.5
Yes	120,480	15.55	4.4	2.3	6.1	14.4	0.7	7.5	21.2	9.6	38.7
Missing	1,141	0.15	3.9	1.1	3.1	11.8	0.3	5.5	14.4	7.4	43.9
Cerebrovascular disease											
No	668,073	86.22	2.1	1.1	3.3	9.0	0.4	4.9	13.4	5.0	53.4
Yes	105,792	13.65	4.0	2.9	5.8	14.0	0.6	7.2	20.7	9.3	37.7
Missing	1,016	0.13	3.2	0.6	2.4	8.9	0.3	4.2	11.4	6.8	43.2
CVA											
No CVA	717,721	92.62	2.2	1.2	3.4	9.3	0.4	5.1	13.8	5.2	52.5
Remote CVA (> 2 weeks)	53,341	6.88	4.2	3.1	6.1	15.3	0.7	7.4	22.0	10.3	35.5
Recent CVA ( $\leq$ 2 weeks)	1,763	0.23	5.0	4.9	6.5	18.8	0.9	8.7	25.4	13.0	32.5
CVA-missing timing	745	0.10	3.8	3.5	6.9	14.0	0.5	5.9	21.7	10.7	34.2
Missing	1,311	0.17	3.3	1.0	2.6	7.4	0.2	4.3	11.4	5.9	47.8
Endocarditis											
No endocarditis	773,002	99.76	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Treated endocarditis	472	0.06	4.4	0.8	5.3	15.3	0.6	8.5	19.9	8.9	33.7
Active endocarditis	110	0.01	2.7	1.8	6.3	20.0	1.8	11.8	24.5	20.0	41.8
Endocarditis-missing type	90	0.01	4.4	4.4	5.8	11.1	1.1	3.3	15.6	2.2	55.6
Missing	1,207	0.16	4.1	1.0	3.5	9.0	0.2	4.6	12.8	7.0	46.2
Renal failure											
No	731,626	94.42	2.1	1.3	3.2	9.0	0.4	5.0	13.4	5.0	52.8
Yes	42,153	5.44	7.2	2.7	14.7	22.5	1.0	9.9	31.9	15.8	23.4
Missing	1,102	0.14	3.1	0.8	2.8	7.4	0.3	3.4	10.8	6.4	46.6
Renal function											
Creatinine < 1.00 mg/dL	274,197	35.39	1.6	1.1	1.5	8.0	0.3	4.4	11.2	4.0	55.6
Creatinine 1-1.49 mg/dL	398,833	51.47	2.0	1.3	3.4	8.9	0.4	5.0	13.5	4.9	53.1
Creatinine 1.5-1.99 mg/dL	57,779	7.46	4.5	2.3	10.8	16.1	0.7	7.8	25.2	10.6	34.5
Creatinine 2.0-2.49 mg/dL	12,463	1.61	6.9	2.9	14.3	21.3	0.9	9.4	31.5	15.3	24.7
Creatinine $\geq 2.5 \text{ mg/dL}$	7,906	1.02	8.2	3.2	20.4	23.4	0.9	11.1	37.9	18.6	20.4
Dialysis	12,415	1.60	8.4	2.7	*NA	25.3	1.2	10.5	31.5	16.4	19.6
Missing	11,288	1.46	3.3	1.2	3.1	7.6	0.3	4.3	12.9	5.9	50.1
Immunosuppressive treatment											
No	758,368	97.87	2.3	1.4	3.6	9.6	0.4	5.2	14.2	5.4	51.5
Yes	14,976	1.93	5.4	1.8	6.3	15.6	0.8	8.7	22.5	10.8	37.0
Missing	1,537	0.20	3.3	0.8	2.8	6.5	0.4	4.6	11.4	6.1	46.8
Prior CABG Surgery											
No	735,033	94.86	2.2	1.4	3.5	9.4	0.4	5.1	14.1	5.4	51.7
Yes	36,693	4.74	5.3	1.6	5.8	14.7	0.5	7.5	20.9	7.8	42.6
Missing	3,155	0.41	2.7	1.1	3.3	8.9	0.5	4.8	12.9	6.8	48.9
Prior valve surgery											
No	769,434	99.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.3
Yes	2,280	0.29	5.9	1.9	6.8	15.3	0.7	8.6	22.5	11.1	32.0
Missing	3,167	0.41	2.9	1.2	3.5	8.6	0.5	4.4	12.7	6.3	50.0
Prior other cardiac surgery											
No	755,653	97.52	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.3
Yes	15,218	1.96	3.9	1.5	4.9	13.1	0.6	6.6	18.6	7.6	45.5
Missing	4,010	0.52	2.8	1.0	2.9	8.5	0.4	4.4	12.2	5.9	50.5
Number of previous CV surgeries											
No previous CV surgery	723,623	93.39	2.2	1.4	3.5	9.4	0.4	5.1	14.0	5.4	51.7
One prior CV surgery	40,474	5.22	4.7	1.6	5.4	13.8	0.5	7.3	19.9	7.7	44.1
Two or more prior CV Surgeries	4,840	0.62	6.2	1.4	5.6	14.7	0.6	8.0	22.0	8.4	41.5
Missing	5,944	0.77	2.9	1.1	3.2	9.8	0.6	5.5	14.3	6.1	51.2

Table 1. Continued

	Numb Patie		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Prior PCI											
No PCI	606,824	78.31	2.3	1.4	3.6	9.5	0.4	5.1	14.2	5.6	51.1
$PCI \le 6 \text{ hours}$	7,373	0.95	8.9	2.1	7.4	25.8	0.6	10.5	32.6	11.3	35.5
PCI > 6 hours	155,161	20.02	2.3	1.2	3.5	9.6	0.4	5.4	14.3	5.1	52.4
PCI-missing timing	2,456	0.32	3.0	0.6	3.3	8.0	0.8	5.1	13.4	6.8	48.9
Missing	3,067	0.40	3.3	1.0	3.0	9.8	0.5	4.7	13.7	6.2	47.3
Acuity status											
Elective	381,116	49.18	1.5	1.1	2.9	6.6	0.4	4.3	11.1	4.1	55.6
Urgent	356,287	45.98	2.4	1.5	3.9	10.8	0.5	5.6	15.7	6.2	48.5
Emergent	34,513	4.45	8.1	2.6	8.3	29.6	0.7	10.4	34.1	13.3	33.2
Emergent salvage	1,967	0.25	38.6	4.9	17.4	52.7	0.7	18.4	70.0	23.5	12.6
Missing	998	0.13	3.2	1.3	3.6	9.2	0.5	4.8	13.7	6.5	43.6
MI											
No prior MI	424,599	54.80	1.5	1.1	2.8	6.9	0.3	4.5	11.3	4.1	55.4
MI > 21 days	137,522	17.75	2.1	1.3	3.5	8.9	0.5	5.2	13.9	5.4	50.4
MI 8–21 days	26,205	3.38	4.0	1.8	6.0	14.4	0.8	7.5	20.7	10.2	38.1
MI 1–7 days	148,659	19.18	3.4	1.8	4.8	14.0	0.5	6.1	18.9	7.5	45.7
MI > 6 and < 24 hours	21,044	2.72	6.0	2.4	6.7	23.6	0.5	8.1	28.1	10.4	39.1
$MI \le 6 \text{ hours}$	11,539	1.49	10.4	2.6	8.6	31.2	0.6	10.6	36.8	13.3	33.5
MI-missing timing	4,064	0.52	3.6	1.6	4.6	11.3	0.5	5.6	17.5	7.2	43.9
Missing	1,249	0.16	2.1	1.1	2.4	6.6	0.2	3.8	10.2	6.7	49.4
Angina											
No	130,143	16.80	2.5	1.4	3.8	9.5	0.4	5.6	14.7	6.2	48.5
Yes	643,815	83.09	2.3	1.3	3.6	9.7	0.4	5.2	14.3	5.4	51.8
Missing	923	0.12	2.3	1.0	2.6	8.8	0.5	4.0	11.2	8.2	43.9
Cardiogenic shock											
No	758,766	97.92	2.0	1.3	3.4	8.9	0.4	5.0	13.6	5.2	51.9
Yes	14,919	1.93	18.0	3.6	14.6	49.6	1.0	15.3	55.7	23.1	18.3
Missing	1,196	0.15	2.7	1.1	3.2	8.0	0.4	4.4	12.0	7.4	44.7
Resuscitation	,										
No	766,674	98.94	2.2	1.3	3.5	9.4	0.4	5.1	14.1	5.4	51.5
Yes	6,939	0.90	17.1	3.0	11.4	37.5	0.9	14.0	46.1	18.2	24.3
Missing	1,268	0.16	2.2	0.8	3.4	8.0	0.6	3.9	11.5	7.3	45.0
Arrhythmia	,										
No arrhythmia	706,709	91.20	2.0	1.3	3.3	8.9	0.4	4.9	13.4	5.0	53.1
AFib/flutter	39,125	5.05	5.4	2.3	7.1	16.4	0.7	8.5	23.8	11.9	29.4
Heart block	10,026	1.29	5.8	1.9	6.8	16.8	0.6	9.2	24.2	9.4	36.4
Sustained VT/VF	14,336	1.85	8.2	2.0	6.8	23.8	0.6	11.1	31.5	12.0	33.0
Arrhythmia–other	1,853	0.24	3.8	1.6	5.3	12.9	0.6	6.5	19.1	7.3	39.2
Arrhythmia–missing type	1,344	0.17	3.9	1.7	4.4	11.9	0.7	7.3	17.5	8.3	37.9
Missing	1,488	0.19	2.7	1.0	3.0	7.1	0.5	3.8	11.1	6.5	45.5
Preoperative IABP	1,100	0.13	,	110	0.0	,,,	0.0	0.0	1111	0.0	10.0
No	714,824	92.25	2.0	1.3	3.3	8.0	0.4	4.9	12.8	4.9	52.8
Yes	58,134	7.50	6.9	2.2	7.7	30.8	0.6	9.6	34.4	12.9	32.0
Missing	1,923	0.25	4.2	1.7	4.3	10.9	0.6	5.8	16.0	7.2	45.7
NYHA class	1,720	0.20	1.2	1.7	1.0	10.7	0.0	3.0	10.0	7.2	10.7
I	97,812	12.62	1.5	1.1	2.5	6.3	0.3	4.4	10.6	3.9	57.0
II	187,947	24.25	1.3	1.1	2.6	6.5	0.3	4.2	10.7	3.8	56.5
III	287,760	37.14	2.0	1.3	3.6	9.0	0.3	5.0	13.9	5.4	51.3
IV	165,325	21.34	4.5	1.9	5.5	16.6	0.4	7.1	21.9	8.8	42.5
Missing	36,037	4.65	4.5 2.4	1.9	3.6	8.9	0.6	5.3	13.6	5.8	42.5 47.7
9	30,037	4.03	4.4	1.4	3.0	0.7	0.3	5.5	13.0	5.0	4/./
Congestive heart failure	666 E00	86.02	10	1.2	2.0	7.0	0.2	47	12.2	4.2	E4 7
No Voc	666,592 106,700	86.03	1.8	1.2	2.9	7.9	0.3	4.7	12.2	4.3	54.7
Yes	106,700	13.77	5.9	2.4	8.5	21.0	0.9	8.7	28.0	13.2	29.5
Missing	1,589	0.21	3.3	1.4	3.1	9.2	0.4	4.5	13.0	7.4	49.6

Table 1. Continued

	Number of Patients		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Number of diseased coronary vessels											
None	2,012	0.26	2.3	0.4	2.8	8.9	0.4	4.6	12.6	5.5	53.1
One	32,311	4.17	1.5	0.6	1.9	6.1	0.2	4.4	9.8	3.1	66.3
Two	150,881	19.47	1.8	1.0	2.7	8.0	0.4	4.5	12.0	4.5	56.3
Three	586,658	75.71	2.5	1.5	4.0	10.4	0.4	5.5	15.3	6.0	49.1
Missing	3,019	0.39	2.6	0.6	1.8	5.5	0.2	4.5	10.8	5.9	54.2
Left main disease ≥ 50%											
No	554,355	71.54	2.1	1.3	3.4	8.8	0.4	5.0	13.5	5.1	52.7
Yes	217,548	28.08	3.0	1.5	4.3	11.9	0.5	5.9	16.8	6.6	47.6
Missing	2,978	0.38	2.3	1.4	2.7	6.3	0.3	5.5	11.9	5.9	45.4
Ejection fraction (%)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,										
< 25	25,323	3.27	7.2	2.2	8.0	25.2	0.8	10.5	31.9	13.7	27.8
25–34	57,460	7.42	4.6	2.1	6.1	17.6	0.6	7.6	23.8	10.3	36.8
35–44	108,623	14.02	3.0	1.7	4.7	12.4	0.6	6.0	17.5	7.2	45.7
45–54	189,478	24.45	1.9	1.3	3.4	8.7	0.4	4.8	13.2	5.0	53.1
≥ 55	351,455	45.36	1.5	1.1	2.7	6.8	0.3	4.4	11.1	3.9	56.1
	42,542	5.49	3.4	1.4	4.1	10.8	0.3	5.6	16.0	6.1	50.0
Missing	42,342	3.49	3.4	1.4	4.1	10.6	0.4	3.0	10.0	0.1	30.0
Mitral stenosis	75.6.600	07.64	2.2	1.4	2.6	0.7	0.4	F 0	111		F1 0
No	756,609	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Yes	2,703	0.35	5.5	2.4	6.4	17.0	0.7	7.5	22.9	10.5	35.7
Missing	15,569	2.01	2.1	1.3	3.4	8.3	0.4	4.6	13.1	5.0	53.1
Aortic stenosis											
No	750,185	96.81	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.4
Yes	11,386	1.47	4.7	2.1	6.5	14.8	0.7	7.9	21.5	9.7	36.6
Missing	13,310	1.72	2.3	1.3	3.3	8.5	0.4	4.7	13.1	5.0	52.5
Tricuspid stenosis											
No	756,574	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	597	0.08	3.4	2.3	6.6	14.9	0.7	6.0	20.9	10.1	43.6
Missing	17,710	2.29	2.1	1.3	3.6	8.5	0.4	4.7	13.4	5.0	53.2
Pulmonic stenosis											
No	753,975	97.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	445	0.06	3.4	2.2	3.9	12.6	0.0	6.3	20.2	6.3	49.4
Missing	20,461	2.64	2.2	1.4	3.8	8.7	0.4	5.0	13.9	5.3	52.5
Mitral insufficiency											
None	622,173	80.29	2.1	1.2	3.3	8.9	0.4	4.9	13.4	5.0	53.2
Trivial	49,152	6.34	2.4	1.6	4.2	10.5	0.4	5.7	15.7	6.2	47.9
Mild	60,811	7.85	3.7	2.0	5.7	14.3	0.5	6.9	20.3	8.6	40.3
Moderate	16,723	2.16	6.7	2.7	7.9	20.1	0.7	9.6	28.0	12.5	30.3
Severe	2,143	0.28	8.7	3.1	8.9	24.1	0.6	11.0	32.6	15.1	28.2
Missing	23,879	3.08	2.1	1.2	3.0	7.5	0.4	4.7	12.0	5.2	51.5
Aortic insufficiency	20,019	3.00	2.1	1.2	3.0	7.0	0.1	1.7	12.0	0.2	01.0
None	705,771	91.08	2.3	1.3	3.5	9.5	0.4	5.1	14.1	5.4	51.9
Trivial M:14	17,988	2.32	3.6	2.1	5.6	13.4	0.5	7.0	19.4	8.3	40.9
Mild	18,571	2.40	4.1	2.2	5.9	14.3	0.4	7.3	20.8	9.0	37.9
Moderate	3,576	0.46	5.3	2.6	7.0	16.2	0.5	7.9	23.2	10.2	32.8
Severe	411	0.05	7.1	1.9	6.7	15.6	0.7	9.5	25.8	10.9	37.2
Missing	28,564	3.69	2.1	1.2	3.2	7.9	0.4	4.6	12.5	5.3	51.4
Tricuspid insufficiency											
None	675,778	87.21	2.2	1.3	3.4	9.4	0.4	5.1	13.9	5.3	52.1
Trivial	32,856	4.24	2.5	1.6	4.5	11.1	0.4	6.1	16.6	6.7	47.4
Mild	29,611	3.82	3.9	2.2	5.9	14.7	0.5	7.4	21.0	9.1	39.3
Moderate	5,753	0.74	7.6	3.0	9.0	22.7	0.5	9.8	30.2	13.7	26.9
Severe	728	0.09	9.1	2.9	10.5	24.2	0.4	10.9	33.0	17.2	26.2
Missing	30,155	3.89	2.2	1.2	3.2	7.9	0.4	4.6	12.6	5.2	51.7

Table 1. Continued

	Number of Patients		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Pulmonic insufficiency											
None	724,258	93.47	2.3	1.4	3.6	9.7	0.4	5.2	14.3	5.5	51.4
Trivial	10,726	1.38	2.8	1.5	4.3	12.3	0.5	6.5	17.3	7.3	44.8
Mild	4,867	0.63	3.8	2.1	5.6	14.1	0.4	7.4	21.0	9.1	39.7
Moderate	546	0.07	6.6	3.1	7.8	17.6	0.2	7.9	24.4	11.5	29.7
Severe	217	0.03	5.1	0.5	5.1	9.7	0.5	6.5	15.7	8.8	50.7
Missing	34,267	4.42	2.2	1.3	3.5	8.3	0.4	4.8	13.2	5.5	50.7

CABG = coronary artery bypass graft surgery; Comp = composite adverse outcome (any); DSWI = deep sternal wound infection; IABP = intra-aortic balloon pump; CVA = cerebrovascular accident (stroke); MI = mvocardial Mort = mortality; Na = not applicable; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; Reop = reoperation; RF = renal failure; PLOS = prolonged length of stay; SLOS = short length of stay; Vent = prolonged ventila-VT = ventricular tachycardia. VF = ventricular fibrillation;

cholesterolemia, a decision was made not to include this variable in the new models.

#### Predictor Frequency

For each variable, the QMTF explored the overall prevalence and missing data frequency per year. Predictor variables that are rarely present in the development sample are difficult to model. For this reason, mitral (0.35%), tricuspid (0.08%), and pulmonic stenosis (0.06%), pulmonic insufficiency (0.10%), and endocarditis (0.09%) were not considered as variables in the new isolated CABG models.

#### Inconsistently Coded Variables

A few variables have been collected inconsistently or with questionable reliability, often for clinically unavoidable reasons. For example, pulmonary artery mean pressure data were missing for 70% of patients during 2002 to 2006. Furthermore, the value of this continuous variable may vary substantially depending on the clinical state and volume-loading status of the patient when the measurement is obtained. Because of these concerns, pulmonary artery pressure was not included in the models.

#### Derived or Redundant Variables

Several derived variables were considered for inclusion in the models. For example, body mass index (BMI) is a useful measure of overall body habitus. However, because BMI is highly correlated with body surface area (BSA), the more commonly used anthropometric measure in most previous STS models, the latter was retained in the new models. Similarly, there is a theoretical superiority to inclusion of glomerular filtration rate (GFR) rather than serum creatinine as a measure of renal function. However, the Modification of Diet in Renal Disease formula for estimating GFR is a complex function of creatinine, race, sex, and age, and not all laboratories perform this calculation automatically. Furthermore, as age, sex, and race are already model covariates, using GFR would complicate the interpretation of their regression coefficients. Some of the prognostic value of GFR

comes from these variables that are already included in the model. Finally, previous studies suggest that various measures of renal function used in CABG mortality risk models have similar performance [19]. For all these reasons, serum creatinine was retained as the measure of renal function.

#### Controversial Variables

RACE. Several variables raised particular clinical, statistical, or health policy issues. For example, race was an obvious candidate variable because it was a significant predictor (p < 0.001) of each endpoint except mortality and because the proportion of nonwhite patients varied substantially across institutions. In exploratory analyses, the association between race and outcomes persisted after adjusting for hospital identity, suggesting that this association is not explained by differences in hospital quality.

However, general principles of risk model development complicated the decision as to whether or not to include race in the models. When the dominant purpose of a risk model is adjustment of provider results, it is advisable to include only biological and clinical patient variables that are present before a patient's first contact with the provider. In this context, race is clearly a fixed biological characteristic, but its impact on patient outcomes may be mediated through other mechanisms. It is possible that certain racial and ethnic groups have worse outcomes not because of inherent biological characteristics but because of differences in the quality of care delivered to them. In this case, including race and ethnicity in a risk model could essentially select out or obscure the very disparity issues that society wishes to identify and correct. Inclusion of race and ethnicity in a risk model would say, in effect, that we expect nonwhites to have inferior results and would make an allowance for providers who care for such patients, just as we would for providers who care for patients in cardiogenic shock.

After deliberation regarding the pros and cons, the QMTF ultimately elected to retain race and ethnicity in the new models because of their impact on outcomes,

#### Table 2. Initial List of Potential Candidate Variables

#### Demographics

- 1. Age
- 2. Sex
- 3. Race (black, Caucasian, Hispanic, Asian, Native American, other)

Note: Data collection changed in v2.61. New version allows for multiple races (check all that apply). Added Hawaiian/Pacific Islander category. Hispanic ethnicity is a separate variable.

#### Anthropometric

- 4. Height
- 5. Weight

#### Status

- 6. Status (elective, urgent, emergent, salvage)
- 7. Shock
- 8. Resuscitation

#### Cardiac variables

9. Angina, angina type (STS categories are unstable, stable, no angina)

Note: Angina was removed on v2.61 data collection form. The new form has a variable called "cardiac presentation on admission." Angina is one of possible response categories to that field.

10. New York Heart Association functional class

Note: In v2.61, NYHA class is only collected if patient has congestive heart failure.

- 11. Arrhythmia and arrhythmia type (sustained VT/VF; heart block; AFib/flutter, None)
- 12. Myocardial infarction timing: ( $\leq 6$ , > 6 and < 24 hours; 1–7, 8–21, > 21 days)

#### Hemodynamic/catheterization variables

- 13. Ejection fraction
- 14. Number of diseased vessels (0, 1, 2, 3)
- 15. Left main disease
- 16. Pulmonary artery mean pressure
- 17. Mitral stenosis
- 18. Aortic stenosis
- 19. Tricuspid stenosis
- 20. Pulmonic stenosis
- 21. Mitral insufficiency (none, trivial, mild, moderate, severe)
- 22. Aortic insufficiency (none, trivial, mild, moderate, severe)
- 23. Tricuspid insufficiency (none, trivial, mild, moderate, severe)
- 24. Pulmonic insufficiency (none, trivial, mild, moderate, severe)

#### Comorbidities

- 25. Serum creatinine
- 26. Dialysis
- 27. Renal failure

Note: This variable was removed in v2.61.

- 28. Endocarditis (active, treated, none)
- 29. Diabetes and treatment (insulin, oral, diet, untreated, no diabetes)
- 30. Chronic lung disease (none, mild, moderate, severe)
- 31. Congestive heart failure
- 32. Peripheral vascular disease
- 33. Cerebrovascular disease
- 34. CVA and CVA timing (recent, remote, none)

Note: CVA is a child field of cerebrovascular disease in v2.61.

35. Hypercholesterolemia (v2.35, v2.41) and Dyslipidemia (v2.52)

Note: Data from all 3 versions were merged and analyzed under the variable name "hypercholesterolemia."

- 36. Hypertension
- 37. Smoker

Note: Major definition change in v2.61.

#### Preoperative interventions

- 38. Preoperative intra-aortic balloon pump
- 39. Preoperative inotropes
- 40. Immunosuppressive treatment
- 41. Prior percutaneous coronary intervention and timing ( $\leq$  6 hours, > 6 hours, none)

#### **Previous Interventions**

- 42. Prior coronary artery bypass graft surgery
- 43. Prior valve surgery
- 44. Prior other cardiac surgery
- 45. Number of previous cardiovascular surgeries

while recognizing the potential limitations of this decision.

PREOPERATIVE INTRA-AORTIC BALLOON PUMP. Preoperative intra-aortic balloon pump (IABP) is a proxy for more serious preoperative status of the patient (eg, unstable angina, ventricular dysfunction). It captures information that may not be present in other data elements, and it is associated with higher risk of postoperative morbidity and mortality. For these reasons, most CABG risk models include preoperative IABP as a risk predictor. However, placement of an IABP is also a highly discretionary care process the frequency of which varies widely among participating institutions. Indications are subjective and are often dictated by the cardiologist before even referring the patient for cardiac surgery. Based on CABG risk models, an institution that liberally utilizes IABPs will have a higher expected risk of morbidity and mortality (according to the model) compared with another institution with a similar case-mix but a more restrictive IABP policy. That would impact their relative O/E ratios and risk-adjusted outcomes.

Despite its discretionary nature (and the potential for gaming), the QMTF decided to retain IABP use in the models because it is such an important predictor. Ultimately, it was elected to model preoperative IABP as a joint variable with preoperative inotrope use as an overall measure of preoperative acuity/severity.

#### Review of External Sources

The QMTF also reviewed multiple external resources to aid in the selection of potential candidate variables [15, 16, 20]. First, all previous versions of the STS CABG risk models were reviewed. The QMTF also examined other CABG risk models including the European System for Cardiac Operative Risk Evaluation (EuroSCORE) [21], the New York Cardiac Surgery Reporting System [22], the Veterans Affairs Administration cardiac surgery models [23, 24], and the Northern New England Cardiovascular Disease Study Group model [25, 26]. We particularly wanted to identify variables that were found in some form across all the risk models. Subject to the constraints of version 2.61 data specifications, we made a special effort to include such variables in the new STS risk models, in some instances requiring us to "force" them into the models, as described in the section on the final variable selection procedure.

#### Missing Data

Missing data in the STS NCD are rare, having a frequency of less than 1% for most variables. Candidate predictor variables missing most commonly were ejection fraction (5.5%), New York Heart Association (NYHA) class (4.7%), tricuspid insufficiency (3.9%), aortic insufficiency (3.7%), mitral insufficiency (3.1%), aortic stenosis (1.7%), and creatinine/dialysis (1.5%).

Missing predictor values in the STS NCD were managed using imputation. Multiple imputation is the generally preferred statistical method [27], but single imputation was also considered based on the following

practical considerations: (a) the fraction of missing data in the STS NCD was small and, hence, single and multiple imputation would likely give similar point estimates; (b) a slight adjustment to the standard errors would not impact the study conclusions or the published risk algorithms; (c) the large sample size would make multiple imputation less practical to implement because of long computational times.

Prior to selecting an imputation strategy, exploratory analyses were performed using CABG data from 2002 to 2003 to compare single versus multiple imputation results for predicting mortality. These analyses confirmed that the choice between single versus multiple imputation would have only a slight impact on regression coefficients. For example, the estimated odds ratio for a 5-unit increase in ejection fraction was 0.90 (with a 95% confidence interval extending from 0.83 to 0.97) under single imputation and was 0.92 (with a confidence interval extending from 0.85 to 0.99) under multiple imputation. Other variables were missing less frequently than ejection fraction and were even less sensitive to the choice between single versus multiple imputation. Additional analyses of missing data consisted of reestimating the final model coefficients using single versus multiple imputation and comparing results. A summary of these investigations, as well as model coefficients and covariance matrices, are available at www.sts.org/riskmodels. For most patients, if risk were calculated using the multiple imputation model instead of single imputation, the relative change in their risk estimate would only be 1% to 2% (eg, 5% to 5.1% is a 2% change).

Based on the considerations described above, single imputation was used with the following specific rules: (1) binary (yes/no) risk factors were modeled as yes versus no or missing. Missing data for such variables usually implies their absence, and for most binary variables the composite event rates were similar for "no" and "missing" categories; (2) missing data on categorical predictor variables were imputed to the lowest risk value, which, in most instances, was the mode. In most instances, composite event rates for patients with missing data were among the lowest. It is the policy of the STS Data Warehouse and Analysis Center to discourage missing data through this default coding practice; and (3) missing data on continuous predictor variables were imputed to the conditional median. For ejection fraction, we conditioned on congestive heart failure (CHF) and sex. For BSA, we conditioned on sex. For serum creatinine, we conditioned on renal failure (although this approach will be modified when the model is ultimately applied to version 2.61 data, as renal failure has been removed).

For model endpoints (eg, mortality), missing data were handled by modeling yes versus no or missing. Thus, cases with missing data for an endpoint were analyzed as if the endpoint did not occur. Complete case analysis was not used because "missing" was not considered to be consistently coded for these variables. For example, some STS data managers have reported that they set complications to "no" unless there is explicit documentation in the medical record that the complication occurred. Other

data managers may leave the field missing unless there is explicit documentation that the complication did not occur. Thus, missing data may reflect differences in coding practices rather than truly unknown or missing data.

## Preliminary Analyses for Ordinal Categorical Variables and Continuous Variables

The QMTF conducted preliminary analyses to determine how best to model ordinal categorical variables and continuous variables. Categorical variables were entered into a logistic regression model by including a separate parameter for each category. Continuous variables were entered as piecewise linear functions (splines) with several changes of slope (knots). Terms were then removed one at a time using backward selection based on the Wald statistic. At each iteration, either two adjacent categories were collapsed into a single category or else two adjacent line segments were collapsed into a single line with no change of slope. The backward selection terminated when all adjacent categories and slopes were statistically different from one another at p < 0.001. This variable selection routine was performed separately for each endpoint. An expert panel determined the final coding based on the results of the backwards selection algorithm, supplemented by their clinical judgment and practical considerations. Table 3 summarizes these coding decisions.

#### **Specific Coding Decisions**

RACE AND ETHNICITY. In versions 2.35, 2.41, and 2.52.1, race was collected by choosing one of the following mutually exclusive response categories: Caucasian, black, Hispanic, Asian, Native American, and other. In version 2.61, the data collection form was modified to conform to standards adopted by the US Census Bureau. It allows for selecting one or more races per patient (ie, select all that apply), and treats ethnicity (Hispanic versus non-Hispanic) as a separate variable. Because of these differences, the mapping of race among data versions is not straightforward.

Ultimately, the QMTF decided to model race as black, Asian, Hispanic, and Caucasian/other (collapsed). Initially, these categories will be mapped to version 2.61 as follows: (1) black will include all black patients, regardless of ethnicity or additional races; (2) Hispanic will include all nonblack Hispanic patients; (3) Asian will include all Asian patients who are not also identified as black or Hispanic; and (4) all remaining patients will be placed in the Caucasian/other category. The validity of this mapping will be assessed once 2.61 data become available and future versions could employ race "bridging" methodologies.

BODY SURFACE AREA. Height and weight were replaced by BSA, which was modeled as a quadratic trend to allow for a possible U-shaped relationship with outcomes (eg, extreme obesity and cachexia). This quadratic polynomial was modeled separately for males and females. Any BSA values below 1.4 or above 2.6 were mapped to these

values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

ANGINA. Version 2.61 of the data collection form eliminates angina and substitutes a new variable called "cardiac presentation on admission," within which unstable angina is one of the possible response categories. The QMTF believed that unstable angina would be coded more consistently than any other angina class, and also that this was the most important type of angina presentation to include in the models. Angina coding was therefore restricted in the new risk models to "unstable angina without MI < 7 days (yes/no)." It was necessary to exclude patients with myocardial infarction less than 7 days because the new version 2.61 does not permit simultaneous coding of angina and acute myocardial infarction.

REOPERATIVE STATUS. The most important consideration with regard to reoperative status is the number of prior sternotomies, irrespective of the specific type of procedure performed. The revised models replaced prior CABG, prior valve, and prior "other" cardiac surgery with simply the number of previous cardiovascular surgeries.

ACUITY STATUS. The new models combine resuscitation with salvage status. By definition, all salvage patients should have resuscitation coded "yes."

NUMBER OF DISEASED CORONARY VESSELS. Outcomes are modeled using the number of diseased vessels (grouped as 0 or 1 versus 2 versus 3), as a linear effect across the three categories. This approach is consistent with the previous STS CABG models and was supported by the data.

NYHA CLASS. Version 2.61 uses NYHA class as a subfield of CHF. The grouping of NYHA IV versus less than IV (I–III) classes is consistent with all existing STS models. The final categories were no CHF, CHF not NYHA IV, and CHF plus NYHA IV.

AGE. Age was modeled as a linear spline with knots at ages 50 and 60 years.

EJECTION FRACTION. Ejection fraction (EF) was modeled linearly, and EFs below 10% and above 50% were mapped to these values respectively. Only 0.03% of patients have EFs lower than 10%; such values are considered invalid and are treated like missing data. The coding decision regarding EF values above 50% was based on preliminary analyses in which the data were used to suggest the functional form of continuous variables.

CREATININE. Creatinine was modeled as a linear spline with knots at 1.0 and 1.5. Creatinine levels less than 0.5 or greater than 5.0 were mapped to these values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

MORTALITY AND LENGTH OF STAY. The QMTF changed the previous STS definition of the "short postoperative length of stay (SLOS)" endpoint. The original definition did not specifically exclude early postoperative deaths, and such patients could have been inappropriately included with the remaining SLOS patients who had a particularly short and uncomplicated postoperative course. In the new models, patients who die within 5 days of surgery are included in the analysis but are not counted as a short stay.

Table 3. Final List of Candidate Variables and Coding For STS Risk Models

Candidate Variables	Coding
Continuous variables	
Age <sup>a</sup>	Linear spline with knots at 50 and 60.
Ejection fraction <sup>a</sup>	Linear; values $>$ 50 are mapped to 50. Only 0.03% of patients have ejection fraction $<$ 10, and that is presumed to be a data entry error these values are considered invalid and are treated like missing data. The decision to consolidate values $>$ 50 was based on initial exploratory analyses in which data were used to suggest the functional form of continuous variables.
Body surface area <sup>a</sup>	Quadratic polynomial modeled separately for males and females. Note: body surface areas $< 1.4$ and $> 2.6$ were mapped to these values, respectively. <sup>c</sup>
Creatinine <sup>a</sup>	Linear spline with knots at 1.0 and 1.5. (Only for patients not on dialysis.) Note: Creatinine values < 0.5 and > 5.0 were mapped to these values, respectively.
Time trend <sup>a</sup>	Ordinal categorical variable with separate category for each 6-month harvest interval.
Binary variables	
Dialysis <sup>a</sup>	Yes/no
Preoperative atrial fibrillation <sup>b</sup>	Yes/no
Shock	Yes/no
Female <sup>a</sup>	Yes/no
Hypertension	Yes/no
Immunosuppressive treatment	Yes/no
Percutaneous coronary intervention $\leq$ 6 hours	Yes/no
Preoperative intra-aortic balloon pump or inotropes	Yes/no
Peripheral vascular disease	Yes/no
Unstable angina (no myocardial infarction < 7 days)	Yes/no
Left main disease	Yes/no
Aortic stenosis	Yes/no
Aortic insufficiency	Defined as at least moderate (yes/no)
Mitral insufficiency	Defined as at least moderate (yes/no)
Tricuspid insufficiency	Defined as at least moderate (yes/no)
Categorical variables	· ·
Chronic lung disease	4 groups: (1) none, (2) mild, (3) moderate, (4) severe
CVD/CVA	3 groups: (1) no CVD, (2) CVD no CVA, (3) CVD + CVA
Diabetes mellitus	3 groups: (1) insulin diabetes, (2) noninsulin diabetes, (3) other or no diabetes
Number diseased coronary vessels	3 groups: (1) fewer than 2 diseased vessels, (2) 2 disease vessels, (3) 3 diseased vessels; modeled as linear across the categories.
Myocardial infarction	4 groups: (1) $\leq$ 6 hours, (2) $>$ 6 and $<$ 24 hours, (3) 1 to 21 days, (4) $>$ 21 days or no myocardial infarction.
Race	4 groups: (1) black, (2) Asian, (3) Hispanic, (4) other, including Caucasian
Status	4 groups: (1) elective, (2) urgent, (3) emergent, no resuscitation, (4) salvage or emergent with resuscitation
Previous cardiovascular operations	3 groups: 0 previous, 1 previous, 2 or more previous
CHF and NYHA class	3 groups: no CHF, CHF not NYHA IV, CHF + NYHA IV
Interactions	
Age by reoperation <sup>a</sup>	
Age by emergent status <sup>a</sup>	

<sup>&</sup>lt;sup>a</sup> These variables were forced into each model. <sup>b</sup> Preoperative atrial fibrillation was forced into the model for stroke. <sup>c</sup> These are the approximate 1st and 99th percentiles of the empirical distribution. Values less than 1.4 were mapped to 1.4. Values greater than 2.6 were mapped to 2.6. Estimates in the extreme tails of the body surface area distribution are highly influenced by data from other regions of the body surface area distribution (owing to use of a parametric, quadratic model) and may not be reliable. <sup>d</sup> These are approximately the 1st and 99th percentiles of the empirical distribution. Although we used a flexible spline model, linear splines can have unreliable extreme results in the tails due to the assumption that the effect is linear above the largest knot and below the smallest knot.

Table 4. Discrimination of Models (C-Index)

New STS	models—devel	opment sample	(C-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.810	0.716	0.795	0.756	0.706	0.657	0.724	0.769	0.727
New STS	models—valida	ntion sample (C	-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.812	0.720	0.793	0.754	0.689	0.653	0.725	0.767	0.726
Old STS r	nodels—validat	tion sample (C-	index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.807	0.713	0.750	0.742	0.672	0.645	0.711	0.754	0.713
		outcom a (amy).	CVAt1	DCMI — 1		stion. Most – se	t-lit DI OC	

 $\begin{array}{lll} Comp = composite \ adverse \ outcome \ (any); & CVA = stroke; \\ length \ of \ stay; & Reop = reoperation; & RF = renal \ failure; \\ prolonged \ ventilation. & \end{array}$ 

 $\begin{aligned} DSWI &= \text{deep sternal wound infection;} &\quad Mort &= \text{mortality;} &\quad PLOS &= \text{prolonged} \\ SLOS &= \text{short length of stay;} &\quad STS &= \text{The Society of Thoracic Surgeons;} &\quad Vent &= \end{aligned}$ 

#### Final Variable Selection Procedure

#### Backward Selection

Using the remaining candidate variables and the coding schemes described previously, a supervised backward selection approach was then performed. Initial variable selection used the Wald  $\chi^2$  statistic with a significance criterion of 0.001. This high level of significance was chosen because of the very large sample size that resulted in quite small p values. An expert panel of cardiothoracic surgeons and biostatisticians then reviewed the selected variables and made several modifications. Measures of model performance (discrimination and calibration) were similar when all variables were retained in the models regardless of statistical significance or expert panel review.

#### Forced Variables

Several variables were included in the models regardless of statistical significance. These included all of the continuous variables (age, BSA, date of surgery [in 6-month intervals], creatinine, ejection fraction), plus sex and dialysis. In addition, atrial fibrillation was included a priori in the model for permanent stroke.

The rationale for including surgery date, a nonmodifiable variable of no intrinsic interest, was to adjust for changes in the frequency of adverse outcomes over the 5-year study period. We adjusted for surgery date to reduce potential confounding by time trends when estimating regression coefficients for variables that are of primary interest, such as preoperative clinical characteristics. For example, temporal changes in the frequency of coding for dyslipidemia, if they occur coincidentally with a secular declining trend in mortality rates, may lead to the unwarranted causal inferences unless there is adjustment for surgery date.

Date of surgery was categorized by 6-month intervals (corresponding to STS data harvests) and modeled as a linear trend across the ordinal categories. Surgery date is not included in the final risk algorithm and a patient's predicted risk is not dependent upon it. The intercept

parameter published in the Appendix has been adjusted to incorporate the time trend, and it reflects the baseline risk for a reference period of July to December 2006.

#### Interaction Terms

These models focused on main effects, and the final models included only four sets of preselected variable interactions: (1) sex by BSA; (2) sex by BSA squared; (3) age by reoperation; (4) age by emergent status. More extensive investigation for interactions was considered, including nonlinear, machine-learning approaches. However, the incremental value of such approaches remains uncertain [28], and interpretability can also become more problematic with numerous interaction terms.

Although multiple terms were allotted for modeling the main effects of age and reoperation, only a single degree of freedom was allotted for their interaction. The models defined a single variable interaction term for age and reoperation. It was equal to the patient's age minus 50 if the patient was at least 50 years old and had a previous CV surgery; otherwise it was equal to zero. This term represents the difference in the change of the slope of age at age 50 for patients who have had at least one previous CV surgery compared with patients who have not had a previous CV surgery. Similarly, only one degree of freedom was allotted for the interaction between age and status. The interaction represents the difference in the change of the slope of age at age 50 for patients with emergent or salvage status compared with patients with elective or urgent status. Although these interaction terms complicate the interpretation of other model variables, this was considered to be acceptable because the main focus of the analysis was prediction, not effect estimation.

#### Results

#### Model Performance

Table 4 presents the discrimination of each of the isolated CABG models as well as a comparison with the previous

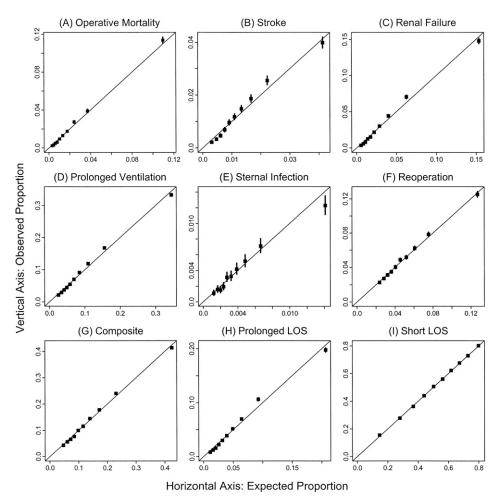


Fig 1. Plots of observed (O) versus expected (E) in validation sample

STS CABG risk models. For the new CABG models, discrimination ranged from 0.657 to 0.810 in the development sample and from 0.653 to 0.812 in the validation sample. The close agreement between c-indices from the development and validation samples reflects the large sample size and suggests that the models did not overfit the data. When the discrimination of the new and previous STS models were compared using the validation sample, the c-index of the new model was larger for each endpoint.

The Hosmer-Lemeshow test is not reported as an overall measure of calibration for these models because of its sensitivity to sample size. With samples as large as those used to develop these models, the null hypothesis will inevitably be proven false, given that all such models are only approximations [29]. As an alternative to such global measures of calibration, Figure 1 shows plots of observed versus expected event proportions within deciles of predicted risk for a variety of endpoints. For each endpoint, the absolute difference between the observed and expected proportions was less than 1.5% in each decile category. Additional analyses of model fit and discrimination are available online at www.sts.org/riskmodels.

#### Final Models

After calculating these measures of model performance, the final regression coefficients were estimated from the combined training and validation samples. Odds ratios for each predictor variable and model endpoint are summarized in Table 5. "Not applicable" indicates that the specific predictor was not included in a particular risk model. These final models were estimated using generalized estimating equations with empirical (sandwich) standard error estimates to account for clustering of patients within institutions [30]. An independence working correlation matrix was used to apply the generalized estimating equations method. With this approach, the estimated regression coefficients were identical to those obtained using ordinary logistic regression, but the standard errors were adjusted to account for correlated observations within hospitals.

#### Final Model Intercept and Coefficients

The Appendix contains the algorithm, intercept and coefficients for the final STS 2008 CABG risk models. The variance/covariance matrix is available on the web at www.sts.org/riskmodels. An on-line risk calculator is available at http://209.220.160.181/STSWebRiskCalc261/.

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Table 5. Estimated Odds Ratios for CABG Mortality, Morbidity, and Length of Stay Models

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50 (no reoperation, elective)	1.36 (1.24, 1.49)	1.78 (1.58, 1.99)	1.24 (1.16, 1.33)	1.06 (1.02, 1.10)	1.43 (1.23, 1.67)	1.14 (1.09, 1.19)	1.08 (1.05, 1.11)	1.35 (1.27, 1.43)	0.77 (0.75, 0.78)
Age 70 versus 50 (no reoperation, elective)	2.53 (2.31, 2.76)	2.43 (2.19, 2.71)	1.93 (1.81, 2.07)	1.42 (1.37, 1.47)	1.70 (1.47, 1.97)	1.45 (1.39, 1.51)	1.49 (1.44, 1.53)	2.17 (2.05, 2.29)	0.44 (0.43, 0.45)
Age 80 versus 50 (no reoperation, elective)	4.70 (4.29, 5.15)	3.34 (2.99, 3.72)	3.01 (2.80, 3.24)	1.90 (1.82, 1.99)	2.02 (1.73, 2.36)	1.85 (1.76, 1.94)	2.05 (1.98, 2.12)	3.48 (3.28, 3.69)	0.25 (0.24, 0.26)
BSA 1.6 versus 2.0 among females	1.26 (1.19, 1.32)	1.15 (1.08, 1.23)	0.84 (0.80, 0.89)	1.03 (1.00, 1.06)	0.49 (0.43, 0.57)	1.23 (1.18, 1.28)	1.03 (1.01, 1.06)	0.94 (0.90, 0.97)	1.17 (1.14, 1.20)
BSA 1.6 versus 2.0 among males	1.75 (1.64, 1.86)	1.19 (1.08, 1.31)	1.24 (1.17, 1.32)	1.40 (1.34, 1.46)	0.77 (0.63, 0.93)	1.40 (1.33, 1.46)	1.35 (1.30, 1.40)	1.43 (1.36, 1.50)	0.79 (0.77, 0.82)
BSA 1.8 versus 2.0 among females	1.02 (0.99, 1.05)	1.07 (1.03, 1.11)	0.86 (0.84, 0.88)	0.95 (0.94, 0.97)	0.67 (0.63, 0.71)	1.06 (1.04, 1.08)	0.96 (0.94, 0.97)	0.90 (0.88, 0.92)	1.14 (1.13, 1.16)
BSA 1.8 versus 2.0 among males	1.20 (1.17, 1.23)	1.09 (1.05, 1.13)	1.02 (1.00, 1.04)	1.09 (1.07, 1.10)	0.85 (0.79, 0.91)	1.13 (1.11, 1.15)	1.08 (1.07, 1.09)	1.10 (1.08, 1.12)	0.96 (0.95, 0.97)
BSA 2.2 versus 2.0 among females	1.20 (1.14, 1.27)	0.95 (0.88, 1.02)	1.32 (1.27, 1.37)	1.18 (1.15, 1.22)	1.62 (1.51, 1.74)	1.03 (1.00, 1.07)	1.19 (1.16, 1.21)	1.28 (1.24, 1.32)	0.78 (0.77, 0.80)
BSA 2.2 versus 2.0 among males	1.01 (0.99, 1.03)	0.92 (0.90, 0.95)	1.17 (1.15, 1.19)	1.10 (1.08, 1.11)	1.27 (1.22, 1.32)	0.97 (0.96, 0.99)	1.07 (1.06, 1.08)	1.08 (1.07, 1.10)	0.90 (0.89, 0.91)
Creatinine 1.5 versus 1.0	1.66 (1.57, 1.76)	1.39 (1.30, 1.49)	3.36 (3.16, 3.58)	1.56 (1.51, 1.62)	1.44 (1.28, 1.62)	1.33 (1.28, 1.38)	1.76 (1.70, 1.82)	1.65 (1.59, 1.72)	0.69 (0.67, 0.71)
Creatinine 2.0 versus 1.0	1.94 (1.84, 2.04)	1.49 (1.39, 1.58)	4.06 (3.83, 4.31)	1.73 (1.68, 1.79)	1.47 (1.30, 1.65)	1.44 (1.40, 1.49)	2.05 (1.98, 2.11)	1.92 (1.86, 2.00)	0.55 (0.53, 0.57)
Creatinine 2.5 versus 1.0	2.26 (2.14, 2.39)	1.59 (1.47, 1.71)	4.90 (4.61, 5.21)	1.92 (1.85, 1.99)	1.50 (1.30, 1.72)	1.57 (1.51, 1.64)	2.39 (2.30, 2.48)	2.24 (2.15, 2.34)	0.44 (0.42, 0.46)
Dialysis versus no dialysis and creatinine = 1.0	3.84 (3.54, 4.16)	1.67 (1.48, 1.88)	NA	2.85 (2.68, 3.03)	2.13 (1.78, 2.56)	1.86 (1.73, 2.00)	2.46 (2.33, 2.60)	2.80 (2.63, 2.98)	0.27 (0.25, 0.29)
EF per 10-unit decrease	1.19 (1.17, 1.22)	1.14 (1.11, 1.16)	1.08 (1.06, 1.10)	1.18 (1.16, 1.20)	1.11 (1.07, 1.16)	1.11 (1.09, 1.13)	1.16 (1.15, 1.18)	1.17 (1.15, 1.19)	0.84 (0.83, 0.85)
Preoperative atrial fibrillation	1.36 (1.28, 1.44)	1.21 (1.12, 1.30)	1.24 (1.18, 1.30)	1.20 (1.16, 1.24)	NA	1.26 (1.21, 1.31)	1.24 (1.21, 1.28)	1.42 (1.37, 1.48)	0.61 (0.59, 0.63)
CHF not NYHA IV	1.21 (1.15, 1.28)	NA	1.36 (1.30, 1.43)	1.31 (1.26, 1.35)	1.33 (1.19, 1.48)	1.16 (1.11, 1.21)	1.27 (1.23, 1.31)	1.43 (1.38, 1.48)	0.72 (0.70, 0.75)
CHF NYHA IV	1.39 (1.31, 1.47)	NA	1.35 (1.28, 1.42)	1.52 (1.45, 1.59)	1.45 (1.25, 1.67)	1.26 (1.20, 1.32)	1.48 (1.42, 1.54)	1.50 (1.44, 1.57)	0.65 (0.61, 0.68)
Chronic lung disease, mild	1.22 (1.16, 1.29)	NA	1.14 (1.08, 1.21)	1.36 (1.31, 1.41)	1.56 (1.40, 1.73)	1.11 (1.07, 1.15)	1.23 (1.19, 1.27)	1.34 (1.29, 1.39)	0.79 (0.76, 0.82)
Chronic lung disease, moderate	1.40 (1.32, 1.49)	NA	1.25 (1.18, 1.33)	1.65 (1.57, 1.73)	1.80 (1.58, 2.06)	1.20 (1.14, 1.26)	1.42 (1.36, 1.47)	1.65 (1.58, 1.73)	0.68 (0.65, 0.71)
Chronic lung disease, severe	2.35 (2.19, 2.52)	NA	1.66 (1.54, 1.79)	2.37 (2.24, 2.51)	2.40 (2.06, 2.79)	1.54 (1.44, 1.64)	1.98 (1.90, 2.07)	2.46 (2.34, 2.60)	0.48 (0.45, 0.51)
CVD with CVA	1.31 (1.24, 1.38)	2.09 (1.96, 2.22)	1.18 (1.12, 1.23)	1.35 (1.31, 1.39)	NA	1.21 (1.17, 1.26)	1.32 (1.29, 1.36)	1.45 (1.40, 1.51)	0.70 (0.68, 0.72)

Table 5. Continued

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
CVD without CVA	1.14 (1.08, 1.20)	1.65 (1.54, 1.75)	1.11 (1.06, 1.17)	1.15 (1.11, 1.18)	NA	1.12 (1.08, 1.17)	1.17 (1.14, 1.20)	1.14 (1.10, 1.18)	0.85 (0.81, 0.89)
Diabetes, insulin dependent	1.30 (1.24, 1.37)	1.19 (1.12, 1.27)	1.80 (1.72, 1.87)	1.22 (1.18, 1.26)	2.24 (2.02, 2.48)	1.14 (1.10, 1.18)	1.30 (1.27, 1.34)	1.59 (1.53, 1.64)	0.64 (0.62, 0.66)
Diabetes, noninsulin dependent	1.01 (0.97, 1.06)	1.16 (1.11, 1.22)	1.32 (1.28, 1.36)	1.04 (1.02, 1.07)	1.38 (1.27, 1.49)	0.98 (0.96, 1.01)	1.08 (1.06, 1.10)	1.15 (1.12, 1.17)	0.87 (0.86, 0.88)
Diseased vessels (2 versus 1, or 3 versus 2)	1.17 (1.12, 1.23)	1.35 (1.29, 1.42)	1.23 (1.19, 1.27)	1.19 (1.16, 1.22)	1.15 (1.07, 1.24)	1.07 (1.05, 1.10)	1.16 (1.14, 1.18)	1.15 (1.11, 1.18)	0.81 (0.80, 0.82)
Preoperative IABP/ inotropes	1.41 (1.33, 1.49)	NA	1.43 (1.36, 1.51)	2.56 (2.42, 2.72)	NA	1.37 (1.31, 1.43)	1.96 (1.86, 2.06)	1.60 (1.53, 1.67)	0.60 (0.57, 0.63)
Shock	2.29 (2.12, 2.47)	1.38 (1.23, 1.55)	1.65 (1.54, 1.77)	2.08 (1.96, 2.21)	NA	1.43 (1.34, 1.52)	2.10 (1.99, 2.23)	1.73 (1.62, 1.84)	0.58 (0.54, 0.62)
Female versus male (at BSA = 1.8)	1.31 (1.25, 1.36)	1.32 (1.24, 1.39)	1.25 (1.21, 1.31)	1.33 (1.29, 1.36)	1.19 (1.06, 1.35)	0.90 (0.87, 0.93)	1.18 (1.15, 1.21)	1.24 (1.20, 1.28)	0.65 (0.63, 0.66)
Hypertension	NA	1.29 (1.22, 1.37)	1.25 (1.20, 1.30)	1.10 (1.08, 1.13)	NA	NA	1.12 (1.10, 1.15)	1.07 (1.04, 1.11)	0.92 (0.90, 0.94)
Immunosuppressive treatment	1.48 (1.37, 1.60)	NA	1.21 (1.12, 1.31)	1.11 (1.05, 1.18)	NA	1.32 (1.24, 1.41)	1.20 (1.14, 1.26)	1.28 (1.20, 1.37)	0.80 (0.76, 0.84)
Aortic insufficiency, moderate/severe	NA	0.82 (0.75, 0.89)							
Mitral insufficiency, moderate/severe	1.31 (1.21, 1.41)	NA	NA	1.12 (1.06, 1.18)	NA	1.24 (1.16, 1.32)	1.20 (1.15, 1.26)	1.15 (1.09, 1.22)	0.85 (0.80, 0.91)
Tricuspid insufficiency, moderate/severe	NA	NA	1.31 (1.17, 1.45)	1.28 (1.18, 1.39)	NA	NA	1.24 (1.16, 1.33)	NA	0.78 (0.71, 0.87)
$PCI \le 6 \text{ hours}$	1.37 (1.24, 1.50)	NA	1.29 (1.16, 1.43)	1.21 (1.13, 1.29)	NA	1.30 (1.19, 1.42)	1.31 (1.23, 1.39)	1.17 (1.07, 1.27)	0.79 (0.74, 0.84)
Peripheral vascular disease	1.42 (1.36, 1.48)	1.32 (1.26, 1.39)	1.21 (1.17, 1.26)	1.22 (1.19, 1.26)	1.36 (1.24, 1.48)	1.24 (1.20, 1.28)	1.25 (1.22, 1.28)	1.31 (1.28, 1.35)	0.82 (0.81, 0.84)
Aortic stenosis	NA	NA	NA	1.18 (1.11, 1.26)	NA	NA	1.16 (1.10, 1.22)	1.15 (1.07, 1.23)	0.87 (0.82, 0.92)
Left main disease	NA	NA	NA	1.07 (1.04, 1.09)	NA	NA	1.04 (1.02, 1.06)	NA	NA
MI 1–21 days	1.37 (1.32, 1.44)	1.31 (1.25, 1.37)	1.27 (1.22, 1.32)	1.34 (1.29, 1.38)	NA	NA	1.23 (1.20, 1.25)	1.22 (1.18, 1.25)	0.88 (0.86, 0.90)
MI > 6 and < 24 hours	1.59 (1.46, 1.74)	1.59 (1.43, 1.76)	1.48 (1.36, 1.60)	1.59 (1.49, 1.68)	NA	NA	1.43 (1.37, 1.50)	1.31 (1.24, 1.39)	0.80 (0.76, 0.84)
$MI \leq 6 \text{ hours}$	1.70 (1.53, 1.89)	1.49 (1.31, 1.68)	1.43 (1.29, 1.57)	1.56 (1.45, 1.67)	NA	NA	1.44 (1.35, 1.53)	1.30 (1.21, 1.40)	0.82 (0.77, 0.87)
Time trend, per 6- month harvest interval	0.97 (0.97, 0.98)	0.97 (0.96, 0.98)	1.01 (1.00, 1.02)	1.01 (1.01, 1.02)	0.97 (0.95, 0.99)	0.99 (0.99, 1.00)	1.00 (1.00, 1.01)	1.00 (0.99, 1.01)	0.99 (0.98, 1.00)
Race Asian	NA	1.33 (1.14, 1.55)	1.08 (0.96, 1.22)	1.33 (1.21, 1.47)	1.00 (0.66, 1.51)	1.31 (1.17, 1.46)	1.23 (1.15, 1.31)	1.26 (1.13, 1.40)	0.70 (0.61, 0.81)
Race black	NA	1.41 (1.30, 1.54)	1.24 (1.16, 1.33)	1.37 (1.27, 1.48)	1.30 (1.13, 1.51)	1.21 (1.14, 1.30)	1.31 (1.24, 1.38)	1.43 (1.34, 1.51)	0.69 (0.65, 0.73)
Race Hispanic	NA	1.12 (0.98, 1.27)	1.24 (1.11, 1.39)	1.16 (1.07, 1.26)	1.30 (1.07, 1.58)	1.05 (0.97, 1.13)	1.12 (1.05, 1.19)	1.09 (0.99, 1.20)	0.85 (0.77, 0.94)

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SCTS
Reoperation, 1 previous operation <sup>a</sup>	3.13 (2.74, 3.57)	NA	1.52 (1.35, 1.71)	.52 (1.35, 1.71) 1.72 (1.58, 1.86)	NA	1.57 (1.43, 1.74)	1.57 (1.43, 1.74) 1.61 (1.50, 1.72) 1.62 (1.47, 1.80) 0.72 (0.67, 0.78)	1.62 (1.47, 1.80)	0.72 (0.67, 0.78)
Reoperation, ≥ 2 previous operations <sup>a</sup>	4.19 (3.45, 5.09)	NA	1.58 (1.33, 1.87)	.58 (1.33, 1.87) 1.86 (1.62, 2.14)	NA	1.71 (1.44, 2.03)	1.71 (1.44, 2.03) 1.84 (1.65, 2.05)	1.79 (1.53, 2.08)	0.64 (0.56, 0.73)
Status urgent <sup>a</sup>	1.16 (1.10, 1.22)	1.11 (1.06, 1.17)	1.12 (1.05, 1.19)	1.24 (1.18, 1.31)	1.20 (1.10, 1.32)	1.18 (1.13, 1.23)	1.18 (1.14, 1.22)	1.20 (1.15, 1.25)	0.86 (0.83, 0.90)
Status emergent, no resuscitation <sup>a</sup>	2.83 (2.52, 3.18)	2.12 (1.82, 2.48)	1.68 (1.49, 1.89)	2.14 (1.96, 2.34)	1.87 (1.46, 2.40)	1.83 (1.68, 1.99)	1.77 (1.64, 1.91)	2.12 (1.93, 2.32)	0.62 (0.58, 0.67)
Status emergent with resuscitation or salvage <sup>a</sup>	8.00 (6.91, 9.26)	8.00 (6.91, 9.26) 2.51 (1.98, 3.18)	2.16 (1.82, 2.55)	3.01 (2.68, 3.38)	2.09 (1.45, 3.01)	2.34 (2.06, 2.65) 3.65 (3.26, 4.09)	3.65 (3.26, 4.09)	2.39 (2.10, 2.72) 0.34 (0.30, 0.38)	0.34 (0.30, 0.38)
Unstable angina	1.12 (1.07, 1.17)	NA	1.11 (1.05, 1.17)	.11 (1.05, 1.17) 1.05 (1.01, 1.10)	NA	NA	NA	NA	NA

<sup>a</sup> Variable interacts with age. Reported odds ratio represents effect of risk factor for patients aged 50 years old.

CVD = cerebrovascular disease; = renal failure; NA = not applicable; = cerebrovascular accident, or stroke; Mort = mortality; = peripheral vascular disease; Comp = composite adverse outcome (any); .BP = intra-aortic balloon pump; MI = r = intra-aortic balloon pump; N PLOS = prolonged length of stay; BSA = body surface area; CH = deep sternal wound infection; Heart Association; short length of stay; Previously, the STS risk models were completely upgraded every 3 years, with annual recalibration in the interim to assure that the benchmark O/E ratio is always 1. In the near future, annual upgrades of the models are planned.

#### Limitations

Regardless of sample size or degree of statistical sophistication, all risk models are imperfect representations of reality. Although the STS risk models are based upon excellent clinical data and large sample sizes, there are some risk factors that are rare in the overall population but, when present, may be important predictors of outcome for specific patients. Some such variables, such as liver disease, are not included in the risk models, and the mortality risk for patients with these risk factors may be underestimated. Addition of a number of such variables will be considered at the next major specification upgrade.

There are other variables whose specifications undergo small but important changes over time, often in response to comments from STS database participants. These refinements are discussed on regular biweekly conference calls open to database participants, and suggested changes are regularly communicated to participants through a variety of means including FAQ's. With each major specification upgrade, they are incorporated into the new software specifications.

Audit is extremely important to assure the accuracy of any data registry. For the STS database and the risk models derived from it, robust audit is particularly critical as this registry is increasingly used for public reporting of outcomes and pay for performance. Studies suggest that the accuracy of the STS database is high for most important variables [31-35], although these audits are currently restricted to a limited number of sites annually because of budgetary constraints. In these audits, one of the most problematic variables has been 30-day mortality status (as opposed to in-hospital mortality). This is often a difficult endpoint to ascertain and may require more substantial investment of time and effort by participants, particularly for patients referred from outside their own institutions. Analysis of STS data suggests that approximately 90% of 30-day deaths occur in-hospital. Thus, if some patients recorded as being alive at 30 days have actually had their status ascertained only during the index hospitalization, the impact of this misclassification on the risk models should be negligible. This hypothesis was confirmed by comparing the odds ratios of all model variables for in-hospital versus 30-day mortality. Differences between the two were quite small, and these data are available on the web at www. sts.org/riskmodels. A new risk model for in-hospital mortality has been developed and placed on the same STS website. Furthermore, an aggressive program is in place to further enhance the accuracy of 30-day follow-up. In 2009, STS instituted a requirement that participants maintain documentation of the method by which they ascertained 30-day status, and that has become part of our routine audit. Linkage of the STS database with external death registries, such as the Social Security Death Master File, will

further support this capability. Finally, plans are being developed to expand the audit of certain key variables such as 30-day mortality to a significantly greater number of sites annually.

#### **Conclusions**

Risk-adjustment models account for the effect of patient comorbidities on outcomes. STS risk models are based upon clinical data from the STS NCD, one of the oldest and largest of all specialty registries. The value of such clinical registries is particularly evident in today's health care environment, where accreditation, regulatory compliance, reimbursement, and referrals are increasingly based upon objective data. Organizations such as the AQA and the National Quality Forum that evaluate and endorse performance measures strongly advocate the use of risk-adjusted outcomes measures.

STS believes that clinical data are superior to those derived from administrative sources. Furthermore, given the substantial implications of risk-adjusted outcomes, we believe that all risk models used for profiling quality of care should be transparent to permit comprehensive peer review and to foster credibility among stakeholders.

We present a detailed exposition of the development and validation of the 2008 STS CABG risk model. This describes not only the statistical considerations but, just as importantly, the many clinical and pragmatic judgments that are always necessary in risk model development.

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#### **Appendix**

Regression Coefficients and Variable Definitions for STS 2008 CABG Models

For each endpoint, the formula for calculating a patient's predicted risk of the endpoint has the form:

Predicted Risk = 
$$\frac{e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}{1+e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}$$

where  $x_1, x_2, \ldots, x_n$  denote patient preoperative risk factors (eg, quantitative variables such as age, and comorbidities coded as 1 = present, 0 = absent), and  $\beta_0, \beta_1, \ldots, \beta_n$  denote regression coefficients (numerical constants). Regression coefficients for each endpoint are presented in Appendix Table 1. The variables  $x_1, x_2, \ldots, x_n$  are the same for each endpoint and are defined in Appendix Table 2. The regression coefficient for the time trend is not presented. Instead, the intercept has been adjusted to incorporate the time trend. This adjusted intercept reflects the baseline risk for a reference period of July to December 2006.

Appendix Table 1. Regression Coefficients

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Intercept	-6.34090	-7.18174	-7.94605	-4.15175	-6.75378	-3.84861	-3.71671	-5.35975	2.84959
Atrial fibrillation	0.30830	0.18935	0.21351	0.17871	0.00000	0.23031	0.21565	0.35322	-0.49309
Age	-0.00259	0.00996	0.00678	0.00170	-0.00665	-0.00013	0.00247	0.00914	-0.01781
Age function 1	0.03325	0.04742	0.01496	0.00393	0.04270	0.01305	0.00515	0.02085	-0.00895
Age function 2	0.03140	-0.02582	0.02249	0.02366	-0.01895	0.01133	0.02441	0.01734	-0.02904
Age by reoperation function	-0.01714	-0.00098	-0.00291	-0.00459	0.00304	-0.00720	-0.00444	-0.00809	0.00449
Age by status function	-0.01366	-0.01363	-0.00022	-0.00106	-0.00352	-0.00435	0.00270	-0.00833	-0.00266
BSA function 1	-1.39342	-0.44041	-0.53672	-0.83950	0.65513	-0.83758	-0.75006	-0.89037	0.57952
BSA function 2	2.41303	0.06122	2.19879	2.15647	0.90025	1.16543	1.81770	2.15270	-1.83776
CHF but not NYHA IV	0.19229	0.00000	0.30971	0.26853	0.28272	0.14692	0.23695	0.35623	-0.32350
CHF and NYHA IV	0.32663	0.00000	0.30013	0.41599	0.36909	0.22846	0.39005	0.40757	-0.43827
Chronic lung disease mild	0.20273	0.00000	0.13488	0.30473	0.44371	0.10432	0.20878	0.29051	-0.23600
Chronic lung disease moderate	0.33843	0.00000	0.22530	0.50235	0.59021	0.18071	0.34720	0.50246	-0.39085
Chronic lung disease severe	0.85513	0.00000	0.50645	0.86175	0.87366	0.43034	0.68538	0.90211	-0.73862
Creatinine function 1	0.19353	0.02822	1.91934	-0.02712	-0.37465	0.01583	0.13361	-0.09060	0.00773
Creatinine function 2	0.82140	0.63174	0.50685	0.92120	1.09976	0.55107	0.99190	1.09571	-0.75781
Creatinine function 3	-0.70646	-0.52856	-2.04970	-0.68907	-0.68466	-0.39956	-0.81791	-0.70069	0.30449
CVD without prior CVA	0.13177	0.49807	0.10637	0.13792	0.00000	0.11403	0.15561	0.13271	-0.16385
CVD and prior CVA	0.26877	0.73600	0.16135	0.29946	0.00000	0.19208	0.28099	0.37248	-0.35706
Diabetes noninsulin dependent	0.01375	0.14992	0.27443	0.04283	0.31888	-0.01929	0.07453	0.13541	-0.13813
Diabetes insulin dependent	0.26312	0.14332	0.58581	0.19735	0.80627	0.12930	0.26525	0.46226	-0.44725
Dialysis	1.53777	0.54158	0.00000	1.01943	0.38312	0.63691	1.03466	0.93792	-1.30294
Ejection fraction function	0.01765	0.01274	0.00754	0.01669	0.01081	0.03091	0.01496	0.93792	-0.01756
Female	0.26801	0.01274	0.00754	0.28338	0.01081	-0.10270	0.01436	0.01342	-0.01750 $-0.43658$
Female by BSA function 1	0.82285	0.08974	0.96428	0.76954	1.11546	0.31901	0.66663	1.05623	-0.96846
Female by BSA function 2	0.05606	0.06490	-0.61086	-0.62558	0.17399	-0.02390	-0.25077	-0.35160	0.46088
Hypertension	0.00000	0.25718	0.22126	0.09930	0.00000	0.00000	0.11674	0.07200	-0.08155
IABP or inotropes	0.34193	0.00000	0.36023	0.94050	0.00000	0.31326	0.67253	0.47092	-0.51444
Immunosuppressive treatment	0.39159	0.00000	0.18881	0.10686	0.00000	0.27802	0.18030	0.24833	-0.22718
Insufficiency, aortic	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.19889
Insufficiency, mitral	0.26631	0.00000	0.00000	0.11169	0.00000	0.21170	0.18225	0.14174	-0.15962
Insufficiency, tricuspid	0.00000	0.00000	0.26729	0.24834	0.00000	0.00000	0.21893	0.00000	-0.24548
Left main disease	0.00000	0.00000	0.00000	0.06629	0.00000	0.00000	0.03570	0.00000	0.00000
MI 1 to 21 days	0.31810	0.27134	0.23962	0.28925	0.00000	0.00000	0.20524	0.19517	-0.12752
MI > 6 and < 24 hours	0.46614	0.46063	0.38917	0.46158	0.00000	0.00000	0.35859	0.27109	-0.22557
$MI \le 6 \text{ hours}$	0.53242	0.39601	0.35421	0.44230	0.00000	0.00000	0.36337	0.26311	-0.19946
No. diseased vessel function	0.16120	0.30339	0.20729	0.17622	0.13869	0.06895	0.15075	0.13589	-0.21043
PCI ≤ 6 hours	0.31149	0.00000	0.25189	0.18695	0.00000	0.26256	0.26774	0.15633	-0.23860
Peripheral vascular disease	0.34951	0.27985	0.19308	0.20240	0.30529	0.21306	0.22277	0.27380	-0.19321
Race black	0.00000	0.34423	0.21696	0.31563	0.26572	0.19456	0.26634	0.35426	-0.37515
Race Hispanic	0.00000	0.11002	0.21645	0.14802	0.26330	0.04798	0.11289	0.08968	-0.16091
Race Asian	0.00000	0.28567	0.07579	0.28561	-0.00145	0.26855	0.20484	0.23064	-0.35049
Reop, 1 previous operation	1.13997	0.00000	0.41962	0.53987	0.00000	0.45372	0.47614	0.48534	-0.32375
Reop, $\geq$ 2 previous operations	1.43250	0.00000	0.45592	0.62211	0.00000	0.53695	0.61014	0.57945	-0.44745
Shock	0.82667	0.32434	0.50003	0.73290	0.00000	0.35800	0.74320	0.54575	-0.54475
Status urgent	0.14608	0.10671	0.11226	0.21738	0.18496	0.16500	0.16492	0.18202	-0.14608
Status emergent	1.04010	0.75216	0.51857	0.76090	0.62665	0.60549	0.56983	0.75083	-0.47745
Status salvage	2.07934	0.91950	0.76808	1.10085	0.73651	0.84873	1.29422	0.87072	-1.08265
Stenosis aortic	0.00000	0.00000	0.00000	0.16529	0.00000	0.00000	0.14706	0.13988	-0.14173
Unstable angina	0.11217	0.00000	0.10287	0.05060	0.00000	0.00000	0.00000	0.00000	0.00000

 $BSA = body \ surface \ area; \ CHF = congestive \ heart \ failure; \ Comp = composite \ adverse \ event \ (any); \ CVA = cerebrovascular \ accident \ (stroke); \ CVD = cerebrovascular \ disease; \ DSWI = deep \ sternal \ wound \ infection; \ IABP = intra-aortic \ balloon \ pump; \ MI = myocardial \ infarction; \ Mort = mortality; \ NYHA = New \ York \ Heart \ Association; \ PCI = percutaneous \ coronary \ intervention; \ PLOS = prolonged \ length \ of \ stay; \ Reop = reoperation; \ RF = renal \ failure; \ SLOS = short \ length \ of \ stay; \ Vent = prolonged \ ventilation.$ 

#### Appendix Table 2. Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	$= \max(age-50, 0)$
Age function 2	$= \max(age-60, 0)$
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	$= (BSA \text{ function } 1)^2$
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
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Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral Insufficiency, tricuspid	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
, I	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI > 6 and <24 hours prior to surgery, = 0 otherwise
$MI \le 6 \text{ hours}$	= 1 if history of MI $\leq$ 6 hours prior to surgery, = 0 otherwise
No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
$PCI \leq 6 \text{ hours}$	= 1 if patient had $PCI \le 6$ hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, ≥ 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwis

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

# **2a.14. Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method)

The risk adjusted model is a hierarchical logistic regression model with participant level intercept. logit(outcome)  $\sim X\beta + (\gamma | participant)$ 

where X is the patient's risk factors,  $\theta$  is the regression coefficients of patient-level risk factors and  $\gamma$  is the participant level regression coefficient.

#### **Inclusion Criteria**

The patient level risk adjusted model was developed using a population of patients undergoing isolated CABG procedure in the time period January 2002 – December 2006. For this measurement we re-fit the patient-level model using the latest two and a half years of data (January 2008 – June 2010) from the STS Adult Cardiac Surgery Database.

#### Variable Definitions and Selection

All variables for consideration are listed in the table below.

#### Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	= max (age–50, 0)
Age function 2	= max (age-60, 0)
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	= (BSA function 1) <sup>2</sup>
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
Insufficiency, tricuspid	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI >6 and <24 hours prior to surgery, = 0 otherwise
MI ≤ 6 hours	= 1 if history of MI ≤ 6 hours prior to surgery, = 0 otherwise

No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
PCI ≤ 6 hours	= 1 if patient had PCI ≤ 6 hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, 2 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwise
-	

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

The final patient-level model was built by backward selection method with several variables forced into the model. For the final patient-level model, please see the attachment.

# **1b.2.** Summary of Measure Results Demonstrating Performance Gap (Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.)

The summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. A high OR is undesirable and we define the percentiles with decreasing OR. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile" below.

Measurement	Surgical Re-exploration	
N	640	
Mean	1.0	
1 <sup>st</sup>	2.0	
5 <sup>th</sup>	1.7	
10 <sup>th</sup>	1.5	
25 <sup>th</sup>	1.2	
Median	1.0	
75 <sup>th</sup>	0.8	
90 <sup>th</sup>	0.7	
95 <sup>th</sup>	0.6	
99 <sup>th</sup>	0.5	
Outlier	71 (11.1)	
High	19	
Low	52	

Also provided is the distribution of the risk adjusted event rate (see below). The risk adjusted rate is an estimate of the participant's event rate if, hypothetically, the case-mix of the patients treated by the participants is the same as the overall STS case-mix. It is calculated by the OR of the participant, other patient level parameter estimates from the hierarchical logistic model, and the overall STS event rate, by:

STS event rate \* (Participant's Expected Event Rate) / (Participant's Expected Event Rate Assuming Its Performance = STS Average Performance)

In the above equation, "Participant's Expected Event Rate" is calculated with the participant's actual OR, and "Participant's Expected Event Rate Assuming Its Performance = STS Average Performance" is calculated by assuming the participant's OR = 1 (i.e. no difference in performance from the STS average).

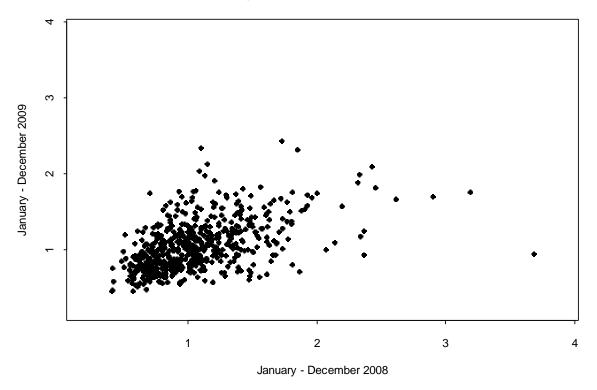
Measurement	Surgical Re-exploration	
N	640	
Mean	4.8	
1 <sup>st</sup>	2.5	
5 <sup>th</sup>	2.9	

Measurement	Surgical Re-exploration
10 <sup>th</sup>	3.2
25 <sup>th</sup>	3.8
Median	4.6
75 <sup>th</sup>	5.7
90 <sup>th</sup>	6.9
95 <sup>th</sup>	7.6
99 <sup>th</sup>	9.0
Outlier	71 (11.1)
High	19
Low	52

**2b.3. Testing Results** (Reliability statistics, assessment of adequacy in the context of norms for the test conducted)

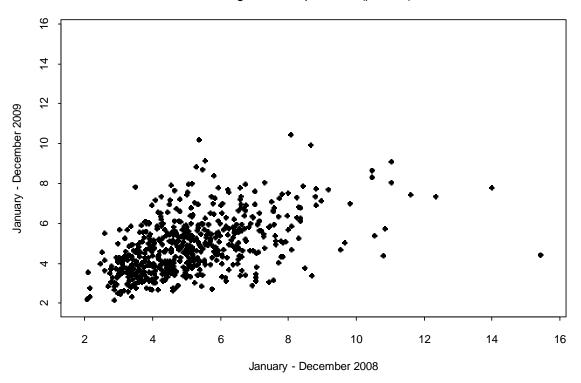
Testing results:  $\rho = 0.52$ 

Surgical Re-exploration ( $\rho$ =0.52)



Risk Adjusted Rate:

Surgical Re-exploration ( $\rho$ =0.52)



# **2f.3. Measure Scores from Testing or Current Use** (Description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)

Results below are from January 1, 2009-December 31, 2009. Sample contains 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months.

Measurement	Surgical Re-exploration	
N	640	
Mean	1.0	
1 <sup>st</sup>	2.0	
5 <sup>th</sup>	1.7	
10 <sup>th</sup>	1.5	
25 <sup>th</sup>	1.2	
Median	1.0	
75 <sup>th</sup>	0.8	
90 <sup>th</sup>	0.7	
95 <sup>th</sup>	0.6	
99 <sup>th</sup>	0.5	
Outlier†	71 (11.1)	
High	19	
Low	52	

#### Risk Adjusted Rate:

Measurement	Surgical Re-exploration	
N	640	
Mean	4.8	
1 <sup>st</sup>	2.5	
5 <sup>th</sup>	2.9	
10 <sup>th</sup>	3.2	
25 <sup>th</sup>	3.8	
Median	4.6	
75 <sup>th</sup>	5.7	
90 <sup>th</sup>	6.9	
95 <sup>th</sup>	7.6	
99 <sup>th</sup>	9.0	
Outlier†	71 (11.1)	
High	19	
Low	52	

<sup>†</sup>Represents the number of participants that are outliers according to two-sided 95% confidence interval of odds ratio.

#### **3a.6. Results** (Qualitative or quantitative results and conclusions)

Although formal testing of interpretability has not been performed, this measure has been used and reported for STS Adult Cardiac Surgery database participants since 2007. Current report presentation and interpretation manuals are presented below. These materials are updated as needed based upon feedback from database participants.

#### 1) Report Overview and Interpretation Manual:

#### **The NQF Measures Report**

#### a. Organization

This report section is separated into three areas corresponding to: 1) NQF volume measures, 2) NQF process measures, and 3) NQF outcomes measures, in that order. The header at the top of each page references the report section for that page. Each NQF measure is presented on a single row in the section. Tabular data are on the left-hand side of each page and a standard graphic representation is shown on the right-hand side.

#### b. Statistical Calculation and Details – NQF Measures

**Time period:** This report section contains information on the individual STS participant and overall STS performance for the <u>most recent 12 months for volume, process and CABG outcomes measures and the most recent 60 months for Valve and Valve + CABG outcomes. The 5 years (60 months) of performance for outcomes involving Valve procedures is necessary due to smaller sample sizes.</u>

**Volume Measures:** The NQF report provides average annual case volumes data for three surgery categories: i) Isolated CABG, ii) Valve without CABG, and iii) combined CABG + Valve. Definitions of the three surgery categories are provided in Table 2 of this NQF Report Overview. For each type of surgery, the <u>participant's annualized volume</u> is calculated as:

Participant Annualized Volume = 12 x (# of surgeries) / (# of months)

where (# of surgeries) denotes the number of surgeries of the specified type performed by the participant during the specified time period, and (# of months) is the number of months during the specified time period for which the participant submitted at least one cardiac surgery of any type. The intent of calculating "annualized" volumes is to adjust for participants who participated in the database for fewer months than the time period specified. For participants who participated in the database and submitted cases every month during 2006, the annualized volume for 2006 is simply the total number of cases.

The <u>STS</u> Average Annualized Volume is the average value of all of the participant annualized volumes across the entire population of STS participants. The <u>Participant Percentile</u> indicates the percent of STS participants whose annualized volumes are less than, or equal to, your own. Higher percentiles indicate higher volumes in relation to other STS participant sites. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant annualized volumes across all database participants. For example, 90% of participants have annualized volumes less than or equal to the value marked "90<sup>th</sup> percentile." Confidence intervals are not provided for volume measures, as volume is known with certainty and is not estimated.

**Process Measures:** The NQF process measures provide data on the frequency of usage of five therapies among subsets of Isolated CABG patients. The therapies are: i) preoperative beta blockade therapy, ii) use of IMA, iii) discharge anti-platelet medication, iv) discharge beta blockade therapy, and v) discharge anti-lipid medication. The patient population for each measure differs, in accordance with the NQF specifications (see Table 2 of this NQF Report Overview for details). The number of Eligible

Procedures is the number of cases performed by the participant during the specified time period who meet the eligibility requirements to be included in the calculations when summarizing the participant's data. Beginning with the 2008 Harvest 3 report (covering the procedure time period through 6/30/2008), STS implementation of NQF medication process measures using data version 2.61 excludes records for which the medication was contraindicated/not indicated from the eligible population. The main summary statistic, Participant Usage, is the percent of eligible Isolated CABG cases during the specified time period for which the patient received the specified therapy. The Overall STS Usage is the percent of all eligible patients in the entire STS population during the specified time period who received the specified therapy. In calculating these percentages, missing data are treated as a "No", emphasizing the importance of having complete data in these fields.

The <u>Participant Percentile</u> indicates the percent of STS participants who applied the therapy in their respective populations less frequently than or as frequently as did your institution. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant usage across all participants in the database. For example, 90% of participants use the therapy less frequently than the amount indicated by the "90<sup>th</sup> percentile". A bar identified as "Participant" indicates the point estimate and limits of a 95% Confidence Interval (CI) for the participant's usage of therapy. The underlying parameter being estimated is the long-run usage rate that would be observed in a large sample of patients. The 95% CI indicates the range of usage rates that are consistent with the data in light of sampling variability.

Outcomes Measures: The NQF outcomes data provide risk-adjusted analyses of mortality and morbidity for Isolated CABG surgery as well as risk-adjusted operative mortality for Isolated AVR, Isolated MVR, AVR+CABG, and MVR+CABG. The main summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. The interpretation is similar to that of an O/E ratio (see the Risk-Adjusted Results: Overview portion of the General Report Overview for details on STS risk adjustment). An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. Each measure is calculated among patients undergoing surgery of the type specified during the time period specified who additionally meet certain eligibility requirements. The column labeled Eligible Procedures indicates the number of patients who met the inclusion criteria to be included in the analysis for the indicated measure. The Participant Percentile is the percent of STS participants who have an estimated OR that is greater than or equal to your estimated OR. Note that this is different than performance percentiles for process measures, where the percentile indicates the percentage of STS participants with performance that is less than the specified number. This simply reflects the fact that high process compliance is desirable, whereas a high OR is undesirable.

The <u>Observed Participant Rate</u> is the percent of eligible patients who experienced the specified outcome. Unlike the participant estimated OR, the observed participant rate is not risk-adjusted. The estimated OR is the main summary statistic for summarizing the NQF measure in this report.

The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of estimated Odds Ratios across all STS participants. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile." The line that extends to the left and right of the Participant Value indicates the lower and upper limits of a 95% Confidence Interval (CI) surrounding the participant's estimated OR.

#### c. Technical Notes

**Calculation of Percentiles for the Distribution of Participant Values:** The graph provided for each measure contains information about the distribution of the value of the measure across all STS

participants, namely the minimum, maximum,  $10^{th}$  percentile,  $50^{th}$  percentile, and 90th percentile. The " $X^{th}$ " percentile, denoted  $P_x$ , is loosely defined as the number having the property that X% of the participant values are less than  $P_x$ , and (100 - X)% of the participant values are greater than  $P_x$ . For process measures, participants with greater than 5% missing data were excluded when calculating percentiles of the STS distribution and do not have a calculated participant percentile. For participants having less than 5% missing data on a process measure, the missing values on the process measure were converted to "No" before calculating percentiles. For outcomes measures, all participants submitting at least one eligible case were included when calculating percentiles of the STS distribution. Missing data on outcomes variables were treated as "No."

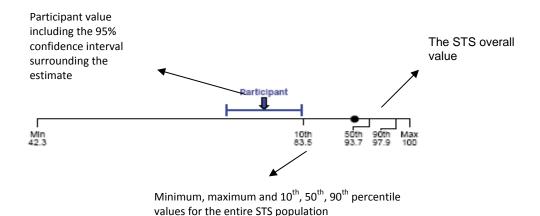
NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion criteria, and rules for handling missing data in the NQF section versus the rest of the report. Definitions used in the NQF report were designed to match current NQF specifications as closely as possible. It is expected that these differences will eventually disappear as the NQF measures are refined. Some important differences are:

Case Volumes – The NQF report section presents "annualized" volumes. These are case volumes that have been adjusted for the number of months that a participant was an active contributor to the database. Elsewhere in the STS report, total case volumes are presented without adjustment for the length of participation.

Eligible Cases - The NQF report also presents the number of "eligible cases" for each measure. Separate inclusion criteria are applied to each measure, and these inclusion criteria do not always match the definitions used elsewhere in the STS report. Please refer to the footnotes in each section for specific details.

#### **Interpretation Manual**

In addition to the statistics provided for each of the STS Composite Quality Domains and NQF measures, a figure representing the distribution of values for the entire STS population is provided.



The figure allows participants to quickly judge their performance relative to the overall STS. The scale of the figure is set up such that the right side of the distribution represents the <u>most</u> favorable performance and the left side represents the <u>least</u> favorable performance (Note that in some cases smaller numbers will be on the left; in other instances, smaller numbers will be on the right. For example, for the Pre-operative Beta Blockade Therapy measure, the far left side of the distribution will contain the *lowest* percentage Beta Blockade Therapy for an STS participant – this corresponds to least

favorable performance. Alternatively, for the Operative Mortality Measure, the far left side of the distribution will contain the *highest* Estimated Odds Ratio – this also corresponds to least favorable performance). If a participant's value for a given measure is to the left of the STS overall value, the participant is performing worse on that measure than the overall STS. Conversely, if the participant's value for a given measure is located to the right of the overall STS value, the participant is performing better than the overall STS.

**NOTE!** Care should be given to reading these figures. In some instances, the various percentiles presented cluster very close together in the data. In such cases, the label for the percentile is not necessarily located immediately at the point on the distribution where the percentile occurs. An example of this is apparent in the figure above: The 50<sup>th</sup> percentile corresponds to a value of 93.7 and looks to align fairly closely with the STS overall value as represented by the large black dot. However, the expandable figure marking actually points to a place somewhere to the right of the STS overall value for the 50<sup>th</sup> percentile marking. So the STS overall value would be some amount less than 93.7.

Also, please note that in some cases, small sample sizes preclude valid comparisons between the participant and the STS overall. Such instances are clearly noted in the report output.

### a. NQF Measures Interpretation Example

Sample CABG Operative Mortality results – tabular and figure representation.

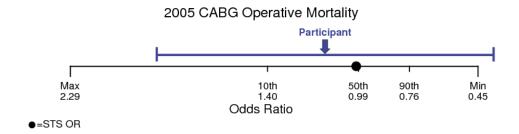
NQF	Eligible	Participant	Participant	Participant
Measure	Procedures	Estimated OR	Percentile	Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

Eligible Procedures: 74 patients met the inclusion criteria for the indicated measure.

Participant Estimated OR (Odds Ratio): The main summary statistic measuring the impact that a participant's performance has on a patient's probability of experiencing an adverse outcome has a value of 1.14 indicating worse than expected performance.

Participant Percentile: 26.3% of STS participants had an estimated OR greater than or equal to your estimated OR. In other words, 26.3% had the same or worse performance.

Participant Observed Rate: 5.4% of the 74 eligible patients experienced the specified outcome.



The highest OR among all STS participants = 2.29 The lowest OR among all STS participants = 0.45 The STS average OR is 1.00

### 2) Sample page from section of the report that contains NQF measure results:



# NQF Measures Process Measures Participant 99999 STS Period Ending 12/31/2008



NQF Measure	Eligible Procedures	Participant Usage (95% CI)	Participant Percentile	Overall STS Usage	Distribution of Participant Values
Jan 2008 - Dec 2008 Preoperative Beta Blockade Therapy <sup>1</sup>	541	89.3% (86.4 , 91.8)	69.9	82.1%	Participant    Min   10th   50th   90th   Max   95.6   100
Jan 2008 - Dec 2008 Use of IMA <sup>2</sup>	536	96.5% (94.5 , 97.9)	63.3	94.2%	Participant  Min 10th 50th 90th Max 53.2 87.8 85.2 98.9 100
Jan 2008 - Dec 2008 Discharge Anti-Platelet Medication <sup>3</sup>	536	98.7% (97.3 , 99.5)	68.7	96.1%	Participant  Min 10th 50th 90th Max 18.7 92.1 97.5 100 100
Jan 2008 - Dec 2008 Discharge Beta Blockade Therapy <sup>4</sup>	538	96.1% (94.1 , 97.6)	53.4	93.7%	Participant  Min 10th 50th 80th Max 15.1 85.3 85.7 100 100
Jan 2008 - Dec 2008 Discharge Anti-Lipid Treatment⁴	535	91.8% (89.1 , 94.0)	40.7	91.4%	Participant

Excludes v2.61 contranindicated / not indicated records.

Excludes patients with prior CABG surgery

Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

Excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

### NATIONAL QUALITY FORUM

# Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

### Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 0119	NQF Project: Surgery Endorsement Maintenance 2010
MEAS	SURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Risk-Adjusted Operative	e Mortality for CABG
die, including both 1) all deaths occurring du	t of patients aged 18 years and older undergoing isolated CABG who uring the hospitalization in which the CABG was performed, even if after discharge from the hospital, but within 30 days of the procedure
1.1-2 Type of Measure: Outcome De.3 If included in a composite or paired w OT1-013-09 - The STS CABG Composite Score	vith another measure, please identify composite or paired measure
De.4 National Priority Partners Priority Are De.5 IOM Quality Domain: Safety De.6 Consumer Care Need: Getting better	•

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission  A.4 Measure Steward Agreement attached: STS Measure Steward Agreement. Fully Executed-634267306975205026.pdf	A Y N

<b>B.</b> The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y□ N□
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  ▶ Purpose: Public reporting, Internal quality improvement	C Y N
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.  D.1Testing: Yes, fully developed and tested  D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y   N
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
1. IMI OKTANCE TO MEASURE AND RELOKT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	Eval Rating
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2  1a.3 Summary of Evidence of High Impact: Mortality is probably the single most important negative outcome that can be associated with a surgical procedure. Operative mortality, defined as mortality within 30 days of surgery or on the same hospital admission, should include nearly all deaths that occur as a direct	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2  1a.3 Summary of Evidence of High Impact: Mortality is probably the single most important negative outcome that can be associated with a surgical procedure. Operative mortality, defined as mortality within	

mortality and morbidity risk models. Ann Thorac Surg. 2003;75:1856-1865.  - Williams ML, Muhlbaier LH, Schroder JN, et. al. Risk-adjusted short- and long-term outcomes for on-pump versus off-pump coronary artery bypass surgery. Circulation. 2005 Aug 30;112(9 Suppl):1366-70.  - Shroyer AL, Grover FL, Hattler B, et. al. On-pump versus off-pump coronary artery bypass surgery. N Engl J Med. 2009 Nov 5;361(19):1827-37.  - Hannan EL, Wu C, Smith CR, et. al. Off-pump versus on-pump coronary artery bypass graft surgery: differences in short-term outcomes and in long-term mortality and need for subsequent revascularization. Circulation. 2007 Sep 4;116(10):1145-52. Epub 2007 Aug 20.	
1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: Mortality is probably the single most important negative outcome that can be associated with a surgical procedure. Operative mortality, defined as mortality within 30 days of surgery or on the same hospital admission, should include nearly all deaths that occur as a direct result of the surgery or an immediate postoperative complication. Critical evaluation of operative mortality allows one to evaluate the risk associated with a given procedure for various patient characteristics, and more importantly, aggressively search for ways to minimize that risk.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: Please see attachment	
1b.3 Citations for data on performance gap: Dates: January 1, 2009-December 31, 2009	
Analysis includes 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data (not restricted to this measure) to the STS Adult Cardiac Surgery Database for all 12 months.	
1b.4 Summary of Data on disparities by population group: N/A	1b C□ P□
1b.5 Citations for data on Disparities: N/A	M D
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Mortality is probably the single most important negative outcome that can be associated with a surgical procedure. Operative mortality, defined as mortality within 30 days of surgery or on the same hospital admission, should include nearly all deaths that occur as a direct result of the surgery or an immediate postoperative complication.	
<b>1c.2-3. Type of Evidence:</b> Observational study, Randomized controlled trial, Expert opinion, Systematic synthesis of research, Other Clinical results from approximately 90% of cardiac surgery centers in the US	
1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):  The published literature on coronary bypass grafting, including the aforementioned references, is full of examples of services/care processes that impact operative mortality. Pre-operative patient selecting, surgical timing post coronary event, intraoperative conduct of the case, and many aspects to postoperative	
care have all been shown to have significant impact on the operative mortality over the last few decades.	
care have all been shown to have significant impact on the operative mortality over the last few decades.  1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):	1c C P

1c.7 Summary of Controversy/Contradictory Evidence:	
<b>1c.8 Citations for Evidence (</b> <i>other than guidelines</i> <b>):</b> - Ferguson TB, Hammill BG, et al. A decade of change—risk profiles and outcomes for isolated coronary artery bypass grafting procedures, 1990-1999: a report from the STS National Database Committee and the Duke Clinical Research Institute. Ann Thorac Surg. 2002;73(2):480-489; discussion 489-490.	
- Grover FL, Shroyer AL, et al. A decade's experience with quality improvement in cardiac surgery using the Veterans Affairs and Society of Thoracic Surgery national databases. Ann Thorac Surg.2001; 234(4):464-472; discussion 472-474.	
<ul> <li>Hogue CW, Barzilai B, et al. Gender differences in neurologic outcomes and mortality after cardiac surgery: an STS National Database report. Circulation. 103:2133-2137.</li> <li>Shroyer AL, Coombs LP, Peterson ED, et al. The Society of Thoracic Surgeons: 30-day operative</li> </ul>	
mortality and morbidity risk models. Ann Thorac Surg. 2003;75:1856-1865.  - Williams ML, Muhlbaier LH, Schroder JN, et. al. Risk-adjusted short- and long-term outcomes for on-pump versus off-pump coronary artery bypass surgery. Circulation. 2005 Aug 30;112(9 Suppl):1366-70.  - Shroyer AL, Grover FL, Hattler B, et. al. On-pump versus off-pump coronary artery bypass surgery. N Engl J Med. 2009 Nov 5;361(19):1827-37.	
- Hannan EL, Wu C, Smith CR, et. al. Off-pump versus on-pump coronary artery bypass graft surgery: differences in short-term outcomes and in long-term mortality and need for subsequent revascularization. Circulation. 2007 Sep 4;116(10):1145-52. Epub 2007 Aug 20.	
1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):	
1c.10 Clinical Practice Guideline Citation: 1c.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):	
1c.13 Method for rating strength of recommendation (If different from <u>USPSTF system</u> , also describe rating and how it relates to USPSTF):	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y_ N_
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ( <u>evaluation criteria</u> )	Eval Rating
2a. MEASURE SPECIFICATIONS	
<ul><li>S.1 Do you have a web page where current detailed measure specifications can be obtained?</li><li>S.2 If yes, provide web page URL:</li></ul>	2a- specs
2a. Precisely Specified	C □ P □
<b>2a.1 Numerator Statement</b> (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):	M

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

**2a.2 Numerator Time Window** (*The time period in which cases are eligible for inclusion in the numerator*): During hospitalization regardless of length of stay or within 30 days of surgery if discharged

**2a.3 Numerator Details** (All information required to collect/calculate the numerator, including all codes, logic, and definitions):

Number of isolated CABG procedures with an operative mortality;

Number of isolated CABG procedures in which Mortality [Mortality (STS Adult Cardiac Surgery Database Version 2.73)] and Mortality Operative Death (MtOpD) are marked "yes." Operative mortality is further verified by the following variables: Mortality Status at 30 days (Mt30Stat), Mortality Date (MtDate), Mortality Discharge Status (MtDCStat)

**2a.4 Denominator Statement** (Brief, text description of the denominator - target population being measured):

All patients undergoing isolated CABG

2a.5 Target population gender: Female, Male 2a.6 Target population age range: 18 and older

**2a.7 Denominator Time Window** (The time period in which cases are eligible for inclusion in the denominator):

12 months

**2a.8 Denominator Details (**All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):

Number of isolated CABG procedures

Isolated CABG is determined as a procedure for which all of the following apply:

- OpCAB is marked "Yes"
- (VADProc is marked "No" or "Missing") or (VADProc is marked "Yes, Implanted" and UnplVAD is marked "yes")
- OCarASDTy is marked "PFO" or "missing"
- OCarAFibAProc is marked "primarily epicardial" or "missing" and
- OpValve, VSAV, VSAVPr, ResectSubA, VSMV, VSMVPr, OpTricus, OpPulm, OpONCard, OCarLVA, OCarVSD, OCarSVR, OCarCong, OCarTrma, OCarCrTx, OCAoProcType, EndoProc, OCTumor, OCPulThromDis, OCarOthr are all marked "no" or "missing"
- 2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): N/A
- **2a.10 Denominator Exclusion Details (**All information required to collect exclusions to the denominator, including all codes, logic, and definitions):

  N/A
- **2a.11 Stratification Details/Variables (**All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):

  N/A
- 2a.12-13 Risk Adjustment Type: Case-mix adjustment
- **2a.14 Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

  Please see attachment
- 2a.15-17 Detailed risk model available Web page URL or attachment: Attachment 2a.15 Detailed Risk Model-634267308759980238.pdf
- 2a.18-19 Type of Score: Rate/proportion

NQ	F #0119
2a.20 Interpretation of Score: Better quality = Lower score 2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps):  N/A	
<b>2a.22 Describe the method for discriminating performance</b> (e.g., significance testing): Participant specific odds ratios and their 95% CI were estimated in the hierarchical model. These model-based estimates were used to control variation due to random statistical fluctuations while estimating true signal variation. A 95% CI excluding zero indicates the participant's performance is significantly lower or higher than an "average" STS participant.	
<b>2a.23 Sampling (Survey) Methodology</b> If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A	
2a.24 Data Source (Check the source(s) for which the measure is specified and tested) Registry data	
2a.25 Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): STS Adult Cardiac Surgery Database - Version 2.73	
2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL Data Collection Form (an updated version will be made available on the STS Website in mid-December of 2010)http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataCollectionForm2_7_Annotated_20101021.pdf	
2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataSpecificationsV2_7_20101021.pdf an updated version will be made available on the STS Website in mid-December of 2010	
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested) Clinicians: Group, Facility/Agency, Population: national, Population: regional/network, Population: states, Population: counties or cities	
2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested) Hospital	
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)	
TESTING/ANALYSIS	
2b. Reliability testing	
<b>2b.1 Data/sample</b> (description of data/sample and size): STS Adult Cardiac Surgery Database - Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009.	
<b>2b.2 Analytic Method</b> (type of reliability & rationale, method for testing): Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009. Excluded from analysis are participants that did not submit results for both time periods. Because database participants can change their underlying care processes at any time, we would not expect perfect correlation between two sets of results from even proximate time periods.	2b C□
2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted): Please see attachment	P N
2c. Validity testing	2c
2c.1 Data/sample (description of data/sample and size): STS Adult Cardiac Surgery Database	C □   P □

	M
Audits conducted in 2010, all cases performed in 2009; $N = 40$ randomly selected sites participating in the STS Adult Cardiac Surgery Database	Ν
<b>2c.2 Analytic Method</b> (type of validity & rationale, method for testing): Participating sites are randomly selected for participation in STS Adult Cardiac Surgery Database Audit, which is designed to evaluate the accuracy, consistency, and comprehensiveness of data collection and ultimately validate the integrity of the data contained in the database. The lowa Foundation for Medical Care (IFMC), the quality improvement organization for lowa and Illinois, has conducted audits on behalf of STS since 2006.	
Each year, the IFMC conducts audits at randomly selected sites throughout the country and tracks the individual agreement rates by variable and by year. More specifically, for each site, agreement rates are calculated for 73 individual elements. In addition, aggregate agreement rates for each element, variable category (e.g., pre-operative risk factors, previous interventions, etc), and overall for all categories are calculated for all sites. While this is not region specific, it is data point specific and comparison agreement rates confirm the improvement over time as well as the consistency.	
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test	
conducted): Mortality Operative Death: 100.0% agreement rate	
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s): N/A	
2d.2 Citations for Evidence:	
2d.3 Data/sample (description of data/sample and size):	2d
2d.4 Analytic Method (type analysis & rationale):	C □ P □
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):	M ☐ N ☐ NA ☐
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): Please see Risk Adjustment Type section above	
<b>2e.2 Analytic Method</b> (type of risk adjustment, analysis, & rationale): Detailed information regarding the risk adjustment model can be found in the attachment:	
Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, Normand SL, DeLong ER, Shewan CM, Dokholyan RS, Peterson ED, Edwards FH, Anderson RP. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1coronary artery bypass grafting surgery. Ann Thorac Surg. 2009 Jul;88(1 Suppl):S2-22.	2e
2e.3 Testing Results (risk model performance metrics):	P   M   N
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	NA.
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:  2f. Identification of Meaningful Differences in Performance	NA ☐ 2f C ☐

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance	
(type of analysis & rationale):  We calculated the risk adjusted event rate with the participant's Odds Ratio (OR) estimate and the overall STS event rate. Therefore, the risk adjusted rate is closely related to OR estimate. If OR > 1, then the participant's risk adjusted rate will be greater than the overall STS event rate; if OR < 1, then the participant's risk adjusted rate will be smaller than the overall STS event rate. The statistical significance is defined by the 95% confidence interval (CI) or the OR estimate. If the 95% CI for a participant's OR includes the null value 1.0, then we cannot distinguish this participant's performance from the STS average - either the participant's performance was close to average or else the participant's sample size was too small to make a reliable inference. Otherwise, if the 95% CI falls to the right of 1.0, then the participant's performance is considered significantly lower than the average STS results; if the 95% CI falls to the left of 1.0, then the participant's performance is considered significantly higher than the average STS results.	
<b>2f.3 Provide Measure Scores from Testing or Current Use</b> (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  Please see attachment	
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size): N/A	2
2g.2 Analytic Method (type of analysis & rationale):	2g C P M
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	N   NA
2h. Disparities in Care	2h
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A	C □ P □
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	M   N   NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure	2
Properties, met? Rationale:	C
3. USABILITY	- ,
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information	
3a.1 Current Use: In use	
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org	3a C P M
Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily	N

participate in this initiative.	
<b>3a.3 If used in other programs/initiatives</b> (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). <u>If not used for QI</u> , state the plans to achieve use for QI within 3 years):	
CMS Physician Quality Reporting Initiative (PQRI), www.cms.hhs.gov/pqri	
Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)  3a.4 Data/sample (description of data/sample and size): See 3a.6 below	
3a.5 Methods (e.g., focus group, survey, QI project):	
3a.6 Results (qualitative and/or quantitative results and conclusions): Please see attachment	
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures:  OT1-013-09 - The STS CABG Composite Score; Component measures: 0114 Risk-Adjusted Post-Operative Renal Failure, 0115 Risk-Adjusted Surgical Re-exploration, 0116 Anti-Platelet Medication at Discharge, 0117 Beta Blockade at Discharge, 0118 Anti-Lipid Treatment at Discharge, 0119 Risk-Adjusted Operative Mortality for CABG, 0127 Pre-Operative Beta Blockade, 0129 Risk-Adjusted Prolonged Intubation (ventilation), 0130 Risk-Adjusted Deep Sternal Wound Infection Rate, 0131 Risk-Adjusted Stroke/Cerebrovascular Accident, 0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why? N/A; however, data definitions and key elements have been established by a multi-societal writing committee called the "ACCF/AHA Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards" with representatives from each of the following organizations:	
Agency for Healthcare Research and Quality American College of Cardiology American College of Emergency Physicians American College of Physicians American College of Physicians American College of Preventative Medicine American Heart Association American Medical Association Centers for Disease Control and Prevention Emergency Nurses Association Food and Drug Administration Joint Commission on Accreditation of Healthcare Organizations National Association of Emergency Medical Technicians National Association of EMS Physicians National Heart, Lung, and Blood Institute Preventive Cardiovascular Nurses Association Society for Academic Emergency Medicine Society of General Internal Medicine Society of General Internal Medicine Society of Thoracic Surgeons	3b C P N NA
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-	3c C□

endorsed measures:	P
N/A	M
5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:  N/A	NA.
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	
TALY WORKSTOUP. What are the strengths and weaknesses in relation to the substituting for Osubhity.	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met?	3
Rationale:	C∐   P∐
	M□   N□
4. FEASIBILITY	N_
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. ( <a href="evaluation criteria">evaluation criteria</a> )	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	
4a.1-2 How are the data elements that are needed to compute measure scores generated?	4a
Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition),	C∐   P∏
Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-	M
9 codes on claims, chart abstraction for quality measure or registry)	N_
4b. Electronic Sources	
4b.1 Are all the data elements available electronically? (elements that are needed to compute measure	46
scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) Yes	4b   C□
4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	P_
45.2 If not, specify the hear-term path to achieve electronic capture by most providers.	N_
4c. Exclusions	4c
4c.1 Do the specified exclusions require additional data sources beyond what is required for the	C□
numerator and denominator specifications?	P M
	N 🗆
4c.2 If yes, provide justification.	NA.
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and	
describe how these potential problems could be audited. If audited, provide results.  This measure may be susceptible to human error (i.e., recording the measure inaccurately or not at all).	
When data collection on this measure is done through participation in the STS Adult Cardiac Surgery Database, an auditing strategy is in place.	
Both STS and the Duke Clinical Research Institute have a list of database participants making participation in the STS Adult Cardiac Surgery Database easy to track.	4d
Each participant is responsible for the quality and accuracy of the data they submit to the database. The	C□
participant agrees to the following quality control measures in the participation agreement: i) Participant hereby warrants that all data submitted for inclusion in the STS National Database will be	P
accurate and complete, and acknowledges that such data may be subject to independent audit. Participant	N □

will use its best efforts to address any data or related deficiencies identified by the independent data	
warehouse service provider and agrees to cooperate with and assist STS and its designees in connection with	
the performance of any independent audit.	
ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for	
inclusion in the STS National Database, including but not limited to apprising the Director of the STS	
National Database and the independent data warehouse service provider about any other Participation	
Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto	
(as amended from time to time) is also named.	
STS audited for these potential problems during testing. Please see IFMC audit results.	
3	
4e. Data Collection Strategy/Implementation	
40.4 Describe what you have learned/medified as a result of testing and/or energtional use of the	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data	
collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation	
issues:	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary	
measures):	
Data Collection:	
There are no direct costs to collect the data for this measure. Costs to develop the measure included	
volunteer cardiothoracic surgeon time, STS staff time, and DCRI statistician and project management time.	
Other fees:	
STS Adult Cardiac Surgery Database participants (single cardiothoracic surgeons or a group of surgeons) pay	
annual participant fees of \$2,950 or \$3,700, depending on whether participants are STS members (or	
whether the majority of surgeons in a group are STS members). As a benefit of STS membership, STS members are charged the lesser of the two fees.	
	4e
4e.3 Evidence for costs:	C
	P M
4e.4 Business case documentation:	N□
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	
TALL WORKSTOUP. What are the strengths and weakhesses in relation to the subcriteria for reasibility.	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met?	4
Rationale:	C□
	P□
	M∐   N□
RECOMMENDATION RECOMMENDATION	• • •
	T'
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement?	Υ□
Comments:	N
	A
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner)	
Co.1 <u>Organization</u> Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611	

### Co.2 Point of Contact

Jane, Han, MSW, jhan@sts.org, 312-202-5856-

### Measure Developer If different from Measure Steward

### Co.3 Organization

Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611

### Co.4 Point of Contact

Jane, Han, MSW, jhan@sts.org, 312-202-5856-

### Co.5 Submitter If different from Measure Steward POC

Jane, Han, MSW, jhan@sts.org, 312-202-5856-, Society of Thoracic Surgeons

Co.6 Additional organizations that sponsored/participated in measure development

### ADDITIONAL INFORMATION

### Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Members of the STS Task Force on Quality Initiatives provide clinical expertise as needed. The STS Workforce on National Databases meets at the STS Annual Meeting and reviews the measures on a yearly basis. Changes or updates to the measure will be at the recommendation of the Workforce.

### Ad.2 If adapted, provide name of original measure:

Ad.3-5 If adapted, provide original specifications URL or attachment

### Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released: 2004

Ad.7 Month and Year of most recent revision: 12, 2010

Ad.8 What is your frequency for review/update of this measure? annually

Ad.9 When is the next scheduled review/update for this measure? 2011

### Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment 0119 Sections 2a.14, 1b.2, 2b.3, 2f.3, 3a.6.pdf

Date of Submission (MM/DD/YY): 01/12/2011

# **2a.14. Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method)

The risk adjusted model is a hierarchical logistic regression model with participant level intercept. logit(outcome)  $\sim X\beta + (\gamma | participant)$ 

where X is the patient's risk factors,  $\theta$  is the regression coefficients of patient-level risk factors and  $\gamma$  is the participant level regression coefficient.

### **Inclusion Criteria**

The patient level risk adjusted model was developed using a population of patients undergoing isolated CABG procedure in the time period January 2002 – December 2006. For this measurement we re-fit the patient-level model using the latest two and a half years of data (January 2008 – June 2010) from the STS Adult Cardiac Surgery Database.

### Variable Definitions and Selection

All variables for consideration are listed in the table below.

### Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	= max (age–50, 0)
Age function 2	= max (age-60, 0)
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	= (BSA function 1) <sup>2</sup>
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
Insufficiency, tricuspid	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI >6 and <24 hours prior to surgery, = 0 otherwise
MI ≤ 6 hours	= 1 if history of MI ≤ 6 hours prior to surgery, = 0 otherwise

No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
PCI ≤ 6 hours	= 1 if patient had PCI ≤ 6 hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, 2 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwise
•	

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

The final patient-level model was built by backward selection method with several variables forced into the model. For the final patient-level model, please see the attachment.

# **1b.2.** Summary of Measure Results Demonstrating Performance Gap (Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.)

The summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. A high OR is undesirable and we define the percentiles with decreasing OR. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile" below.

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	1.0
1 <sup>st</sup>	2.2
5 <sup>th</sup>	1.7
10 <sup>th</sup>	1.5
25 <sup>th</sup>	1.2
Median	1.0
75 <sup>th</sup>	0.8
90 <sup>th</sup>	0.7
95 <sup>th</sup>	0.6
99 <sup>th</sup>	0.5
Outlier	35 (5.5)
High	7
Low	28

Also provided is the distribution of the risk adjusted event rate (see below). The risk adjusted rate is an estimate of the participant's event rate if, hypothetically, the case-mix of the patients treated by the participants is the same as the overall STS case-mix. It is calculated by the OR of the participant, other patient level parameter estimates from the hierarchical logistic model, and the overall STS event rate, by:

STS event rate \* (Participant's Expected Event Rate) / (Participant's Expected Event Rate Assuming Its Performance = STS Average Performance)

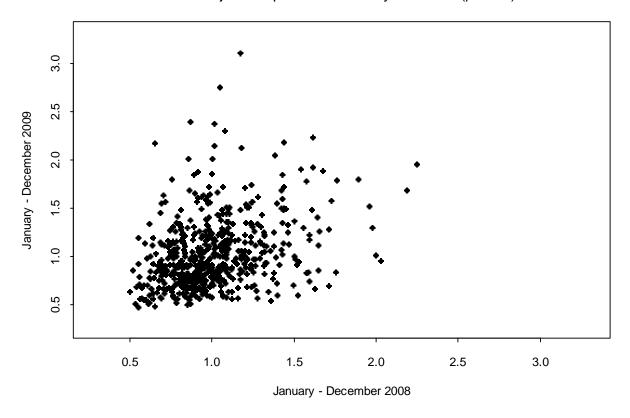
In the above equation, "Participant's Expected Event Rate" is calculated with the participant's actual OR, and "Participant's Expected Event Rate Assuming Its Performance = STS Average Performance" is calculated by assuming the participant's OR = 1 (i.e. no difference in performance from the STS average).

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	2.0
1 <sup>st</sup>	1.1
5 <sup>th</sup>	1.2
10 <sup>th</sup>	1.3
25 <sup>th</sup>	1.5
Median	1.9
75 <sup>th</sup>	2.3
90 <sup>th</sup>	2.8
95 <sup>th</sup>	3.2
99 <sup>th</sup>	4.1

Measurement	Risk-Adjusted Operative Mortality for CABG							
Outlier	35 (5.5)							
High	33 (3.3) 7							
Low	28							

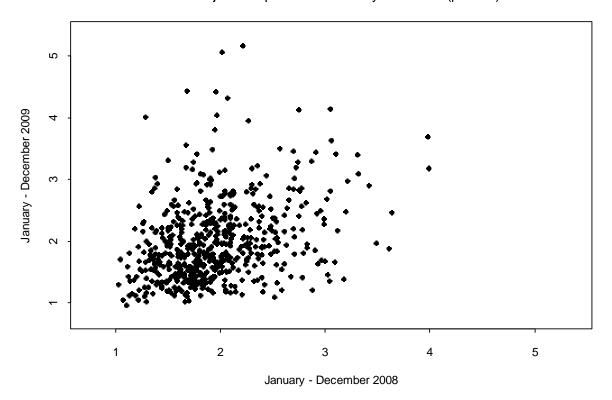
Testing results:  $\rho = 0.34$ 

Risk-Adjusted Operative Mortatility for CABG (ρ=0.34)



Risk Adjusted Rate:

Risk-Adjusted Operative Mortatility for CABG (ρ=0.34)



Results below are from January 1, 2009-December 31, 2009. Sample contains 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months.

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	1.0
1 <sup>st</sup>	2.2
5 <sup>th</sup>	1.7
10 <sup>th</sup>	1.5
25 <sup>th</sup>	1.2
Median	1.0
75 <sup>th</sup>	0.8
90 <sup>th</sup>	0.7
95 <sup>th</sup>	0.6
99 <sup>th</sup>	0.5
Outlier†	35 (5.5)
High	7
Low	28

### Risk Adjusted Rate:

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	2.0
1 <sup>st</sup>	1.1
5 <sup>th</sup>	1.2
10 <sup>th</sup>	1.3
25 <sup>th</sup>	1.5
Median	1.9
75 <sup>th</sup>	2.3
90 <sup>th</sup>	2.8
95 <sup>th</sup>	3.2
99 <sup>th</sup>	4.1
Outlier†	35 (5.5)
High	7
Low	28

<sup>†</sup>Represents the number of participants that are outliers according to two-sided 95% confidence interval of odds ratio.

### **3a.6. Results** (Qualitative or quantitative results and conclusions)

Although formal testing of interpretability has not been performed, this measure has been used and reported for STS Adult Cardiac Surgery database participants since 2007. Current report presentation and interpretation manuals are presented below. These materials are updated as needed based upon feedback from database participants.

### 1) Report Overview and Interpretation Manual:

### **The NQF Measures Report**

### a. Organization

This report section is separated into three areas corresponding to: 1) NQF volume measures, 2) NQF process measures, and 3) NQF outcomes measures, in that order. The header at the top of each page references the report section for that page. Each NQF measure is presented on a single row in the section. Tabular data are on the left-hand side of each page and a standard graphic representation is shown on the right-hand side.

### b. Statistical Calculation and Details – NQF Measures

**Time period:** This report section contains information on the individual STS participant and overall STS performance for the <u>most recent 12 months for volume</u>, <u>process and CABG outcomes measures and the most recent 60 months for Valve and Valve + CABG outcomes</u>. The 5 years (60 months) of <u>performance for outcomes involving Valve procedures is necessary due to smaller sample sizes</u>.

**Volume Measures:** The NQF report provides average annual case volumes data for three surgery categories: i) Isolated CABG, ii) Valve without CABG, and iii) combined CABG + Valve. Definitions of the three surgery categories are provided in Table 2 of this NQF Report Overview. For each type of surgery, the <u>participant's annualized volume</u> is calculated as:

Participant Annualized Volume = 12 x (# of surgeries) / (# of months)

where (# of surgeries) denotes the number of surgeries of the specified type performed by the participant during the specified time period, and (# of months) is the number of months during the specified time period for which the participant submitted at least one cardiac surgery of any type. The intent of calculating "annualized" volumes is to adjust for participants who participated in the database for fewer months than the time period specified. For participants who participated in the database and submitted cases every month during 2006, the annualized volume for 2006 is simply the total number of cases.

The <u>STS Average Annualized Volume</u> is the average value of all of the participant annualized volumes across the entire population of STS participants. The <u>Participant Percentile</u> indicates the percent of STS participants whose annualized volumes are less than, or equal to, your own. Higher percentiles indicate higher volumes in relation to other STS participant sites. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant annualized volumes across all database participants. For example, 90% of participants have annualized volumes less than or equal to the value marked "90<sup>th</sup> percentile." Confidence intervals are not provided for volume measures, as volume is known with certainty and is not estimated.

**Process Measures:** The NQF process measures provide data on the frequency of usage of five therapies among subsets of Isolated CABG patients. The therapies are: i) preoperative beta blockade therapy, ii) use of IMA, iii) discharge anti-platelet medication, iv) discharge beta blockade therapy, and v) discharge anti-lipid medication. The patient population for each measure differs, in accordance with the NQF specifications (see Table 2 of this NQF Report Overview for details). The number of <u>Eligible</u>

Procedures is the number of cases performed by the participant during the specified time period who meet the eligibility requirements to be included in the calculations when summarizing the participant's data. Beginning with the 2008 Harvest 3 report (covering the procedure time period through 6/30/2008), STS implementation of NQF medication process measures using data version 2.61 excludes records for which the medication was contraindicated/not indicated from the eligible population. The main summary statistic, Participant Usage, is the percent of eligible Isolated CABG cases during the specified time period for which the patient received the specified therapy. The Overall STS Usage is the percent of all eligible patients in the entire STS population during the specified time period who received the specified therapy. In calculating these percentages, missing data are treated as a "No", emphasizing the importance of having complete data in these fields.

The <u>Participant Percentile</u> indicates the percent of STS participants who applied the therapy in their respective populations less frequently than or as frequently as did your institution. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant usage across all participants in the database. For example, 90% of participants use the therapy less frequently than the amount indicated by the "90<sup>th</sup> percentile". A bar identified as "Participant" indicates the point estimate and limits of a 95% Confidence Interval (CI) for the participant's usage of therapy. The underlying parameter being estimated is the long-run usage rate that would be observed in a large sample of patients. The 95% CI indicates the range of usage rates that are consistent with the data in light of sampling variability.

Outcomes Measures: The NQF outcomes data provide risk-adjusted analyses of mortality and morbidity for Isolated CABG surgery as well as risk-adjusted operative mortality for Isolated AVR, Isolated MVR, AVR+CABG, and MVR+CABG. The main summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. The interpretation is similar to that of an O/E ratio (see the Risk-Adjusted Results: Overview portion of the General Report Overview for details on STS risk adjustment). An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. Each measure is calculated among patients undergoing surgery of the type specified during the time period specified who additionally meet certain eligibility requirements. The column labeled Eligible Procedures indicates the number of patients who met the inclusion criteria to be included in the analysis for the indicated measure. The Participant Percentile is the percent of STS participants who have an estimated OR that is greater than or equal to your estimated OR. Note that this is different than performance percentiles for process measures, where the percentile indicates the percentage of STS participants with performance that is less than the specified number. This simply reflects the fact that high process compliance is desirable, whereas a high OR is undesirable.

The <u>Observed Participant Rate</u> is the percent of eligible patients who experienced the specified outcome. Unlike the participant estimated OR, the observed participant rate is not risk-adjusted. The estimated OR is the main summary statistic for summarizing the NQF measure in this report.

The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of estimated Odds Ratios across all STS participants. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile." The line that extends to the left and right of the Participant Value indicates the lower and upper limits of a 95% Confidence Interval (CI) surrounding the participant's estimated OR.

### c. Technical Notes

**Calculation of Percentiles for the Distribution of Participant Values:** The graph provided for each measure contains information about the distribution of the value of the measure across all STS

participants, namely the minimum, maximum,  $10^{th}$  percentile,  $50^{th}$  percentile, and 90th percentile. The " $X^{th}$ " percentile, denoted  $P_x$ , is loosely defined as the number having the property that X% of the participant values are less than  $P_x$ , and (100 - X)% of the participant values are greater than  $P_x$ . For process measures, participants with greater than 5% missing data were excluded when calculating percentiles of the STS distribution and do not have a calculated participant percentile. For participants having less than 5% missing data on a process measure, the missing values on the process measure were converted to "No" before calculating percentiles. For outcomes measures, all participants submitting at least one eligible case were included when calculating percentiles of the STS distribution. Missing data on outcomes variables were treated as "No."

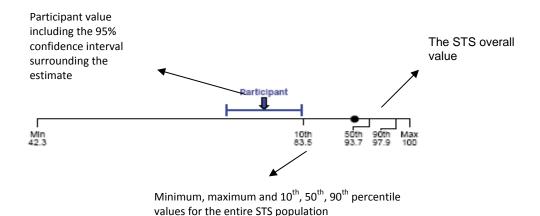
NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion criteria, and rules for handling missing data in the NQF section versus the rest of the report. Definitions used in the NQF report were designed to match current NQF specifications as closely as possible. It is expected that these differences will eventually disappear as the NQF measures are refined. Some important differences are:

Case Volumes – The NQF report section presents "annualized" volumes. These are case volumes that have been adjusted for the number of months that a participant was an active contributor to the database. Elsewhere in the STS report, total case volumes are presented without adjustment for the length of participation.

Eligible Cases - The NQF report also presents the number of "eligible cases" for each measure. Separate inclusion criteria are applied to each measure, and these inclusion criteria do not always match the definitions used elsewhere in the STS report. Please refer to the footnotes in each section for specific details.

### **Interpretation Manual**

In addition to the statistics provided for each of the STS Composite Quality Domains and NQF measures, a figure representing the distribution of values for the entire STS population is provided.



The figure allows participants to quickly judge their performance relative to the overall STS. The scale of the figure is set up such that the right side of the distribution represents the <u>most</u> favorable performance and the left side represents the <u>least</u> favorable performance (Note that in some cases smaller numbers will be on the left; in other instances, smaller numbers will be on the right. For example, for the Pre-operative Beta Blockade Therapy measure, the far left side of the distribution will contain the *lowest* percentage Beta Blockade Therapy for an STS participant – this corresponds to least

favorable performance. Alternatively, for the Operative Mortality Measure, the far left side of the distribution will contain the *highest* Estimated Odds Ratio – this also corresponds to least favorable performance). If a participant's value for a given measure is to the left of the STS overall value, the participant is performing worse on that measure than the overall STS. Conversely, if the participant's value for a given measure is located to the right of the overall STS value, the participant is performing better than the overall STS.

**NOTE!** Care should be given to reading these figures. In some instances, the various percentiles presented cluster very close together in the data. In such cases, the label for the percentile is not necessarily located immediately at the point on the distribution where the percentile occurs. An example of this is apparent in the figure above: The 50<sup>th</sup> percentile corresponds to a value of 93.7 and looks to align fairly closely with the STS overall value as represented by the large black dot. However, the expandable figure marking actually points to a place somewhere to the right of the STS overall value for the 50<sup>th</sup> percentile marking. So the STS overall value would be some amount less than 93.7.

Also, please note that in some cases, small sample sizes preclude valid comparisons between the participant and the STS overall. Such instances are clearly noted in the report output.

### a. NQF Measures Interpretation Example

Sample CABG Operative Mortality results – tabular and figure representation.

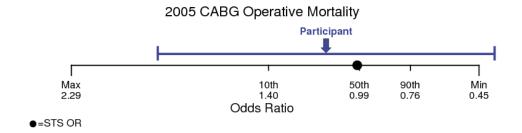
NQF	Eligible	Participant	Participant	Participant
Measure	Procedures	Estimated OR	Percentile	Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

Eligible Procedures: 74 patients met the inclusion criteria for the indicated measure.

Participant Estimated OR (Odds Ratio): The main summary statistic measuring the impact that a participant's performance has on a patient's probability of experiencing an adverse outcome has a value of 1.14 indicating worse than expected performance.

Participant Percentile: 26.3% of STS participants had an estimated OR greater than or equal to your estimated OR. In other words, 26.3% had the same or worse performance.

Participant Observed Rate: 5.4% of the 74 eligible patients experienced the specified outcome.



### 2) Sample page from section of the report that contains NQF measure results:



# NQF Measures Process Measures Participant 99999 STS Period Ending 12/31/2008



NQF Measure	Eligible Procedures	Participant Usage (95% CI)	Participant Percentile	Overall STS Usage	Distribution of Participant Values
Jan 2008 - Dec 2008 Preoperative Beta Blockade Therapy <sup>1</sup>	541	89.3% (86.4 , 91.8)	69.9	82.1%	Participant    Min   10th   50th   90th   Max   95.6   100
Jan 2008 - Dec 2008 Use of IMA <sup>2</sup>	536	96.5% (94.5 , 97.9)	63.3	94.2%	Participant  Min 10th 50th 90th Max 53.2 87.8 85.2 98.9 100
Jan 2008 - Dec 2008 Discharge Anti-Platelet Medication <sup>3</sup>	536	98.7% (97.3 , 99.5)	68.7	96.1%	Participant  Min 10th 50th 90th Max 18.7 92.1 97.5 100 100
Jan 2008 - Dec 2008 Discharge Beta Blockade Therapy <sup>4</sup>	538	96.1% (94.1 , 97.6)	53.4	93.7%	Participant  Min 10th 50th 80th Max 15.1 85.3 85.7 100 100
Jan 2008 - Dec 2008 Discharge Anti-Lipid Treatment⁴	535	91.8% (89.1 , 94.0)	40.7	91.4%	Participant

Excludes v2.61 contranindicated / not indicated records.

Excludes patients with prior CABG surgery

Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

Excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

# The Society of Thoracic Surgeons 2008 Cardiac Surgery Risk Models: Part 1—Coronary Artery Bypass Grafting Surgery

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Background. The first version of The Society of Thoracic Surgeons National Adult Cardiac Surgery Database (STS NCD) was developed nearly 2 decades ago. Since its inception, the number of participants has grown dramatically, patient acuity has increased, and overall outcomes have consistently improved. To adjust for these and other changes, all STS risk models have undergone periodic revisions. This report provides a detailed description of the 2008 STS risk model for coronary artery bypass grafting surgery (CABG).

Methods. The study population consisted of 774,881 isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2002, and December 31, 2006, at 819 STS NCD participating centers. This cohort was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. The validation sample was used to assess model calibration and discrimination. Model outcomes included operative mortality, renal failure, stroke, reoperation for any cause, prolonged ventilation, deep sternal wound infection, composite major morbidity or mortality, prolonged length of stay (> 14 days), and short length of stay (< 6 days and alive). Candidate predictor variables were selected based on their availability in versions 2.35, 2.41, and 2.52.1 of the STS NCD and their presence in (or ability to be mapped to) version 2.61. Potential predictor

variables were screened for overall prevalence in the study population, missing data frequency, coding concerns, bivariate relationships with outcomes, and their presence in previous STS or other CABG risk models. Supervised backwards selection was then performed with input from an expert panel of cardiac surgeons and biostatisticians. After successfully validating the fit of the models, the development and validation samples were subsequently combined, and the final regression coefficients were estimated using the overall combined (development plus validation) sample.

Results. The c-index for the mortality model was 0.812, and the c-indices for other endpoints ranged from 0.653 for reoperation to 0.793 for renal failure in the validation sample. Plots of observed versus predicted event rates revealed acceptable calibration in the overall population and in numerous subgroups. When patients were grouped into categories of predicted risk, the absolute difference between the observed and expected event rates was less than 1.5% for each endpoint. The final model intercept and coefficients are provided.

Conclusions. New STS risk models have been developed for CABG mortality and eight other endpoints. Detailed descriptions of model development and testing are provided, together with the final algorithm. Overall model performance is excellent.

(Ann Thorac Surg 2009;88:S2-22) © 2009 by The Society of Thoracic Surgeons

In 1986, The Society of Thoracic Surgeons (STS) convened an Ad Hoc Committee on Risk Factors for Coronary Artery Bypass Graft Surgery (CABG) [1] and an

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Ad Hoc Committee to Develop a National Database for Cardiothoracic Surgery [2]. This was prompted by the

Drs Shahian, O'Brien, Filardo, Ferraris, Haan, Rich, Normand, DeLong, Shewan, Peterson, Edwards, Anderson, and Ms Dokholyan have no conflicts of interest to declare regarding this work.

### Abbreviations and Acronyms

BSA = body surface area

CABG = coronary artery bypass graft surgery

CHF = congestive heart failure

EF = ejection fraction

GFR = glomerular filtration rate

HCFA = Health Care Financing Administration

IABP = intra-aortic balloon pump NYHA = New York Heart Association NCD = National Adult Cardiac Surgery Database

O/E = observed to expected ratio

QMTF = Quality Measurement Task Force STS = The Society of Thoracic Surgeons

release earlier that year of inadequately risk-adjusted hospital mortality data by the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services. Although the HCFA analytical methodology was widely criticized, STS leadership recognized that the underlying principle of collecting and analyzing data to improve patient outcomes was valid, particularly for complex and costly procedures such as coronary artery bypass grafting surgery (CABG). They believed that it was the responsibility of professional organizations to develop credible clinical data registries for their own specialties, and that risk models derived from such registries would circumvent many of the concerns resulting from the use of unadjusted administrative data. Such clinical registries would be used as credible data sources for quality assessment and improvement activities as well as for research.

These early activities ultimately led to the development of the STS National Adult Cardiac Surgery Database (NCD) [3, 4]. Since its release to members in 1990, the STS NCD has evolved to become one of the largest specialty-specific clinical data registries in the world. It currently has more than 950 participants enrolled, representing just under 90% of the cardiac surgery providers in the United States, with data on more than 3.6 million procedures. Similar STS data registries have now been developed for congenital heart surgery and general thoracic surgery, and future plans include the development of specialty modules (eg, quality metrics, atrial fibrillation surgery, thoracic aortic surgery). Recent enhancements, including the addition of unique physician and patient identifiers, will facilitate linkages with other registries and greatly expand the potential of the STS NCD for longitudinal follow-up, comparative effectiveness, and cost efficiency studies.

In addition to the development of the STS NCD as a comprehensive, nationally representative data registry, the second major goal of the STS was to assure that analyses derived from this registry would be appropriately adjusted for preoperative patient severity, a major deficiency of the HCFA reports that were initially published in 1986. This was accomplished by first identifying

risk factors for specific procedures and outcomes, beginning with isolated CABG, then using these predictor variables to develop risk models. With statistical risk models, which are most often based on logistic regression, the expected outcome for a patient with a given set of risk factors can be determined, and that can be compared with the observed outcome. The observed (O) and expected (E) outcomes are summed over all patients of a particular surgeon or hospital to yield the risk-standardized mortality ratio (O/E), which can then be multiplied by the average rate in the reference population to calculate risk-standardized mortality rates [5–7].

STS CABG risk models have undergone periodic updates and revisions, the most recent of which was based upon 2000 to 2002 STS NCD data. In 2007, the STS Database Modernization Task Force completed a major specification upgrade of the STS NCD data collection instrument from version 2.52.1 to version 2.61. This included refinement, modification, consolidation, or elimination of some data elements, as well as an attempt to harmonize definitions with those of the American College of Cardiology National Cardiovascular Data Registry whenever possible. Given these changes, as well as the number of years since the last risk model update, the STS Quality Measurement Task Force (QMTF) was asked to develop new risk models for isolated CABG, isolated valve repair or replacement, and combined CABG plus valve procedures. The authors of this report include the QMTF members who participated in this initiative.

Implementation of these new models in January 2008 coincided with the release of STS NCD version 2.61. This report, Part 1 of 3, describes the development of the new mortality and morbidity models for isolated CABG surgery.

### **Study Purpose**

The primary goal of this study was to develop risk-prediction algorithms for patients undergoing isolated CABG surgery. As the major intended use of these algorithms was to compare participant outcomes to the overall STS national experience, risk factors were generally restricted to patient and clinical characteristics present preoperatively.

### Risk Model Development and Transparency

The availability of user-friendly statistical software programs and the exponential increase in computing speed have greatly facilitated statistical analyses such as logistic regression, the basis for many risk models. However, despite these technological advances, clinical judgment, experience, intuition, and practicality still play a critical role in risk model development. There are many points in model development at which legitimate differences in approach may lead to substantial differences in the resulting statistical models and the inferences derived from them [8].

We believe the degree of transparency provided in this report regarding the development of the STS CABG risk models is essential in today's health care environment. In an era when society demands full transparency regarding health care performance, the methodologies used to evaluate that performance should be just as transparent [9, 10]. This fundamental principle is among the standards established by the American Heart Association and American College of Cardiology for statistical models used for public reporting [11].

### Study Population and Endpoints

All isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2000, and December 31, 2006, were initially considered for inclusion, although the final development and validation samples were derived from 2002 to 2006 data. Patients missing data on sex (n = 195) were excluded, as these patients are not included in STS performance feedback reports to database participants. That left a study population of 774,881 surgical procedures from 819 database participants. Patients on dialysis preoperatively (n = 12,415) were excluded when developing the risk model for postoperative renal failure.

### Training and Validation Samples

The study population was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. Data from the validation sample were used to assess model fit, discrimination, and calibration. After choosing variables and assessing model fit, the development and validation samples were subsequently combined, and the final model coefficients were estimated using the combined (development plus validation) data.

### **Endpoints**

Risk models were developed for the nine endpoints listed below. Only mortality was recorded beyond the index hospitalization. Morbidity data included only in-hospital complications, although beginning in STS NCD version 2.61, sternal infections will be recorded for up to 30 days postoperatively. The nine endpoints are as follows: (1) operative mortality: death during the same hospitalization as surgery, regardless of timing, or within 30 days of surgery regardless of venue; (2) permanent stroke (cerebrovascular accident): a central neurologic deficit persisting longer than 72 hours; (3) renal failure: a new requirement for dialysis or an increase of the serum creatinine to more than 2.0 mg/dL and double the most recent preoperative creatinine level; (4) prolonged ventilation (longer than 24 hours); (5) deep sternal wound infection; (6) reoperation for any reason; (7) major morbidity or mortality: a composite defined as the occurrence of any of the above endpoints; (8) prolonged postoperative length of stay (PLOS): length of stay (LOS) more than 14 days (alive or dead); and (9) short postoperative LOS (SLOS): LOS less than 6 days and patient alive at discharge (this SLOS definition differs from the previous STS risk models, which did not exclude patients who died in-hospital; patients who died within 5 days of surgery are

included in the new models but are treated as not having a short stay).

Table 1 summarizes the frequencies of these endpoints in the study population for each predictor variable category (ie, the bivariate relationships).

### Selection of Candidate Predictor Variables

Initial Data Screening of Candidate Predictor Variables

We began by considering all possible candidate variables from the development set (Table 2). Because the primary goal of the STS risk models is to adjust surgical outcomes, in general only preoperative patient variables are included. However, because these models are also used for other purposes such as individual patient prediction and counseling, there were a few modifications (which are discussed in the relevant sections) in the application of this general principle.

As there were a large number of procedures and endpoints available, we were not statistically constrained to highly parsimonious models, nor is such an approach generally favored in regression modeling [12–14]. Discarding valid data elements can waste valuable information that has been collected at substantial effort and cost. Furthermore, although much of the discrimination of a predictive model may be contained in a relatively small number of variables [15, 16], some predictor variables that add only modestly to discrimination may still be important predictors of outcomes at the patient level [17, 18].

# Expert Panel Review for Clinical Relevance and Face Validity

All candidate variables available in version 2.61 were individually discussed by a panel of cardiac surgeons and health policy experts to assure that clinical relevance as well as multiple aspects of validity (face, construct, and content) had been considered.

### Data Version for Model Development

Although these new risk models were to be introduced in conjunction with the release of STS NCD version 2.61, they were developed with data collected under the three previous data versions (2.35, 2.41, and 2.52.1) because no 2.61 data were yet available. The QMTF began its predictor selection process with two caveats. First, any candidate variable had to be collected consistently across the three previous data versions. Second, it had to also be available in version 2.61 or have the ability to be mapped to this new version. For example, history of smoking and renal failure were not candidate variables as they were either not included in, or were unable to be mapped to, version 2.61. Renal function is now assessed by the last preoperative serum creatinine value, which is collected in all data versions. Because the definition of hypercholesterolemia has changed substantially over successive STS data versions, and because counterintuitive results have been observed in some previous analyses of hyper-

Table 1. Distribution of Risk Factors and Frequency of Adverse Outcomes in Overall Study Population, Isolated Coronary Artery Bypass Graft Surgery (2002–2006)

	Numl Pati				Perce	nt of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Overall											
Total	774,881	100.0	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Age, years											
< 55	137,318	17.72	1.0	0.5	1.7	7.1	0.3	3.7	10.0	2.7	67.1
55–64	221,697	28.61	1.3	0.9	2.4	7.8	0.4	4.2	11.4	3.8	59.4
65–74	245,132	31.63	2.4	1.6	3.9	10.0	0.5	5.5	14.9	5.9	47.7
≥ 75	170,734	22.03	4.7	2.3	6.4	13.9	0.5	7.5	20.9	9.6	33.0
Sex											
Male	560,006	72.27	2.0	1.2	3.4	8.7	0.4	5.1	13.4	4.9	55.0
Female	214,875	27.73	3.4	1.9	4.1	12.2	0.5	5.6	17.0	7.2	41.5
Race											
Caucasian	665,941	85.94	2.3	1.3	3.5	9.3	0.4	5.1	13.9	5.3	52.2
Black	44,405	5.73	2.7	2.0	5.2	13.5	0.7	6.3	19.0	8.2	41.3
Hispanic	25,103	3.24	2.6	1.5	4.3	11.3	0.5	5.6	16.1	6.1	48.4
Asian	12,509	1.61	2.7	1.9	3.8	12.6	0.3	7.2	17.4	7.0	45.2
Other	21,222	2.74	2.3	1.3	3.6	10.4	0.5	5.5	14.8	6.0	48.7
Missing	5,701	0.74	2.3	1.4	4.1	9.4	0.4	5.2	14.5	6.1	48.9
Body surface area (m <sup>2</sup> )	-,						**-				
< 1.50	14,339	1.85	6.2	2.4	4.6	16.2	0.3	8.3	22.1	9.8	36.5
1.50–1.74	111,458	14.38	3.8	2.0	4.0	12.6	0.3	6.5	17.7	7.4	42.5
1.75–1.99	280,677	36.22	2.4	1.5	3.5	9.6	0.4	5.4	14.4	5.6	50.7
≥ 2.00	363,817	46.95	1.7	1.0	3.6	8.6	0.5	4.6	13.1	4.8	55.0
Missing	4,590	0.59	3.7	1.4	4.0	7.6	0.3	4.7	13.9	6.8	46.0
Body mass index (kg/m²)	4,070	0.07	0.7	1.1	1.0	7.0	0.0	1.7	10.7	0.0	10.0
< 25	169,091	21.82	3.3	1.7	3.5	11.0	0.3	6.7	16.3	6.7	47.6
25–29	303,371	39.15	2.1	1.3	3.1	8.6	0.3	4.9	13.1	4.8	54.2
30–34	186,148	24.02	1.8	1.2	3.6	9.0	0.5	4.5	13.4	5.0	53.1
≥ 35	110,213	14.22	2.3	1.2	5.2	12.0	0.8	4.9	16.8	6.8	45.7
Missing	6,058	0.78	3.7	1.4	4.2	8.6	0.3	4.8	14.5	6.7	47.2
Diabetes mellitus	0,030	0.70	0.7	1.1	1,4	0.0	0.0	1.0	14.5	0.7	17.2
No diabetes	492,800	63.60	2.1	1.2	2.8	8.8	0.3	5.0	13.0	4.7	54.8
Diabetes–noninsulin	195,421	25.22	2.3	1.6	4.3	10.1	0.5	5.2	15.2	6.0	48.2
Diabetes-insulin	84,406	10.89	3.6	1.8	7.1	13.9	1.0	6.5	20.6	9.7	37.5
Diabetes-missing treatment	1,439	0.19	3.1	2.2	4.6	11.1	0.7	4.6	15.7	8.8	41.9
Missing	815	0.13	3.8	0.7	2.6	8.8	0.5	4.5	12.3	6.9	43.7
Hypertension	013	0.11	3.0	0.7	2.0	0.0	0.5	4.5	12.5	0.9	43.7
No	167,260	21.59	1.9	0.9	2.2	8.1	0.3	4.6	11.7	4.2	58.2
Yes	606,813	78.31	2.5	1.5	4.0	10.1	0.5	5.4	15.1	5.9	49.3
Missing	808	0.10	3.8	0.7	2.4	9.3	0.5	5.2	12.7	6.7	43.9
Hypercholesterolemia	808	0.10	3.0	0.7	2.4	9.3	0.5	3.2	12.7	0.7	43.9
No	199,894	25.80	3.0	1.6	3.9	11.0	0.5	5.8	16.1	6.5	48.7
Yes	573,257	73.98	2.1	1.3	3.5	9.2	0.3	5.0	13.8	5.2	52.1
Missing	1,730	0.22	4.1	1.6	3.5	10.3	0.4	4.7	13.9	7.3	47.5
9	1,730	0.22	4.1	1.0	3.3	10.5	0.3	4.7	13.9	7.3	47.3
Past or present smoker No	295,999	38.20	2.4	1.4	3.7	9.0	0.4	E 1	13.9	E 2	50.1
			2.4	1.4			0.4	5.1		5.3	
Yes	477,911	61.68	2.3	1.3	3.6	10.1	0.5	5.3	14.7	5.7	51.9
Missing	971	0.13	3.4	0.7	3.1	9.9	0.4	5.3	13.5	9.1	41.0
Chronic lung disease	(10.011	70.01	2.0	1.0	2.2	0.4	0.2	4.0	12.0	4 7	F2 F
None	612,211	79.01	2.0	1.3	3.3	8.4	0.3	4.9	13.0	4.7	53.7
Mild	85,005	10.97	2.8	1.5	4.2	12.0	0.6	5.8	16.9	7.0	45.7
Moderate	47,745	6.16	3.8	1.6	5.3	15.8	0.8	6.8	20.8	9.6	39.5
Severe	22,302	2.88	7.0	2.0	7.7	22.8	1.1	9.5	29.0	15.3	29.2
Missing	7,618	0.98	2.6	1.4	3.2	8.2	0.2	3.9	12.6	5.7	53.4

Table 1. Continued

	Numb Patie				Percer	nt of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Peripheral vascular disease											
No	653,260	84.30	2.0	1.2	3.2	8.8	0.4	4.8	13.1	4.8	53.5
Yes	120,480	15.55	4.4	2.3	6.1	14.4	0.7	7.5	21.2	9.6	38.7
Missing	1,141	0.15	3.9	1.1	3.1	11.8	0.3	5.5	14.4	7.4	43.9
Cerebrovascular disease											
No	668,073	86.22	2.1	1.1	3.3	9.0	0.4	4.9	13.4	5.0	53.4
Yes	105,792	13.65	4.0	2.9	5.8	14.0	0.6	7.2	20.7	9.3	37.7
Missing	1,016	0.13	3.2	0.6	2.4	8.9	0.3	4.2	11.4	6.8	43.2
CVA											
No CVA	717,721	92.62	2.2	1.2	3.4	9.3	0.4	5.1	13.8	5.2	52.5
Remote CVA (> 2 weeks)	53,341	6.88	4.2	3.1	6.1	15.3	0.7	7.4	22.0	10.3	35.5
Recent CVA ( $\leq$ 2 weeks)	1,763	0.23	5.0	4.9	6.5	18.8	0.9	8.7	25.4	13.0	32.5
CVA-missing timing	745	0.10	3.8	3.5	6.9	14.0	0.5	5.9	21.7	10.7	34.2
Missing	1,311	0.17	3.3	1.0	2.6	7.4	0.2	4.3	11.4	5.9	47.8
Endocarditis											
No endocarditis	773,002	99.76	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Treated endocarditis	472	0.06	4.4	0.8	5.3	15.3	0.6	8.5	19.9	8.9	33.7
Active endocarditis	110	0.01	2.7	1.8	6.3	20.0	1.8	11.8	24.5	20.0	41.8
Endocarditis-missing type	90	0.01	4.4	4.4	5.8	11.1	1.1	3.3	15.6	2.2	55.6
Missing	1,207	0.16	4.1	1.0	3.5	9.0	0.2	4.6	12.8	7.0	46.2
Renal failure											
No	731,626	94.42	2.1	1.3	3.2	9.0	0.4	5.0	13.4	5.0	52.8
Yes	42,153	5.44	7.2	2.7	14.7	22.5	1.0	9.9	31.9	15.8	23.4
Missing	1,102	0.14	3.1	0.8	2.8	7.4	0.3	3.4	10.8	6.4	46.6
Renal function											
Creatinine < 1.00 mg/dL	274,197	35.39	1.6	1.1	1.5	8.0	0.3	4.4	11.2	4.0	55.6
Creatinine 1-1.49 mg/dL	398,833	51.47	2.0	1.3	3.4	8.9	0.4	5.0	13.5	4.9	53.1
Creatinine 1.5-1.99 mg/dL	57,779	7.46	4.5	2.3	10.8	16.1	0.7	7.8	25.2	10.6	34.5
Creatinine 2.0-2.49 mg/dL	12,463	1.61	6.9	2.9	14.3	21.3	0.9	9.4	31.5	15.3	24.7
Creatinine $\geq 2.5 \text{ mg/dL}$	7,906	1.02	8.2	3.2	20.4	23.4	0.9	11.1	37.9	18.6	20.4
Dialysis	12,415	1.60	8.4	2.7	*NA	25.3	1.2	10.5	31.5	16.4	19.6
Missing	11,288	1.46	3.3	1.2	3.1	7.6	0.3	4.3	12.9	5.9	50.1
Immunosuppressive treatment											
No	758,368	97.87	2.3	1.4	3.6	9.6	0.4	5.2	14.2	5.4	51.5
Yes	14,976	1.93	5.4	1.8	6.3	15.6	0.8	8.7	22.5	10.8	37.0
Missing	1,537	0.20	3.3	0.8	2.8	6.5	0.4	4.6	11.4	6.1	46.8
Prior CABG Surgery											
No	735,033	94.86	2.2	1.4	3.5	9.4	0.4	5.1	14.1	5.4	51.7
Yes	36,693	4.74	5.3	1.6	5.8	14.7	0.5	7.5	20.9	7.8	42.6
Missing	3,155	0.41	2.7	1.1	3.3	8.9	0.5	4.8	12.9	6.8	48.9
Prior valve surgery											
No	769,434	99.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.3
Yes	2,280	0.29	5.9	1.9	6.8	15.3	0.7	8.6	22.5	11.1	32.0
Missing	3,167	0.41	2.9	1.2	3.5	8.6	0.5	4.4	12.7	6.3	50.0
Prior other cardiac surgery											
No	755,653	97.52	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.3
Yes	15,218	1.96	3.9	1.5	4.9	13.1	0.6	6.6	18.6	7.6	45.5
Missing	4,010	0.52	2.8	1.0	2.9	8.5	0.4	4.4	12.2	5.9	50.5
Number of previous CV surgeries											
No previous CV surgery	723,623	93.39	2.2	1.4	3.5	9.4	0.4	5.1	14.0	5.4	51.7
One prior CV surgery	40,474	5.22	4.7	1.6	5.4	13.8	0.5	7.3	19.9	7.7	44.1
Two or more prior CV Surgeries	4,840	0.62	6.2	1.4	5.6	14.7	0.6	8.0	22.0	8.4	41.5
Missing	5,944	0.77	2.9	1.1	3.2	9.8	0.6	5.5	14.3	6.1	51.2

Table 1. Continued

Variable	Number of Patients		Percent of Patients Experiencing Endpoint									
	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS	
Prior PCI												
No PCI	606,824	78.31	2.3	1.4	3.6	9.5	0.4	5.1	14.2	5.6	51.1	
$PCI \le 6 \text{ hours}$	7,373	0.95	8.9	2.1	7.4	25.8	0.6	10.5	32.6	11.3	35.5	
PCI > 6 hours	155,161	20.02	2.3	1.2	3.5	9.6	0.4	5.4	14.3	5.1	52.4	
PCI-missing timing	2,456	0.32	3.0	0.6	3.3	8.0	0.8	5.1	13.4	6.8	48.9	
Missing	3,067	0.40	3.3	1.0	3.0	9.8	0.5	4.7	13.7	6.2	47.3	
Acuity status												
Elective	381,116	49.18	1.5	1.1	2.9	6.6	0.4	4.3	11.1	4.1	55.6	
Urgent	356,287	45.98	2.4	1.5	3.9	10.8	0.5	5.6	15.7	6.2	48.5	
Emergent	34,513	4.45	8.1	2.6	8.3	29.6	0.7	10.4	34.1	13.3	33.2	
Emergent salvage	1,967	0.25	38.6	4.9	17.4	52.7	0.7	18.4	70.0	23.5	12.6	
Missing	998	0.13	3.2	1.3	3.6	9.2	0.5	4.8	13.7	6.5	43.6	
MI												
No prior MI	424,599	54.80	1.5	1.1	2.8	6.9	0.3	4.5	11.3	4.1	55.4	
MI > 21 days	137,522	17.75	2.1	1.3	3.5	8.9	0.5	5.2	13.9	5.4	50.4	
MI 8–21 days	26,205	3.38	4.0	1.8	6.0	14.4	0.8	7.5	20.7	10.2	38.1	
MI 1–7 days	148,659	19.18	3.4	1.8	4.8	14.0	0.5	6.1	18.9	7.5	45.7	
MI > 6 and < 24 hours	21,044	2.72	6.0	2.4	6.7	23.6	0.5	8.1	28.1	10.4	39.1	
$MI \le 6 \text{ hours}$	11,539	1.49	10.4	2.6	8.6	31.2	0.6	10.6	36.8	13.3	33.5	
MI-missing timing	4,064	0.52	3.6	1.6	4.6	11.3	0.5	5.6	17.5	7.2	43.9	
Missing	1,249	0.16	2.1	1.1	2.4	6.6	0.2	3.8	10.2	6.7	49.4	
Angina	,											
No	130,143	16.80	2.5	1.4	3.8	9.5	0.4	5.6	14.7	6.2	48.5	
Yes	643,815	83.09	2.3	1.3	3.6	9.7	0.4	5.2	14.3	5.4	51.8	
Missing	923	0.12	2.3	1.0	2.6	8.8	0.5	4.0	11.2	8.2	43.9	
Cardiogenic shock	720	0.12		110		0.0	0.0	1.0	11.2	o. <u>-</u>	1015	
No	758,766	97.92	2.0	1.3	3.4	8.9	0.4	5.0	13.6	5.2	51.9	
Yes	14,919	1.93	18.0	3.6	14.6	49.6	1.0	15.3	55.7	23.1	18.3	
Missing	1,196	0.15	2.7	1.1	3.2	8.0	0.4	4.4	12.0	7.4	44.7	
Resuscitation	1,150	0.10	,		J	0.0	0.1		12.0	,,,	1117	
No	766,674	98.94	2.2	1.3	3.5	9.4	0.4	5.1	14.1	5.4	51.5	
Yes	6,939	0.90	17.1	3.0	11.4	37.5	0.9	14.0	46.1	18.2	24.3	
Missing	1,268	0.16	2.2	0.8	3.4	8.0	0.6	3.9	11.5	7.3	45.0	
Arrhythmia	1,200	0.10		0.0	0.1	0.0	0.0	0.5	11.0	7.0	10.0	
No arrhythmia	706,709	91.20	2.0	1.3	3.3	8.9	0.4	4.9	13.4	5.0	53.1	
AFib/flutter	39,125	5.05	5.4	2.3	7.1	16.4	0.7	8.5	23.8	11.9	29.4	
Heart block	10,026	1.29	5.8	1.9	6.8	16.8	0.6	9.2	24.2	9.4	36.4	
Sustained VT/VF	14,336	1.85	8.2	2.0	6.8	23.8	0.6	11.1	31.5	12.0	33.0	
Arrhythmia-other	1,853	0.24	3.8	1.6	5.3	12.9	0.6	6.5	19.1	7.3	39.2	
Arrhythmia-missing type	1,344	0.24	3.9	1.7	4.4	11.9	0.7	7.3	17.5	8.3	37.9	
Missing	1,488	0.17	2.7	1.0	3.0	7.1	0.5	3.8	11.1	6.5	45.5	
Preoperative IABP	1,100	0.17	2.7	1.0	3.0	7.1	0.0	0.0	11.1	0.0	40.0	
No	714,824	92.25	2.0	1.3	3.3	8.0	0.4	4.9	12.8	4.9	52.8	
Yes	58,134	7.50	6.9	2.2	7.7	30.8	0.4	9.6	34.4	12.9	32.0	
Missing	1,923	0.25	4.2	1.7	4.3	10.9	0.6	5.8	16.0	7.2	45.7	
NYHA class	1,923	0.23	4.2	1.7	4.5	10.9	0.0	5.0	10.0	7.2	45.7	
I	07 812	12.62	15	11	2.5	6.2	0.3	1.1	10.6	2.0	57.0	
II	97,812 187,947	12.62 24.25	1.5 1.3	1.1 1.1	2.6	6.3 6.5	0.3	4.4 4.2	10.6 10.7	3.9 3.8	57.0 56.5	
III		37.14				9.0	0.3		13.9			
	287,760		2.0	1.3	3.6			5.0 7.1		5.4	51.3	
IV Missing	165,325	21.34	4.5	1.9	5.5	16.6	0.6	7.1 5.2	21.9	8.8	42.5	
Missing	36,037	4.65	2.4	1.2	3.6	8.9	0.3	5.3	13.6	5.8	47.7	
Congestive heart failure	666 F03	06.00	4.0	1.0	2.0	<b>F</b> 0	0.2	4 =	10.0	4.0	F4 F	
No	666,592	86.03	1.8	1.2	2.9	7.9	0.3	4.7	12.2	4.3	54.7	
Yes	106,700	13.77	5.9	2.4	8.5	21.0	0.9	8.7	28.0	13.2	29.5	
Missing	1,589	0.21	3.3	1.4	3.1	9.2	0.4	4.5	13.0	7.4	49.6	

Table 1. Continued

	Number of Patients		Percent of Patients Experiencing Endpoint									
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS	
Number of diseased coronary vessels												
None	2,012	0.26	2.3	0.4	2.8	8.9	0.4	4.6	12.6	5.5	53.1	
One	32,311	4.17	1.5	0.6	1.9	6.1	0.2	4.4	9.8	3.1	66.3	
Two	150,881	19.47	1.8	1.0	2.7	8.0	0.4	4.5	12.0	4.5	56.3	
Three	586,658	75.71	2.5	1.5	4.0	10.4	0.4	5.5	15.3	6.0	49.1	
Missing	3,019	0.39	2.6	0.6	1.8	5.5	0.2	4.5	10.8	5.9	54.2	
Left main disease ≥ 50%												
No	554,355	71.54	2.1	1.3	3.4	8.8	0.4	5.0	13.5	5.1	52.7	
Yes	217,548	28.08	3.0	1.5	4.3	11.9	0.5	5.9	16.8	6.6	47.6	
Missing	2,978	0.38	2.3	1.4	2.7	6.3	0.3	5.5	11.9	5.9	45.4	
Ejection fraction (%)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,											
< 25	25,323	3.27	7.2	2.2	8.0	25.2	0.8	10.5	31.9	13.7	27.8	
25–34	57,460	7.42	4.6	2.1	6.1	17.6	0.6	7.6	23.8	10.3	36.8	
35–44	108,623	14.02	3.0	1.7	4.7	12.4	0.6	6.0	17.5	7.2	45.7	
45–54	189,478	24.45	1.9	1.3	3.4	8.7	0.4	4.8	13.2	5.0	53.1	
≥ 55	351,455	45.36	1.5	1.1	2.7	6.8	0.3	4.4	11.1	3.9	56.1	
	42,542	5.49	3.4	1.4	4.1	10.8	0.3	5.6	16.0	6.1	50.0	
Missing	42,342	3.49	3.4	1.4	4.1	10.0	0.4	3.0	10.0	0.1	30.0	
Mitral stenosis	75.6.600	07.64	2.2	1.4	2.6	0.7	0.4	F 0	111		F1 0	
No	756,609	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2	
Yes	2,703	0.35	5.5	2.4	6.4	17.0	0.7	7.5	22.9	10.5	35.7	
Missing	15,569	2.01	2.1	1.3	3.4	8.3	0.4	4.6	13.1	5.0	53.1	
Aortic stenosis												
No	750,185	96.81	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.4	
Yes	11,386	1.47	4.7	2.1	6.5	14.8	0.7	7.9	21.5	9.7	36.6	
Missing	13,310	1.72	2.3	1.3	3.3	8.5	0.4	4.7	13.1	5.0	52.5	
Tricuspid stenosis												
No	756,574	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2	
Yes	597	0.08	3.4	2.3	6.6	14.9	0.7	6.0	20.9	10.1	43.6	
Missing	17,710	2.29	2.1	1.3	3.6	8.5	0.4	4.7	13.4	5.0	53.2	
Pulmonic stenosis												
No	753,975	97.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2	
Yes	445	0.06	3.4	2.2	3.9	12.6	0.0	6.3	20.2	6.3	49.4	
Missing	20,461	2.64	2.2	1.4	3.8	8.7	0.4	5.0	13.9	5.3	52.5	
Mitral insufficiency												
None	622,173	80.29	2.1	1.2	3.3	8.9	0.4	4.9	13.4	5.0	53.2	
Trivial	49,152	6.34	2.4	1.6	4.2	10.5	0.4	5.7	15.7	6.2	47.9	
Mild	60,811	7.85	3.7	2.0	5.7	14.3	0.5	6.9	20.3	8.6	40.3	
Moderate	16,723	2.16	6.7	2.7	7.9	20.1	0.7	9.6	28.0	12.5	30.3	
Severe	2,143	0.28	8.7	3.1	8.9	24.1	0.6	11.0	32.6	15.1	28.2	
Missing	23,879	3.08	2.1	1.2	3.0	7.5	0.4	4.7	12.0	5.2	51.5	
Aortic insufficiency	20,019	3.00	2.1	1.2	3.0	7.5	0.1	1.7	12.0	0.2	01.0	
None	705,771	91.08	2.3	1.3	3.5	9.5	0.4	5.1	14.1	5.4	51.9	
Trivial M:14	17,988	2.32	3.6	2.1	5.6	13.4	0.5	7.0	19.4	8.3	40.9	
Mild	18,571	2.40	4.1	2.2	5.9	14.3	0.4	7.3	20.8	9.0	37.9	
Moderate	3,576	0.46	5.3	2.6	7.0	16.2	0.5	7.9	23.2	10.2	32.8	
Severe	411	0.05	7.1	1.9	6.7	15.6	0.7	9.5	25.8	10.9	37.2	
Missing	28,564	3.69	2.1	1.2	3.2	7.9	0.4	4.6	12.5	5.3	51.4	
Tricuspid insufficiency												
None	675,778	87.21	2.2	1.3	3.4	9.4	0.4	5.1	13.9	5.3	52.1	
Trivial	32,856	4.24	2.5	1.6	4.5	11.1	0.4	6.1	16.6	6.7	47.4	
Mild	29,611	3.82	3.9	2.2	5.9	14.7	0.5	7.4	21.0	9.1	39.3	
Moderate	5,753	0.74	7.6	3.0	9.0	22.7	0.5	9.8	30.2	13.7	26.9	
Severe	728	0.09	9.1	2.9	10.5	24.2	0.4	10.9	33.0	17.2	26.2	
Missing	30,155	3.89	2.2	1.2	3.2	7.9	0.4	4.6	12.6	5.2	51.7	

Table 1. Continued

Variable	Number of Patients		Percent of Patients Experiencing Endpoint									
	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS	
Pulmonic insufficiency												
None	724,258	93.47	2.3	1.4	3.6	9.7	0.4	5.2	14.3	5.5	51.4	
Trivial	10,726	1.38	2.8	1.5	4.3	12.3	0.5	6.5	17.3	7.3	44.8	
Mild	4,867	0.63	3.8	2.1	5.6	14.1	0.4	7.4	21.0	9.1	39.7	
Moderate	546	0.07	6.6	3.1	7.8	17.6	0.2	7.9	24.4	11.5	29.7	
Severe	217	0.03	5.1	0.5	5.1	9.7	0.5	6.5	15.7	8.8	50.7	
Missing	34,267	4.42	2.2	1.3	3.5	8.3	0.4	4.8	13.2	5.5	50.7	

CABG = coronary artery bypass graft surgery; Comp = composite adverse outcome (any); DSWI = deep sternal wound infection; IABP = intra-aortic balloon pump; CVA = cerebrovascular accident (stroke); MI = mvocardial Mort = mortality; Na = not applicable; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; Reop = reoperation; RF = renal failure; PLOS = prolonged length of stay; SLOS = short length of stay; Vent = prolonged ventila-VT = ventricular tachycardia. VF = ventricular fibrillation;

cholesterolemia, a decision was made not to include this variable in the new models.

### Predictor Frequency

For each variable, the QMTF explored the overall prevalence and missing data frequency per year. Predictor variables that are rarely present in the development sample are difficult to model. For this reason, mitral (0.35%), tricuspid (0.08%), and pulmonic stenosis (0.06%), pulmonic insufficiency (0.10%), and endocarditis (0.09%) were not considered as variables in the new isolated CABG models.

### Inconsistently Coded Variables

A few variables have been collected inconsistently or with questionable reliability, often for clinically unavoidable reasons. For example, pulmonary artery mean pressure data were missing for 70% of patients during 2002 to 2006. Furthermore, the value of this continuous variable may vary substantially depending on the clinical state and volume-loading status of the patient when the measurement is obtained. Because of these concerns, pulmonary artery pressure was not included in the models.

### Derived or Redundant Variables

Several derived variables were considered for inclusion in the models. For example, body mass index (BMI) is a useful measure of overall body habitus. However, because BMI is highly correlated with body surface area (BSA), the more commonly used anthropometric measure in most previous STS models, the latter was retained in the new models. Similarly, there is a theoretical superiority to inclusion of glomerular filtration rate (GFR) rather than serum creatinine as a measure of renal function. However, the Modification of Diet in Renal Disease formula for estimating GFR is a complex function of creatinine, race, sex, and age, and not all laboratories perform this calculation automatically. Furthermore, as age, sex, and race are already model covariates, using GFR would complicate the interpretation of their regression coefficients. Some of the prognostic value of GFR

comes from these variables that are already included in the model. Finally, previous studies suggest that various measures of renal function used in CABG mortality risk models have similar performance [19]. For all these reasons, serum creatinine was retained as the measure of renal function.

### Controversial Variables

RACE. Several variables raised particular clinical, statistical, or health policy issues. For example, race was an obvious candidate variable because it was a significant predictor (p < 0.001) of each endpoint except mortality and because the proportion of nonwhite patients varied substantially across institutions. In exploratory analyses, the association between race and outcomes persisted after adjusting for hospital identity, suggesting that this association is not explained by differences in hospital quality.

However, general principles of risk model development complicated the decision as to whether or not to include race in the models. When the dominant purpose of a risk model is adjustment of provider results, it is advisable to include only biological and clinical patient variables that are present before a patient's first contact with the provider. In this context, race is clearly a fixed biological characteristic, but its impact on patient outcomes may be mediated through other mechanisms. It is possible that certain racial and ethnic groups have worse outcomes not because of inherent biological characteristics but because of differences in the quality of care delivered to them. In this case, including race and ethnicity in a risk model could essentially select out or obscure the very disparity issues that society wishes to identify and correct. Inclusion of race and ethnicity in a risk model would say, in effect, that we expect nonwhites to have inferior results and would make an allowance for providers who care for such patients, just as we would for providers who care for patients in cardiogenic shock.

After deliberation regarding the pros and cons, the QMTF ultimately elected to retain race and ethnicity in the new models because of their impact on outcomes,

### Table 2. Initial List of Potential Candidate Variables

### Demographics

- 1. Age
- 2. Sex
- 3. Race (black, Caucasian, Hispanic, Asian, Native American, other)

Note: Data collection changed in v2.61. New version allows for multiple races (check all that apply). Added Hawaiian/Pacific Islander category. Hispanic ethnicity is a separate variable.

### Anthropometric

- 4. Height
- 5. Weight

### Status

- 6. Status (elective, urgent, emergent, salvage)
- 7. Shock
- 8. Resuscitation

### Cardiac variables

9. Angina, angina type (STS categories are unstable, stable, no angina)

Note: Angina was removed on v2.61 data collection form. The new form has a variable called "cardiac presentation on admission." Angina is one of possible response categories to that field.

10. New York Heart Association functional class

Note: In v2.61, NYHA class is only collected if patient has congestive heart failure.

- 11. Arrhythmia and arrhythmia type (sustained VT/VF; heart block; AFib/flutter, None)
- 12. Myocardial infarction timing: ( $\leq 6$ , > 6 and < 24 hours; 1–7, 8–21, > 21 days)

### Hemodynamic/catheterization variables

- 13. Ejection fraction
- 14. Number of diseased vessels (0, 1, 2, 3)
- 15. Left main disease
- 16. Pulmonary artery mean pressure
- 17. Mitral stenosis
- 18. Aortic stenosis
- 19. Tricuspid stenosis
- 20. Pulmonic stenosis
- 21. Mitral insufficiency (none, trivial, mild, moderate, severe)
- 22. Aortic insufficiency (none, trivial, mild, moderate, severe)
- 23. Tricuspid insufficiency (none, trivial, mild, moderate, severe)
- 24. Pulmonic insufficiency (none, trivial, mild, moderate, severe)

### Comorbidities

- 25. Serum creatinine
- 26. Dialysis
- 27. Renal failure

Note: This variable was removed in v2.61.

- 28. Endocarditis (active, treated, none)
- 29. Diabetes and treatment (insulin, oral, diet, untreated, no diabetes)
- 30. Chronic lung disease (none, mild, moderate, severe)
- 31. Congestive heart failure
- 32. Peripheral vascular disease
- 33. Cerebrovascular disease
- 34. CVA and CVA timing (recent, remote, none)

Note: CVA is a child field of cerebrovascular disease in v2.61.

35. Hypercholesterolemia (v2.35, v2.41) and Dyslipidemia (v2.52)

Note: Data from all 3 versions were merged and analyzed under the variable name "hypercholesterolemia."

- 36. Hypertension
- 37. Smoker

Note: Major definition change in v2.61.

### Preoperative interventions

- 38. Preoperative intra-aortic balloon pump
- 39. Preoperative inotropes
- 40. Immunosuppressive treatment
- 41. Prior percutaneous coronary intervention and timing ( $\leq$  6 hours, > 6 hours, none)

### **Previous Interventions**

- 42. Prior coronary artery bypass graft surgery
- 43. Prior valve surgery
- 44. Prior other cardiac surgery
- 45. Number of previous cardiovascular surgeries

while recognizing the potential limitations of this decision.

PREOPERATIVE INTRA-AORTIC BALLOON PUMP. Preoperative intra-aortic balloon pump (IABP) is a proxy for more serious preoperative status of the patient (eg, unstable angina, ventricular dysfunction). It captures information that may not be present in other data elements, and it is associated with higher risk of postoperative morbidity and mortality. For these reasons, most CABG risk models include preoperative IABP as a risk predictor. However, placement of an IABP is also a highly discretionary care process the frequency of which varies widely among participating institutions. Indications are subjective and are often dictated by the cardiologist before even referring the patient for cardiac surgery. Based on CABG risk models, an institution that liberally utilizes IABPs will have a higher expected risk of morbidity and mortality (according to the model) compared with another institution with a similar case-mix but a more restrictive IABP policy. That would impact their relative O/E ratios and risk-adjusted outcomes.

Despite its discretionary nature (and the potential for gaming), the QMTF decided to retain IABP use in the models because it is such an important predictor. Ultimately, it was elected to model preoperative IABP as a joint variable with preoperative inotrope use as an overall measure of preoperative acuity/severity.

### Review of External Sources

The QMTF also reviewed multiple external resources to aid in the selection of potential candidate variables [15, 16, 20]. First, all previous versions of the STS CABG risk models were reviewed. The QMTF also examined other CABG risk models including the European System for Cardiac Operative Risk Evaluation (EuroSCORE) [21], the New York Cardiac Surgery Reporting System [22], the Veterans Affairs Administration cardiac surgery models [23, 24], and the Northern New England Cardiovascular Disease Study Group model [25, 26]. We particularly wanted to identify variables that were found in some form across all the risk models. Subject to the constraints of version 2.61 data specifications, we made a special effort to include such variables in the new STS risk models, in some instances requiring us to "force" them into the models, as described in the section on the final variable selection procedure.

### Missing Data

Missing data in the STS NCD are rare, having a frequency of less than 1% for most variables. Candidate predictor variables missing most commonly were ejection fraction (5.5%), New York Heart Association (NYHA) class (4.7%), tricuspid insufficiency (3.9%), aortic insufficiency (3.7%), mitral insufficiency (3.1%), aortic stenosis (1.7%), and creatinine/dialysis (1.5%).

Missing predictor values in the STS NCD were managed using imputation. Multiple imputation is the generally preferred statistical method [27], but single imputation was also considered based on the following

practical considerations: (a) the fraction of missing data in the STS NCD was small and, hence, single and multiple imputation would likely give similar point estimates; (b) a slight adjustment to the standard errors would not impact the study conclusions or the published risk algorithms; (c) the large sample size would make multiple imputation less practical to implement because of long computational times.

Prior to selecting an imputation strategy, exploratory analyses were performed using CABG data from 2002 to 2003 to compare single versus multiple imputation results for predicting mortality. These analyses confirmed that the choice between single versus multiple imputation would have only a slight impact on regression coefficients. For example, the estimated odds ratio for a 5-unit increase in ejection fraction was 0.90 (with a 95% confidence interval extending from 0.83 to 0.97) under single imputation and was 0.92 (with a confidence interval extending from 0.85 to 0.99) under multiple imputation. Other variables were missing less frequently than ejection fraction and were even less sensitive to the choice between single versus multiple imputation. Additional analyses of missing data consisted of reestimating the final model coefficients using single versus multiple imputation and comparing results. A summary of these investigations, as well as model coefficients and covariance matrices, are available at www.sts.org/riskmodels. For most patients, if risk were calculated using the multiple imputation model instead of single imputation, the relative change in their risk estimate would only be 1% to 2% (eg, 5% to 5.1% is a 2% change).

Based on the considerations described above, single imputation was used with the following specific rules: (1) binary (yes/no) risk factors were modeled as yes versus no or missing. Missing data for such variables usually implies their absence, and for most binary variables the composite event rates were similar for "no" and "missing" categories; (2) missing data on categorical predictor variables were imputed to the lowest risk value, which, in most instances, was the mode. In most instances, composite event rates for patients with missing data were among the lowest. It is the policy of the STS Data Warehouse and Analysis Center to discourage missing data through this default coding practice; and (3) missing data on continuous predictor variables were imputed to the conditional median. For ejection fraction, we conditioned on congestive heart failure (CHF) and sex. For BSA, we conditioned on sex. For serum creatinine, we conditioned on renal failure (although this approach will be modified when the model is ultimately applied to version 2.61 data, as renal failure has been removed).

For model endpoints (eg, mortality), missing data were handled by modeling yes versus no or missing. Thus, cases with missing data for an endpoint were analyzed as if the endpoint did not occur. Complete case analysis was not used because "missing" was not considered to be consistently coded for these variables. For example, some STS data managers have reported that they set complications to "no" unless there is explicit documentation in the medical record that the complication occurred. Other

data managers may leave the field missing unless there is explicit documentation that the complication did not occur. Thus, missing data may reflect differences in coding practices rather than truly unknown or missing data.

# Preliminary Analyses for Ordinal Categorical Variables and Continuous Variables

The QMTF conducted preliminary analyses to determine how best to model ordinal categorical variables and continuous variables. Categorical variables were entered into a logistic regression model by including a separate parameter for each category. Continuous variables were entered as piecewise linear functions (splines) with several changes of slope (knots). Terms were then removed one at a time using backward selection based on the Wald statistic. At each iteration, either two adjacent categories were collapsed into a single category or else two adjacent line segments were collapsed into a single line with no change of slope. The backward selection terminated when all adjacent categories and slopes were statistically different from one another at p < 0.001. This variable selection routine was performed separately for each endpoint. An expert panel determined the final coding based on the results of the backwards selection algorithm, supplemented by their clinical judgment and practical considerations. Table 3 summarizes these coding decisions.

### **Specific Coding Decisions**

RACE AND ETHNICITY. In versions 2.35, 2.41, and 2.52.1, race was collected by choosing one of the following mutually exclusive response categories: Caucasian, black, Hispanic, Asian, Native American, and other. In version 2.61, the data collection form was modified to conform to standards adopted by the US Census Bureau. It allows for selecting one or more races per patient (ie, select all that apply), and treats ethnicity (Hispanic versus non-Hispanic) as a separate variable. Because of these differences, the mapping of race among data versions is not straightforward.

Ultimately, the QMTF decided to model race as black, Asian, Hispanic, and Caucasian/other (collapsed). Initially, these categories will be mapped to version 2.61 as follows: (1) black will include all black patients, regardless of ethnicity or additional races; (2) Hispanic will include all nonblack Hispanic patients; (3) Asian will include all Asian patients who are not also identified as black or Hispanic; and (4) all remaining patients will be placed in the Caucasian/other category. The validity of this mapping will be assessed once 2.61 data become available and future versions could employ race "bridging" methodologies.

BODY SURFACE AREA. Height and weight were replaced by BSA, which was modeled as a quadratic trend to allow for a possible U-shaped relationship with outcomes (eg, extreme obesity and cachexia). This quadratic polynomial was modeled separately for males and females. Any BSA values below 1.4 or above 2.6 were mapped to these

values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

ANGINA. Version 2.61 of the data collection form eliminates angina and substitutes a new variable called "cardiac presentation on admission," within which unstable angina is one of the possible response categories. The QMTF believed that unstable angina would be coded more consistently than any other angina class, and also that this was the most important type of angina presentation to include in the models. Angina coding was therefore restricted in the new risk models to "unstable angina without MI < 7 days (yes/no)." It was necessary to exclude patients with myocardial infarction less than 7 days because the new version 2.61 does not permit simultaneous coding of angina and acute myocardial infarction.

REOPERATIVE STATUS. The most important consideration with regard to reoperative status is the number of prior sternotomies, irrespective of the specific type of procedure performed. The revised models replaced prior CABG, prior valve, and prior "other" cardiac surgery with simply the number of previous cardiovascular surgeries.

ACUITY STATUS. The new models combine resuscitation with salvage status. By definition, all salvage patients should have resuscitation coded "yes."

NUMBER OF DISEASED CORONARY VESSELS. Outcomes are modeled using the number of diseased vessels (grouped as 0 or 1 versus 2 versus 3), as a linear effect across the three categories. This approach is consistent with the previous STS CABG models and was supported by the data.

NYHA CLASS. Version 2.61 uses NYHA class as a subfield of CHF. The grouping of NYHA IV versus less than IV (I–III) classes is consistent with all existing STS models. The final categories were no CHF, CHF not NYHA IV, and CHF plus NYHA IV.

AGE. Age was modeled as a linear spline with knots at ages 50 and 60 years.

EJECTION FRACTION. Ejection fraction (EF) was modeled linearly, and EFs below 10% and above 50% were mapped to these values respectively. Only 0.03% of patients have EFs lower than 10%; such values are considered invalid and are treated like missing data. The coding decision regarding EF values above 50% was based on preliminary analyses in which the data were used to suggest the functional form of continuous variables.

CREATININE. Creatinine was modeled as a linear spline with knots at 1.0 and 1.5. Creatinine levels less than 0.5 or greater than 5.0 were mapped to these values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

MORTALITY AND LENGTH OF STAY. The QMTF changed the previous STS definition of the "short postoperative length of stay (SLOS)" endpoint. The original definition did not specifically exclude early postoperative deaths, and such patients could have been inappropriately included with the remaining SLOS patients who had a particularly short and uncomplicated postoperative course. In the new models, patients who die within 5 days of surgery are included in the analysis but are not counted as a short stay.

Table 3. Final List of Candidate Variables and Coding For STS Risk Models

Candidate Variables	Coding
Continuous variables	
Age <sup>a</sup>	Linear spline with knots at 50 and 60.
Ejection fraction <sup>a</sup>	Linear; values $>$ 50 are mapped to 50. Only 0.03% of patients have ejection fraction $<$ 10, and that is presumed to be a data entry error these values are considered invalid and are treated like missing data. The decision to consolidate values $>$ 50 was based on initial exploratory analyses in which data were used to suggest the functional form of continuous variables.
Body surface area <sup>a</sup>	Quadratic polynomial modeled separately for males and females. Note: body surface areas $< 1.4$ and $> 2.6$ were mapped to these values, respectively. <sup>c</sup>
Creatinine <sup>a</sup>	Linear spline with knots at 1.0 and 1.5. (Only for patients not on dialysis.) Note: Creatinine values < 0.5 and > 5.0 were mapped to these values, respectively. <sup>d</sup>
Time trend <sup>a</sup>	Ordinal categorical variable with separate category for each 6-month harvest interval.
Binary variables	
Dialysis <sup>a</sup>	Yes/no
Preoperative atrial fibrillation <sup>b</sup>	Yes/no
Shock	Yes/no
Female <sup>a</sup>	Yes/no
Hypertension	Yes/no
Immunosuppressive treatment	Yes/no
Percutaneous coronary intervention $\leq$ 6 hours	Yes/no
Preoperative intra-aortic balloon pump or inotropes	Yes/no
Peripheral vascular disease	Yes/no
Unstable angina (no myocardial infarction < 7 days)	Yes/no
Left main disease	Yes/no
Aortic stenosis	Yes/no
Aortic insufficiency	Defined as at least moderate (yes/no)
Mitral insufficiency	Defined as at least moderate (yes/no)
Tricuspid insufficiency	Defined as at least moderate (yes/no)
Categorical variables	· ·
Chronic lung disease	4 groups: (1) none, (2) mild, (3) moderate, (4) severe
CVD/CVA	3 groups: (1) no CVD, (2) CVD no CVA, (3) CVD + CVA
Diabetes mellitus	3 groups: (1) insulin diabetes, (2) noninsulin diabetes, (3) other or no diabetes
Number diseased coronary vessels	3 groups: (1) fewer than 2 diseased vessels, (2) 2 disease vessels, (3) 3 diseased vessels; modeled as linear across the categories.
Myocardial infarction	4 groups: (1) $\leq$ 6 hours, (2) $>$ 6 and $<$ 24 hours, (3) 1 to 21 days, (4) $>$ 21 days or no myocardial infarction.
Race	4 groups: (1) black, (2) Asian, (3) Hispanic, (4) other, including Caucasian
Status	4 groups: (1) elective, (2) urgent, (3) emergent, no resuscitation, (4) salvage or emergent with resuscitation
Previous cardiovascular operations	3 groups: 0 previous, 1 previous, 2 or more previous
CHF and NYHA class	3 groups: no CHF, CHF not NYHA IV, CHF + NYHA IV
Interactions	
Age by reoperation <sup>a</sup>	
Age by emergent status <sup>a</sup>	

<sup>&</sup>lt;sup>a</sup> These variables were forced into each model. <sup>b</sup> Preoperative atrial fibrillation was forced into the model for stroke. <sup>c</sup> These are the approximate 1st and 99th percentiles of the empirical distribution. Values less than 1.4 were mapped to 1.4. Values greater than 2.6 were mapped to 2.6. Estimates in the extreme tails of the body surface area distribution are highly influenced by data from other regions of the body surface area distribution (owing to use of a parametric, quadratic model) and may not be reliable. <sup>d</sup> These are approximately the 1st and 99th percentiles of the empirical distribution. Although we used a flexible spline model, linear splines can have unreliable extreme results in the tails due to the assumption that the effect is linear above the largest knot and below the smallest knot.

Table 4. Discrimination of Models (C-Index)

New STS	models—devel	opment sample	(C-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.810	0.716	0.795	0.756	0.706	0.657	0.724	0.769	0.727
New STS	models—valida	ntion sample (C	-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.812	0.720	0.793	0.754	0.689	0.653	0.725	0.767	0.726
Old STS r	nodels—validat	tion sample (C-	index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.807	0.713	0.750	0.742	0.672	0.645	0.711	0.754	0.713
		outcom a (amy).	CVAt1	DCMI — 1		stion. Most – se	t-lit DI OC	

 $\begin{array}{lll} Comp = composite \ adverse \ outcome \ (any); & CVA = stroke; \\ length \ of \ stay; & Reop = reoperation; & RF = renal \ failure; \\ prolonged \ ventilation. & \end{array}$ 

 $\begin{aligned} & DSWI = deep \ sternal \ wound \ infection; & Mort = mortality; & PLOS = prolonged \\ & SLOS = short \ length \ of \ stay; & STS = The \ Society \ of \ Thoracic \ Surgeons; & Vent = \\ \end{aligned}$ 

#### Final Variable Selection Procedure

#### **Backward Selection**

Using the remaining candidate variables and the coding schemes described previously, a supervised backward selection approach was then performed. Initial variable selection used the Wald  $\chi^2$  statistic with a significance criterion of 0.001. This high level of significance was chosen because of the very large sample size that resulted in quite small p values. An expert panel of cardiothoracic surgeons and biostatisticians then reviewed the selected variables and made several modifications. Measures of model performance (discrimination and calibration) were similar when all variables were retained in the models regardless of statistical significance or expert panel review.

#### Forced Variables

Several variables were included in the models regardless of statistical significance. These included all of the continuous variables (age, BSA, date of surgery [in 6-month intervals], creatinine, ejection fraction), plus sex and dialysis. In addition, atrial fibrillation was included a priori in the model for permanent stroke.

The rationale for including surgery date, a nonmodifiable variable of no intrinsic interest, was to adjust for changes in the frequency of adverse outcomes over the 5-year study period. We adjusted for surgery date to reduce potential confounding by time trends when estimating regression coefficients for variables that are of primary interest, such as preoperative clinical characteristics. For example, temporal changes in the frequency of coding for dyslipidemia, if they occur coincidentally with a secular declining trend in mortality rates, may lead to the unwarranted causal inferences unless there is adjustment for surgery date.

Date of surgery was categorized by 6-month intervals (corresponding to STS data harvests) and modeled as a linear trend across the ordinal categories. Surgery date is not included in the final risk algorithm and a patient's predicted risk is not dependent upon it. The intercept

parameter published in the Appendix has been adjusted to incorporate the time trend, and it reflects the baseline risk for a reference period of July to December 2006.

#### Interaction Terms

These models focused on main effects, and the final models included only four sets of preselected variable interactions: (1) sex by BSA; (2) sex by BSA squared; (3) age by reoperation; (4) age by emergent status. More extensive investigation for interactions was considered, including nonlinear, machine-learning approaches. However, the incremental value of such approaches remains uncertain [28], and interpretability can also become more problematic with numerous interaction terms.

Although multiple terms were allotted for modeling the main effects of age and reoperation, only a single degree of freedom was allotted for their interaction. The models defined a single variable interaction term for age and reoperation. It was equal to the patient's age minus 50 if the patient was at least 50 years old and had a previous CV surgery; otherwise it was equal to zero. This term represents the difference in the change of the slope of age at age 50 for patients who have had at least one previous CV surgery compared with patients who have not had a previous CV surgery. Similarly, only one degree of freedom was allotted for the interaction between age and status. The interaction represents the difference in the change of the slope of age at age 50 for patients with emergent or salvage status compared with patients with elective or urgent status. Although these interaction terms complicate the interpretation of other model variables, this was considered to be acceptable because the main focus of the analysis was prediction, not effect estimation.

#### Results

#### Model Performance

Table 4 presents the discrimination of each of the isolated CABG models as well as a comparison with the previous

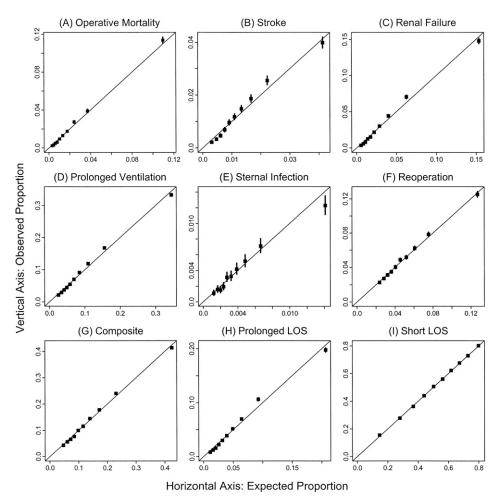


Fig 1. Plots of observed (O) versus expected (E) in validation sample

STS CABG risk models. For the new CABG models, discrimination ranged from 0.657 to 0.810 in the development sample and from 0.653 to 0.812 in the validation sample. The close agreement between c-indices from the development and validation samples reflects the large sample size and suggests that the models did not overfit the data. When the discrimination of the new and previous STS models were compared using the validation sample, the c-index of the new model was larger for each endpoint.

The Hosmer-Lemeshow test is not reported as an overall measure of calibration for these models because of its sensitivity to sample size. With samples as large as those used to develop these models, the null hypothesis will inevitably be proven false, given that all such models are only approximations [29]. As an alternative to such global measures of calibration, Figure 1 shows plots of observed versus expected event proportions within deciles of predicted risk for a variety of endpoints. For each endpoint, the absolute difference between the observed and expected proportions was less than 1.5% in each decile category. Additional analyses of model fit and discrimination are available online at www.sts.org/riskmodels.

#### Final Models

After calculating these measures of model performance, the final regression coefficients were estimated from the combined training and validation samples. Odds ratios for each predictor variable and model endpoint are summarized in Table 5. "Not applicable" indicates that the specific predictor was not included in a particular risk model. These final models were estimated using generalized estimating equations with empirical (sandwich) standard error estimates to account for clustering of patients within institutions [30]. An independence working correlation matrix was used to apply the generalized estimating equations method. With this approach, the estimated regression coefficients were identical to those obtained using ordinary logistic regression, but the standard errors were adjusted to account for correlated observations within hospitals.

#### Final Model Intercept and Coefficients

The Appendix contains the algorithm, intercept and coefficients for the final STS 2008 CABG risk models. The variance/covariance matrix is available on the web at www.sts.org/riskmodels. An on-line risk calculator is available at http://209.220.160.181/STSWebRiskCalc261/.

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Table 5. Estimated Odds Ratios for CABG Mortality, Morbidity, and Length of Stay Models

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50 (no reoperation, elective)	1.36 (1.24, 1.49)	1.78 (1.58, 1.99)	1.24 (1.16, 1.33)	1.06 (1.02, 1.10)	1.43 (1.23, 1.67)	1.14 (1.09, 1.19)	1.08 (1.05, 1.11)	1.35 (1.27, 1.43)	0.77 (0.75, 0.78)
Age 70 versus 50 (no reoperation, elective)	2.53 (2.31, 2.76)	2.43 (2.19, 2.71)	1.93 (1.81, 2.07)	1.42 (1.37, 1.47)	1.70 (1.47, 1.97)	1.45 (1.39, 1.51)	1.49 (1.44, 1.53)	2.17 (2.05, 2.29)	0.44 (0.43, 0.45)
Age 80 versus 50 (no reoperation, elective)	4.70 (4.29, 5.15)	3.34 (2.99, 3.72)	3.01 (2.80, 3.24)	1.90 (1.82, 1.99)	2.02 (1.73, 2.36)	1.85 (1.76, 1.94)	2.05 (1.98, 2.12)	3.48 (3.28, 3.69)	0.25 (0.24, 0.26)
BSA 1.6 versus 2.0 among females	1.26 (1.19, 1.32)	1.15 (1.08, 1.23)	0.84 (0.80, 0.89)	1.03 (1.00, 1.06)	0.49 (0.43, 0.57)	1.23 (1.18, 1.28)	1.03 (1.01, 1.06)	0.94 (0.90, 0.97)	1.17 (1.14, 1.20)
BSA 1.6 versus 2.0 among males	1.75 (1.64, 1.86)	1.19 (1.08, 1.31)	1.24 (1.17, 1.32)	1.40 (1.34, 1.46)	0.77 (0.63, 0.93)	1.40 (1.33, 1.46)	1.35 (1.30, 1.40)	1.43 (1.36, 1.50)	0.79 (0.77, 0.82)
BSA 1.8 versus 2.0 among females	1.02 (0.99, 1.05)	1.07 (1.03, 1.11)	0.86 (0.84, 0.88)	0.95 (0.94, 0.97)	0.67 (0.63, 0.71)	1.06 (1.04, 1.08)	0.96 (0.94, 0.97)	0.90 (0.88, 0.92)	1.14 (1.13, 1.16)
BSA 1.8 versus 2.0 among males	1.20 (1.17, 1.23)	1.09 (1.05, 1.13)	1.02 (1.00, 1.04)	1.09 (1.07, 1.10)	0.85 (0.79, 0.91)	1.13 (1.11, 1.15)	1.08 (1.07, 1.09)	1.10 (1.08, 1.12)	0.96 (0.95, 0.97)
BSA 2.2 versus 2.0 among females	1.20 (1.14, 1.27)	0.95 (0.88, 1.02)	1.32 (1.27, 1.37)	1.18 (1.15, 1.22)	1.62 (1.51, 1.74)	1.03 (1.00, 1.07)	1.19 (1.16, 1.21)	1.28 (1.24, 1.32)	0.78 (0.77, 0.80)
BSA 2.2 versus 2.0 among males	1.01 (0.99, 1.03)	0.92 (0.90, 0.95)	1.17 (1.15, 1.19)	1.10 (1.08, 1.11)	1.27 (1.22, 1.32)	0.97 (0.96, 0.99)	1.07 (1.06, 1.08)	1.08 (1.07, 1.10)	0.90 (0.89, 0.91)
Creatinine 1.5 versus 1.0	1.66 (1.57, 1.76)	1.39 (1.30, 1.49)	3.36 (3.16, 3.58)	1.56 (1.51, 1.62)	1.44 (1.28, 1.62)	1.33 (1.28, 1.38)	1.76 (1.70, 1.82)	1.65 (1.59, 1.72)	0.69 (0.67, 0.71)
Creatinine 2.0 versus 1.0	1.94 (1.84, 2.04)	1.49 (1.39, 1.58)	4.06 (3.83, 4.31)	1.73 (1.68, 1.79)	1.47 (1.30, 1.65)	1.44 (1.40, 1.49)	2.05 (1.98, 2.11)	1.92 (1.86, 2.00)	0.55 (0.53, 0.57)
Creatinine 2.5 versus 1.0	2.26 (2.14, 2.39)	1.59 (1.47, 1.71)	4.90 (4.61, 5.21)	1.92 (1.85, 1.99)	1.50 (1.30, 1.72)	1.57 (1.51, 1.64)	2.39 (2.30, 2.48)	2.24 (2.15, 2.34)	0.44 (0.42, 0.46)
Dialysis versus no dialysis and creatinine = 1.0	3.84 (3.54, 4.16)	1.67 (1.48, 1.88)	NA	2.85 (2.68, 3.03)	2.13 (1.78, 2.56)	1.86 (1.73, 2.00)	2.46 (2.33, 2.60)	2.80 (2.63, 2.98)	0.27 (0.25, 0.29)
EF per 10-unit decrease	1.19 (1.17, 1.22)	1.14 (1.11, 1.16)	1.08 (1.06, 1.10)	1.18 (1.16, 1.20)	1.11 (1.07, 1.16)	1.11 (1.09, 1.13)	1.16 (1.15, 1.18)	1.17 (1.15, 1.19)	0.84 (0.83, 0.85)
Preoperative atrial fibrillation	1.36 (1.28, 1.44)	1.21 (1.12, 1.30)	1.24 (1.18, 1.30)	1.20 (1.16, 1.24)	NA	1.26 (1.21, 1.31)	1.24 (1.21, 1.28)	1.42 (1.37, 1.48)	0.61 (0.59, 0.63)
CHF not NYHA IV	1.21 (1.15, 1.28)	NA	1.36 (1.30, 1.43)	1.31 (1.26, 1.35)	1.33 (1.19, 1.48)	1.16 (1.11, 1.21)	1.27 (1.23, 1.31)	1.43 (1.38, 1.48)	0.72 (0.70, 0.75)
CHF NYHA IV	1.39 (1.31, 1.47)	NA	1.35 (1.28, 1.42)	1.52 (1.45, 1.59)	1.45 (1.25, 1.67)	1.26 (1.20, 1.32)	1.48 (1.42, 1.54)	1.50 (1.44, 1.57)	0.65 (0.61, 0.68)
Chronic lung disease, mild	1.22 (1.16, 1.29)	NA	1.14 (1.08, 1.21)	1.36 (1.31, 1.41)	1.56 (1.40, 1.73)	1.11 (1.07, 1.15)	1.23 (1.19, 1.27)	1.34 (1.29, 1.39)	0.79 (0.76, 0.82)
Chronic lung disease, moderate	1.40 (1.32, 1.49)	NA	1.25 (1.18, 1.33)	1.65 (1.57, 1.73)	1.80 (1.58, 2.06)	1.20 (1.14, 1.26)	1.42 (1.36, 1.47)	1.65 (1.58, 1.73)	0.68 (0.65, 0.71)
Chronic lung disease, severe	2.35 (2.19, 2.52)	NA	1.66 (1.54, 1.79)	2.37 (2.24, 2.51)	2.40 (2.06, 2.79)	1.54 (1.44, 1.64)	1.98 (1.90, 2.07)	2.46 (2.34, 2.60)	0.48 (0.45, 0.51)
CVD with CVA	1.31 (1.24, 1.38)	2.09 (1.96, 2.22)	1.18 (1.12, 1.23)	1.35 (1.31, 1.39)	NA	1.21 (1.17, 1.26)	1.32 (1.29, 1.36)	1.45 (1.40, 1.51)	0.70 (0.68, 0.72)

Table 5. Continued

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
CVD without CVA	1.14 (1.08, 1.20)	1.65 (1.54, 1.75)	1.11 (1.06, 1.17)	1.15 (1.11, 1.18)	NA	1.12 (1.08, 1.17)	1.17 (1.14, 1.20)	1.14 (1.10, 1.18)	0.85 (0.81, 0.89)
Diabetes, insulin dependent	1.30 (1.24, 1.37)	1.19 (1.12, 1.27)	1.80 (1.72, 1.87)	1.22 (1.18, 1.26)	2.24 (2.02, 2.48)	1.14 (1.10, 1.18)	1.30 (1.27, 1.34)	1.59 (1.53, 1.64)	0.64 (0.62, 0.66)
Diabetes, noninsulin dependent	1.01 (0.97, 1.06)	1.16 (1.11, 1.22)	1.32 (1.28, 1.36)	1.04 (1.02, 1.07)	1.38 (1.27, 1.49)	0.98 (0.96, 1.01)	1.08 (1.06, 1.10)	1.15 (1.12, 1.17)	0.87 (0.86, 0.88)
Diseased vessels (2 versus 1, or 3 versus 2)	1.17 (1.12, 1.23)	1.35 (1.29, 1.42)	1.23 (1.19, 1.27)	1.19 (1.16, 1.22)	1.15 (1.07, 1.24)	1.07 (1.05, 1.10)	1.16 (1.14, 1.18)	1.15 (1.11, 1.18)	0.81 (0.80, 0.82)
Preoperative IABP/ inotropes	1.41 (1.33, 1.49)	NA	1.43 (1.36, 1.51)	2.56 (2.42, 2.72)	NA	1.37 (1.31, 1.43)	1.96 (1.86, 2.06)	1.60 (1.53, 1.67)	0.60 (0.57, 0.63)
Shock	2.29 (2.12, 2.47)	1.38 (1.23, 1.55)	1.65 (1.54, 1.77)	2.08 (1.96, 2.21)	NA	1.43 (1.34, 1.52)	2.10 (1.99, 2.23)	1.73 (1.62, 1.84)	0.58 (0.54, 0.62)
Female versus male (at BSA = 1.8)	1.31 (1.25, 1.36)	1.32 (1.24, 1.39)	1.25 (1.21, 1.31)	1.33 (1.29, 1.36)	1.19 (1.06, 1.35)	0.90 (0.87, 0.93)	1.18 (1.15, 1.21)	1.24 (1.20, 1.28)	0.65 (0.63, 0.66)
Hypertension	NA	1.29 (1.22, 1.37)	1.25 (1.20, 1.30)	1.10 (1.08, 1.13)	NA	NA	1.12 (1.10, 1.15)	1.07 (1.04, 1.11)	0.92 (0.90, 0.94)
Immunosuppressive treatment	1.48 (1.37, 1.60)	NA	1.21 (1.12, 1.31)	1.11 (1.05, 1.18)	NA	1.32 (1.24, 1.41)	1.20 (1.14, 1.26)	1.28 (1.20, 1.37)	0.80 (0.76, 0.84)
Aortic insufficiency, moderate/severe	NA	0.82 (0.75, 0.89)							
Mitral insufficiency, moderate/severe	1.31 (1.21, 1.41)	NA	NA	1.12 (1.06, 1.18)	NA	1.24 (1.16, 1.32)	1.20 (1.15, 1.26)	1.15 (1.09, 1.22)	0.85 (0.80, 0.91)
Tricuspid insufficiency, moderate/severe	NA	NA	1.31 (1.17, 1.45)	1.28 (1.18, 1.39)	NA	NA	1.24 (1.16, 1.33)	NA	0.78 (0.71, 0.87)
$PCI \le 6 \text{ hours}$	1.37 (1.24, 1.50)	NA	1.29 (1.16, 1.43)	1.21 (1.13, 1.29)	NA	1.30 (1.19, 1.42)	1.31 (1.23, 1.39)	1.17 (1.07, 1.27)	0.79 (0.74, 0.84)
Peripheral vascular disease	1.42 (1.36, 1.48)	1.32 (1.26, 1.39)	1.21 (1.17, 1.26)	1.22 (1.19, 1.26)	1.36 (1.24, 1.48)	1.24 (1.20, 1.28)	1.25 (1.22, 1.28)	1.31 (1.28, 1.35)	0.82 (0.81, 0.84)
Aortic stenosis	NA	NA	NA	1.18 (1.11, 1.26)	NA	NA	1.16 (1.10, 1.22)	1.15 (1.07, 1.23)	0.87 (0.82, 0.92)
Left main disease	NA	NA	NA	1.07 (1.04, 1.09)	NA	NA	1.04 (1.02, 1.06)	NA	NA
MI 1–21 days	1.37 (1.32, 1.44)	1.31 (1.25, 1.37)	1.27 (1.22, 1.32)	1.34 (1.29, 1.38)	NA	NA	1.23 (1.20, 1.25)	1.22 (1.18, 1.25)	0.88 (0.86, 0.90)
MI > 6 and < 24 hours	1.59 (1.46, 1.74)	1.59 (1.43, 1.76)	1.48 (1.36, 1.60)	1.59 (1.49, 1.68)	NA	NA	1.43 (1.37, 1.50)	1.31 (1.24, 1.39)	0.80 (0.76, 0.84)
$MI \leq 6 \text{ hours}$	1.70 (1.53, 1.89)	1.49 (1.31, 1.68)	1.43 (1.29, 1.57)	1.56 (1.45, 1.67)	NA	NA	1.44 (1.35, 1.53)	1.30 (1.21, 1.40)	0.82 (0.77, 0.87)
Time trend, per 6- month harvest interval	0.97 (0.97, 0.98)	0.97 (0.96, 0.98)	1.01 (1.00, 1.02)	1.01 (1.01, 1.02)	0.97 (0.95, 0.99)	0.99 (0.99, 1.00)	1.00 (1.00, 1.01)	1.00 (0.99, 1.01)	0.99 (0.98, 1.00)
Race Asian	NA	1.33 (1.14, 1.55)	1.08 (0.96, 1.22)	1.33 (1.21, 1.47)	1.00 (0.66, 1.51)	1.31 (1.17, 1.46)	1.23 (1.15, 1.31)	1.26 (1.13, 1.40)	0.70 (0.61, 0.81)
Race black	NA	1.41 (1.30, 1.54)	1.24 (1.16, 1.33)	1.37 (1.27, 1.48)	1.30 (1.13, 1.51)	1.21 (1.14, 1.30)	1.31 (1.24, 1.38)	1.43 (1.34, 1.51)	0.69 (0.65, 0.73)
Race Hispanic	NA	1.12 (0.98, 1.27)	1.24 (1.11, 1.39)	1.16 (1.07, 1.26)	1.30 (1.07, 1.58)	1.05 (0.97, 1.13)	1.12 (1.05, 1.19)	1.09 (0.99, 1.20)	0.85 (0.77, 0.94)

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SCTS
Reoperation, 1 previous operation <sup>a</sup>	3.13 (2.74, 3.57)	NA	1.52 (1.35, 1.71)	.52 (1.35, 1.71) 1.72 (1.58, 1.86)	NA	1.57 (1.43, 1.74)	1.57 (1.43, 1.74) 1.61 (1.50, 1.72) 1.62 (1.47, 1.80) 0.72 (0.67, 0.78)	1.62 (1.47, 1.80)	0.72 (0.67, 0.78)
Reoperation, ≥ 2 previous operations <sup>a</sup>	4.19 (3.45, 5.09)	NA	1.58 (1.33, 1.87)	.58 (1.33, 1.87) 1.86 (1.62, 2.14)	NA	1.71 (1.44, 2.03)	1.71 (1.44, 2.03) 1.84 (1.65, 2.05)	1.79 (1.53, 2.08)	0.64 (0.56, 0.73)
Status urgent <sup>a</sup>	1.16 (1.10, 1.22)	1.11 (1.06, 1.17)	1.12 (1.05, 1.19)	1.24 (1.18, 1.31)	1.20 (1.10, 1.32)	1.18 (1.13, 1.23)	1.18 (1.14, 1.22)	1.20 (1.15, 1.25)	0.86 (0.83, 0.90)
Status emergent, no resuscitation <sup>a</sup>	2.83 (2.52, 3.18)	2.12 (1.82, 2.48)	1.68 (1.49, 1.89)	2.14 (1.96, 2.34)	1.87 (1.46, 2.40)	1.83 (1.68, 1.99)	1.77 (1.64, 1.91)	2.12 (1.93, 2.32)	0.62 (0.58, 0.67)
Status emergent with resuscitation or salvage <sup>a</sup>	8.00 (6.91, 9.26)	8.00 (6.91, 9.26) 2.51 (1.98, 3.18)	2.16 (1.82, 2.55)	3.01 (2.68, 3.38)	2.09 (1.45, 3.01)	2.34 (2.06, 2.65) 3.65 (3.26, 4.09)	3.65 (3.26, 4.09)	2.39 (2.10, 2.72) 0.34 (0.30, 0.38)	0.34 (0.30, 0.38)
Unstable angina	1.12 (1.07, 1.17)	NA	1.11 (1.05, 1.17)	.11 (1.05, 1.17) 1.05 (1.01, 1.10)	NA	NA	NA	NA	NA

<sup>a</sup> Variable interacts with age. Reported odds ratio represents effect of risk factor for patients aged 50 years old.

CVD = cerebrovascular disease; = renal failure; NA = not applicable; = cerebrovascular accident, or stroke; Mort = mortality; = peripheral vascular disease; Comp = composite adverse outcome (any); .BP = intra-aortic balloon pump; MI = r = intra-aortic balloon pump; N PLOS = prolonged length of stay; BSA = body surface area; CH = deep sternal wound infection; Heart Association; short length of stay; Previously, the STS risk models were completely upgraded every 3 years, with annual recalibration in the interim to assure that the benchmark O/E ratio is always 1. In the near future, annual upgrades of the models are planned.

#### Limitations

Regardless of sample size or degree of statistical sophistication, all risk models are imperfect representations of reality. Although the STS risk models are based upon excellent clinical data and large sample sizes, there are some risk factors that are rare in the overall population but, when present, may be important predictors of outcome for specific patients. Some such variables, such as liver disease, are not included in the risk models, and the mortality risk for patients with these risk factors may be underestimated. Addition of a number of such variables will be considered at the next major specification upgrade.

There are other variables whose specifications undergo small but important changes over time, often in response to comments from STS database participants. These refinements are discussed on regular biweekly conference calls open to database participants, and suggested changes are regularly communicated to participants through a variety of means including FAQ's. With each major specification upgrade, they are incorporated into the new software specifications.

Audit is extremely important to assure the accuracy of any data registry. For the STS database and the risk models derived from it, robust audit is particularly critical as this registry is increasingly used for public reporting of outcomes and pay for performance. Studies suggest that the accuracy of the STS database is high for most important variables [31-35], although these audits are currently restricted to a limited number of sites annually because of budgetary constraints. In these audits, one of the most problematic variables has been 30-day mortality status (as opposed to in-hospital mortality). This is often a difficult endpoint to ascertain and may require more substantial investment of time and effort by participants, particularly for patients referred from outside their own institutions. Analysis of STS data suggests that approximately 90% of 30-day deaths occur in-hospital. Thus, if some patients recorded as being alive at 30 days have actually had their status ascertained only during the index hospitalization, the impact of this misclassification on the risk models should be negligible. This hypothesis was confirmed by comparing the odds ratios of all model variables for in-hospital versus 30-day mortality. Differences between the two were quite small, and these data are available on the web at www. sts.org/riskmodels. A new risk model for in-hospital mortality has been developed and placed on the same STS website. Furthermore, an aggressive program is in place to further enhance the accuracy of 30-day follow-up. In 2009, STS instituted a requirement that participants maintain documentation of the method by which they ascertained 30-day status, and that has become part of our routine audit. Linkage of the STS database with external death registries, such as the Social Security Death Master File, will

further support this capability. Finally, plans are being developed to expand the audit of certain key variables such as 30-day mortality to a significantly greater number of sites annually.

#### **Conclusions**

Risk-adjustment models account for the effect of patient comorbidities on outcomes. STS risk models are based upon clinical data from the STS NCD, one of the oldest and largest of all specialty registries. The value of such clinical registries is particularly evident in today's health care environment, where accreditation, regulatory compliance, reimbursement, and referrals are increasingly based upon objective data. Organizations such as the AQA and the National Quality Forum that evaluate and endorse performance measures strongly advocate the use of risk-adjusted outcomes measures.

STS believes that clinical data are superior to those derived from administrative sources. Furthermore, given the substantial implications of risk-adjusted outcomes, we believe that all risk models used for profiling quality of care should be transparent to permit comprehensive peer review and to foster credibility among stakeholders.

We present a detailed exposition of the development and validation of the 2008 STS CABG risk model. This describes not only the statistical considerations but, just as importantly, the many clinical and pragmatic judgments that are always necessary in risk model development.

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#### **Appendix**

Regression Coefficients and Variable Definitions for STS 2008 CABG Models

For each endpoint, the formula for calculating a patient's predicted risk of the endpoint has the form:

Predicted Risk = 
$$\frac{e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}{1+e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}$$

where  $x_1, x_2, \ldots, x_n$  denote patient preoperative risk factors (eg, quantitative variables such as age, and comorbidities coded as 1 = present, 0 = absent), and  $\beta_0, \beta_1, \ldots, \beta_n$  denote regression coefficients (numerical constants). Regression coefficients for each endpoint are presented in Appendix Table 1. The variables  $x_1, x_2, \ldots, x_n$  are the same for each endpoint and are defined in Appendix Table 2. The regression coefficient for the time trend is not presented. Instead, the intercept has been adjusted to incorporate the time trend. This adjusted intercept reflects the baseline risk for a reference period of July to December 2006.

Appendix Table 1. Regression Coefficients

-47	33								
Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Intercept	-6.34090	-7.18174	-7.94605	-4.15175	-6.75378	-3.84861	-3.71671	-5.35975	2.84959
Atrial fibrillation	0.30830	0.18935	0.21351	0.17871	0.00000	0.23031	0.21565	0.35322	-0.49309
Age	-0.00259	0.00996	0.00678	0.00170	-0.00665	-0.00013	0.00247	0.00914	-0.01781
Age function 1	0.03325	0.04742	0.01496	0.00393	0.04270	0.01305	0.00515	0.02085	-0.00895
Age function 2	0.03140	-0.02582	0.02249	0.02366	-0.01895	0.01133	0.02441	0.01734	-0.02904
Age by reoperation function	-0.01714	-0.00098	-0.00291	-0.00459	0.00304	-0.00720	-0.00444	-0.00809	0.00449
Age by status function	-0.01366	-0.01363	-0.00022	-0.00106	-0.00352	-0.00435	0.00270	-0.00833	-0.00266
BSA function 1	-1.39342	-0.44041	-0.53672	-0.83950	0.65513	-0.83758	-0.75006	-0.89037	0.57952
BSA function 2	2.41303	0.06122	2.19879	2.15647	0.90025	1.16543	1.81770	2.15270	-1.83776
CHF but not NYHA IV	0.19229	0.00000	0.30971	0.26853	0.28272	0.14692	0.23695	0.35623	-0.32350
CHF and NYHA IV	0.32663	0.00000	0.30013	0.41599	0.36909	0.22846	0.39005	0.40757	-0.43827
Chronic lung disease mild	0.20273	0.00000	0.13488	0.30473	0.44371	0.10432	0.20878	0.29051	-0.23600
Chronic lung disease moderate	0.33843	0.00000	0.22530	0.50235	0.59021	0.18071	0.34720	0.50246	-0.39085
Chronic lung disease severe	0.85513	0.00000	0.50645	0.86175	0.87366	0.43034	0.68538	0.90211	-0.73862
Creatinine function 1	0.19353	0.02822	1.91934	-0.02712	-0.37465	0.01583	0.13361	-0.09060	0.00773
Creatinine function 2	0.82140	0.63174	0.50685	0.92120	1.09976	0.55107	0.99190	1.09571	-0.75781
Creatinine function 3	-0.70646	-0.52856	-2.04970	-0.68907	-0.68466	-0.39956	-0.81791	-0.70069	0.30449
CVD without prior CVA	0.13177	0.49807	0.10637	0.13792	0.00000	0.11403	0.15561	0.13271	-0.16385
CVD and prior CVA	0.26877	0.73600	0.16135	0.29946	0.00000	0.19208	0.28099	0.37248	-0.35706
Diabetes noninsulin dependent	0.01375	0.14992	0.27443	0.04283	0.31888	-0.01929	0.07453	0.13541	-0.13813
Diabetes insulin dependent	0.26312	0.14332	0.58581	0.19735	0.80627	0.12930	0.26525	0.46226	-0.44725
Dialysis	1.53777	0.54158	0.00000	1.01943	0.38312	0.63691	1.03466	0.93792	-1.30294
Ejection fraction function	0.01765	0.01274	0.00754	0.01669	0.01081	0.03091	0.01496	0.93792	-0.01756
Female	0.26801	0.01274	0.00754	0.28338	0.01081	-0.10270	0.01436	0.01342	-0.01750 $-0.43658$
Female by BSA function 1	0.82285	0.08974	0.96428	0.76954	1.11546	0.31901	0.66663	1.05623	-0.96846
Female by BSA function 2	0.05606	0.06490	-0.61086	-0.62558	0.17399	-0.02390	-0.25077	-0.35160	0.46088
Hypertension	0.00000	0.25718	0.22126	0.09930	0.00000	0.00000	0.11674	0.07200	-0.08155
IABP or inotropes	0.34193	0.00000	0.36023	0.94050	0.00000	0.31326	0.67253	0.47092	-0.51444
Immunosuppressive treatment	0.39159	0.00000	0.18881	0.10686	0.00000	0.27802	0.18030	0.24833	-0.22718
Insufficiency, aortic	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.19889
Insufficiency, mitral	0.26631	0.00000	0.00000	0.11169	0.00000	0.21170	0.18225	0.14174	-0.15962
Insufficiency, tricuspid	0.00000	0.00000	0.26729	0.24834	0.00000	0.00000	0.21893	0.00000	-0.24548
Left main disease	0.00000	0.00000	0.00000	0.06629	0.00000	0.00000	0.03570	0.00000	0.00000
MI 1 to 21 days	0.31810	0.27134	0.23962	0.28925	0.00000	0.00000	0.20524	0.19517	-0.12752
MI > 6 and < 24 hours	0.46614	0.46063	0.38917	0.46158	0.00000	0.00000	0.35859	0.27109	-0.22557
$MI \le 6 \text{ hours}$	0.53242	0.39601	0.35421	0.44230	0.00000	0.00000	0.36337	0.26311	-0.19946
No. diseased vessel function	0.16120	0.30339	0.20729	0.17622	0.13869	0.06895	0.15075	0.13589	-0.21043
PCI ≤ 6 hours	0.31149	0.00000	0.25189	0.18695	0.00000	0.26256	0.26774	0.15633	-0.23860
Peripheral vascular disease	0.34951	0.27985	0.19308	0.20240	0.30529	0.21306	0.22277	0.27380	-0.19321
Race black	0.00000	0.34423	0.21696	0.31563	0.26572	0.19456	0.26634	0.35426	-0.37515
Race Hispanic	0.00000	0.11002	0.21645	0.14802	0.26330	0.04798	0.11289	0.08968	-0.16091
Race Asian	0.00000	0.28567	0.07579	0.28561	-0.00145	0.26855	0.20484	0.23064	-0.35049
Reop, 1 previous operation	1.13997	0.00000	0.41962	0.53987	0.00000	0.45372	0.47614	0.48534	-0.32375
Reop, $\geq$ 2 previous operations	1.43250	0.00000	0.45592	0.62211	0.00000	0.53695	0.61014	0.57945	-0.44745
Shock	0.82667	0.32434	0.50003	0.73290	0.00000	0.35800	0.74320	0.54575	-0.54475
Status urgent	0.14608	0.10671	0.11226	0.21738	0.18496	0.16500	0.16492	0.18202	-0.14608
Status emergent	1.04010	0.75216	0.51857	0.76090	0.62665	0.60549	0.56983	0.75083	-0.47745
Status salvage	2.07934	0.91950	0.76808	1.10085	0.73651	0.84873	1.29422	0.87072	-1.08265
Stenosis aortic	0.00000	0.00000	0.00000	0.16529	0.00000	0.00000	0.14706	0.13988	-0.14173
Unstable angina	0.11217	0.00000	0.10287	0.05060	0.00000	0.00000	0.00000	0.00000	0.00000

 $BSA = body \ surface \ area; \ CHF = congestive \ heart \ failure; \ Comp = composite \ adverse \ event \ (any); \ CVA = cerebrovascular \ accident \ (stroke); \ CVD = cerebrovascular \ disease; \ DSWI = deep \ sternal \ wound \ infection; \ IABP = intra-aortic \ balloon \ pump; \ MI = myocardial \ infarction; \ Mort = mortality; \ NYHA = New \ York \ Heart \ Association; \ PCI = percutaneous \ coronary \ intervention; \ PLOS = prolonged \ length \ of \ stay; \ Reop = reoperation; \ RF = renal \ failure; \ SLOS = short \ length \ of \ stay; \ Vent = prolonged \ ventilation.$ 

#### Appendix Table 2. Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	$= \max(age-50, 0)$
Age function 2	$= \max(age-60, 0)$
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	$= (BSA \text{ function } 1)^2$
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
<del>-</del>	
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral Insufficiency, tricuspid	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
, I	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI > 6 and <24 hours prior to surgery, = 0 otherwise
$MI \le 6 \text{ hours}$	= 1 if history of MI $\leq$ 6 hours prior to surgery, = 0 otherwise
No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
$PCI \leq 6 \text{ hours}$	= 1 if patient had $PCI \le 6$ hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, ≥ 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwis

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

### NATIONAL QUALITY FORUM

# Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

#### Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 0129	NQF Project: Surgery Endorsement Maintenance 2010
MEA	ASURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Risk-Adjusted Prolong	ed Intubation (Ventilation)
De.2 Brief description of measure: Perce require intubation for more than 24 hours	nt of patients aged 18 years and older undergoing isolated CABG who
1.1-2 Type of Measure: Outcome De.3 If included in a composite or paired OT1-013-09 - The STS CABG Composite Sco	with another measure, please identify composite or paired measure re
De.4 National Priority Partners Priority A De.5 IOM Quality Domain: Safety De.6 Consumer Care Need: Getting bette	•

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission  A.4 Measure Steward Agreement attached: STS Measure Steward Agreement. Fully Executed-634267338401654454.pdf	A Y N

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y□ N□
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  ▶ Purpose: Public reporting, Internal quality improvement	C Y□ N□
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.  D.1Testing: Yes, fully developed and tested  D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?  Yes	D Y N
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
4. IMPORTANCE TO MELCURE AND REPORT	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	Eval Rating
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2  1a.3 Summary of Evidence of High Impact: Prolonged ventilation has been shown to substantially increase post-CABG length of stay, the costs of care, and is associated with higher rates of respiratory failure,	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2  1a.3 Summary of Evidence of High Impact: Prolonged ventilation has been shown to substantially increase	

1c.7 Summary of Controversy/Contradictory Evidence:  1c.8 Citations for Evidence (other than guidelines): - Bardell T, Legare JF, Buth KJ, et al. ICU readmission	
1c.6 Method for rating evidence:	1c C□
1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):	
1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):  Prolonged ventilation has been shown to substantially increase post CABG length of stay, the costs of care, and is associated with higher rates of respiratory failure, stroke, renal failure, and death.	
<b>1c.2-3. Type of Evidence:</b> Observational study, Expert opinion, Systematic synthesis of research, Other Clinical results from approximately 90% of cardiac surgery centers in the US	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Prolonged ventilation has been shown to substantially increase post-CABG length of stay, the costs of care, and is associated with higher rates of respiratory failure, stroke, renal failure, and death.	
1c. Outcome or Evidence to Support Measure Focus	N_
1b.5 Citations for data on Disparities:	C
the measure and reported data (not restricted to this measure) to the STS Adult Cardiac Surgery Database for all 12 months.  1b.4 Summary of Data on disparities by population group:	1b
Dates: January 1, 2009-December 31, 2009  Analysis includes 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for	
1b.3 Citations for data on performance gap:	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:  Please see atttachment	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: Modalities to decrease the rate of prolonged intubation include physician supervised protocols for extubation implemented by nurses and respiratory therapists, improved pre-operative preparation of patients, reduction of post-operative bleeding, and intra-operative protocolized anesthesia care. Current implementation is highly variable and great opportunities to increase the implementation of evidence based care exist. Cardiac surgery programs with high implementation have lower than average rates of prolonged ventilation and significantly lower rates of adverse events.	
Medicare program. Ann Thorac Surg. 2008 Jun;85(6):1980-6. PubMed PMID: 18498806.  1b. Opportunity for Improvement	
discussion 45-6. PubMed PMID:19559186.  - Brown PP, Kugelmass AD, Cohen DJ, Reynolds MR, Culler SD, Dee AD, Simon AW. The frequency and cost of complications associated with coronary artery bypass grafting surgery: results from the United States	
coronary artery bypass graft surgery? Ann Thorac Surg. 2009 Dec;88(6):1793-800.  Speir AM, Kasirajan V, Barnett SD, Fonner E Jr. Additive costs of postoperative complications for isolated coronary artery bypass grafting patients in Virginia. Ann Thorac Surg. 2009 Jul;88(1):40-5;	

after cardiac surgery. Eur J Cardiothorac Surg. 2003;23(3):354-359.	
- Meade MO, Guyatt G, Butler R, et al. Trials comparing early vs late extubation following	
cardiovascular surgery. Chest. 2001:120(6 Suppl):445S-453S Naughton C, Reilly N, Powroznyk A, et al. Factors determining the duration of tracheal intubation in	
cardiac surgery: a single-centre sequential patient audit. Eur J Anaesthesiol. 2003;20(3):225-233.	
- Shroyer AL, 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.	
- Welke 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.	
- Engel AM, McDonough S, Smith JM. Does an obese body mass index affect hospital outcomes after	
coronary artery bypass graft surgery? Ann Thorac Surg. 2009 Dec;88(6):1793-800.	
- Speir AM, Kasirajan V, Barnett SD, Fonner E Jr. Additive costs of postoperative complications for	
isolated coronary artery bypass grafting patients in Virginia. Ann Thorac Surg. 2009 Jul;88(1):40-5;	
discussion 45-6. PubMed PMID:19559186 Brown PP, Kugelmass AD, Cohen DJ, Reynolds MR, Culler SD, Dee AD, Simon AW. The frequency and	
cost of complications associated with coronary artery bypass grafting surgery: results from the United States	
Medicare program. Ann Thorac Surg. 2008 Jun;85(6):1980-6. PubMed PMID: 18498806.	
1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):	
1c.10 Clinical Practice Guideline Citation:	
1c.11 National Guideline Clearinghouse or other URL:	
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by	
whom):	
1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe	
rating and how it relates to USPSTF):	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Importance to	
Measure and Report?	1
Steering Committee: Was the threshold criterion, Importance to Measure and Report, met?	1
Rationale:	Y∐   N□
	N .
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about	Eval
the quality of care when implemented. (evaluation criteria)	Rating
2a. MEASURE SPECIFICATIONS	
<ul><li>S.1 Do you have a web page where current detailed measure specifications can be obtained?</li><li>S.2 If yes, provide web page URL:</li></ul>	
2a. Precisely Specified	
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the	2a-
target population, e.g. target condition, event, or outcome):	specs
Number of patients undergoing isolated CABG who require intubation > 24 hours	C
	P
<b>2a.2 Numerator Time Window</b> (The time period in which cases are eligible for inclusion in the numerator):	N

**2a.3 Numerator Details (**All information required to collect/calculate the numerator, including all codes, logic, and definitions):

Number of isolated CABG procedures in which Complications-Pulmonary\_Vent Prolonged (CPVntLng) is marked "yes"

**2a.4 Denominator Statement** (Brief, text description of the denominator - target population being measured):

All patients undergoing isolated CABG

2a.5 Target population gender: Female, Male2a.6 Target population age range: 18 and older

**2a.7 Denominator Time Window** (The time period in which cases are eligible for inclusion in the denominator):

12 months

**2a.8 Denominator Details** (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):

Number of isolated CABG procedures

Isolated CABG is determined as a procedure for which all of the following apply:

- OpCAB is marked "Yes"
- (VADProc is marked "No" or "Missing") or (VADProc is marked "Yes, Implanted" and UnplVAD is marked "yes")
- OCarASDTy is marked "PFO" or "missing"
- OCarAFibAProc is marked "primarily epicardial" or "missing" and
- OpValve, VSAV, VSAVPr, ResectSubA, VSMV, VSMVPr, OpTricus, OpPulm, OpONCard, OCarLVA, OCarVSD, OCarSVR, OCarCong, OCarTrma, OCarCrTx, OCAoProcType, EndoProc, OCTumor, OCPulThromDis, OCarOthr are all marked "no" or "missing"
- 2a.9 Denominator Exclusions (Brief text description of exclusions from the target population):
- **2a.10 Denominator Exclusion Details (**All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
- **2a.11 Stratification Details/Variables (***All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
- 2a.12-13 Risk Adjustment Type: Case-mix adjustment
- **2a.14 Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

  Please see attachment
- 2a.15-17 Detailed risk model available Web page URL or attachment: Attachment 2a.15 Detailed Risk Model-634267353926995758.pdf

2a.18-19 Type of Score: Rate/proportion

2a.20 Interpretation of Score: Better quality = Lower score

**2a.21 Calculation Algorithm** (Describe the calculation of the measure as a flowchart or series of steps):

**2a.22** Describe the method for discriminating performance (e.g., significance testing):

Participant specific OR and their 95% CI were estimated in the hierarchical model. These model-based estimates were used to control variation due to random statistical fluctuations while estimating true signal variation. A 95% CI excluding zero indicates the participant's performance is significantly lower or higher than an "average" STS participant.

2a.23 Sampling (Survey) Methodology If measure is based on a sample (or survey), provide instructions for

obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):	
2a.24 Data Source (Check the source(s) for which the measure is specified and tested) Registry data	
2a.25 Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.): STS Adult Cardiac Surgery Database - Version 2.73	
2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL Data Collection Form (an updated version will be made available on the STS Website in mid-December of 2010)http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataCollectionForm2_7_Annotated_20101021.pdf	
2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataSpecificationsV2_7_20101021.pdf an updated version will be made available on the STS Website in mid-December of 2010	
2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)	
Clinicians: Group, Facility/Agency, Population: national, Population: regional/network, Population: states, Population: counties or cities	
2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested) Hospital	
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)	
TESTING/ANALYSIS	
2b. Reliability testing	
<b>2b.1 Data/sample</b> (description of data/sample and size): STS Adult Cardiac Surgery Database - Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009.	
<b>2b.2 Analytic Method</b> (type of reliability & rationale, method for testing): Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009. Excluded from analysis are participants that did not submit results for both time periods. Because database participants can change their underlying care processes at any time, we would not expect perfect correlation between two sets of results from even proximate time periods.	2b
2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted): Please see attachment	C   P   M   N
2c. Validity testing	
2c.1 Data/sample (description of data/sample and size): STS Adult Cardiac Surgery Database	
Audits conducted in 2010, all cases performed in 2009; N = 40 randomly selected sites participating in the STS Adult Cardiac Surgery Database	
<b>2c.2 Analytic Method</b> (type of validity & rationale, method for testing):  Participating sites are randomly selected for participation in STS Adult Cardiac Surgery Database Audit, which is designed to evaluate the accuracy, consistency, and comprehensiveness of data collection and ultimately validate the integrity of the data contained in the database. The lowa Foundation for Medical Care (IFMC), the quality improvement organization for lowa and Illinois, has conducted audits on behalf of STS since 2006.	2c C   P   M   N

Each year, the IFMC conducts audits at randomly selected sites throughout the country and tracks the individual agreement rates by variable and by year. More specifically, for each site, agreement rates are calculated for 73 individual elements. In addition, aggregate agreement rates for each element, variable category (e.g., pre-operative risk factors, previous interventions, etc), and overall for all categories are calculated for all sites. While this is not region specific, it is data point specific and comparison agreement rates confirm the improvement over time as well as the consistency.	
<b>2c.3 Testing Results</b> (statistical results, assessment of adequacy in the context of norms for the test conducted):	
Re-intubated During Hospital: 99.8% agreement rate Additional # of Hours Ventilated: 97.5% agreement rate	
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s):	
2d.2 Citations for Evidence:	
2d.3 Data/sample (description of data/sample and size):	2d
2d.4 Analytic Method (type analysis & rationale):	C □ P □
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):	M   N   NA
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): Please see Risk Adjustment Type section above	
<b>2e.2 Analytic Method</b> (type of risk adjustment, analysis, & rationale): Detailed information regarding the risk adjustment model can be found in the attachment:	
Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, Normand SL, DeLong ER, Shewan CM, Dokholyan RS, Peterson ED, Edwards FH, Anderson RP. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1coronary artery bypass grafting surgery. Ann Thorac Surg. 2009 Jul;88(1 Suppl):S2-22.	2e
2e.3 Testing Results (risk model performance metrics):	C   P   M
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	N_ NA_
2f. Identification of Meaningful Differences in Performance	
2f.1 Data/sample from Testing or Current Use (description of data/sample and size): 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months; January 1, 2009-December 31, 2009	
<b>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance</b> (type of analysis & rationale): We calculated the risk adjusted event rate with the participant's Odds Ratio (OR) estimate and the overall STS event rate. Therefore, the risk adjusted rate is closely related to OR estimate. If OR > 1, then the participant's risk adjusted rate will be greater than the overall STS event rate; if OR < 1, then the participant's risk adjusted rate will be smaller than the overall STS event rate. The statistical significance is defined by the 95% confidence interval (CI) or the OR estimate. If the 95% CI for a participant's OR includes the null value 1.0, then we cannot distinguish this participant's performance from the STS average	2f C   P   M   N

- either the participant's performance was close to average or else the participant's sample size was too small to make a reliable inference. Otherwise, if the 95% CI falls to the right of 1.0, then the participant's performance is considered significantly lower than the average STS results; if the 95% CI falls to the left of 1.0, then the participant's performance is considered significantly higher than the average STS results.			
<b>2f.3 Provide Measure Scores from Testing or Current Use</b> (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  Please see attachment			
2g. Comparability of Multiple Data Sources/Methods			
2g.1 Data/sample (description of data/sample and size): N/A	2g		
2g.2 Analytic Method (type of analysis & rationale):	CP		
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	M NO NA		
2h. Disparities in Care	26		
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A	2h C□ P□		
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:			
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties?</i>	2		
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:	2 C□		
Rationale:	P □ M □ N □		
3. USABILITY	M□		
	M□		
3. USABILITY  Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand	M N		
3. USABILITY  Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	M N		
3. USABILITY  Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)  3a. Meaningful, Understandable, and Useful Information	M N		
3. USABILITY  Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)  3a. Meaningful, Understandable, and Useful Information  3a.1 Current Use: In use  3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website,	M N		
3. USABILITY  Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)  3a. Meaningful, Understandable, and Useful Information  3a.1 Current Use: In use  3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org  Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily	M N		

	1
3a.4 Data/sample (description of data/sample and size): See 3a.6 below	
3a.5 Methods (e.g., focus group, survey, Ql project):	
end methods (eng.) Joeds group, survey, q. projects.	
3a.6 Results (qualitative and/or quantitative results and conclusions): Please see attachment	
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures:	
OT1-013-09 - The STS CABG Composite Score; Component measures: 0114 Risk-Adjusted Post-Operative	
Renal Failure, 0115 Risk-Adjusted Surgical Re-exploration, 0116 Anti-Platelet Medication at Discharge, 0117	
Beta Blockade at Discharge, 0118 Anti-Lipid Treatment at Discharge, 0119 Risk-Adjusted Operative Mortality for CABG, 0127 Pre-Operative Beta Blockade, 0129 Risk-Adjusted Prolonged Intubation (ventilation), 0130	
Risk-Adjusted Deep Sternal Wound Infection Rate, 0131 Risk-Adjusted Stroke/Cerebrovascular Accident,	
0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization	
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target	
population/setting/data source or different topic but same target population):	
3b.2 Are the measure specifications harmonized? If not, why?	
N/A; however, data definitions and key elements have been established by a multi-societal writing committee called the "ACCF/AHA Writing Committee to Develop Acute Coronary Syndromes and Coronary	
Artery Disease Clinical Data Standards" with representatives from each of the following organizations:	
Agency for Healthcare Research and Quality	
American College of Cardiology American College of Chest Physicians	
American College of Emergency Physicians	
American College of Physicians	
American College of Preventative Medicine	
American Heart Association American Medical Association	
Centers for Disease Control and Prevention	
Emergency Nurses Association	
Food and Drug Administration	
Joint Commission on Accreditation of Healthcare Organizations	
National Association of Emergency Medical Technicians National Association of EMS Physicians	
National Heart, Lung, and Blood Institute	3b
Preventive Cardiovascular Nurses Association	C
Society for Academic Emergency Medicine	P
Society of Chest Pain Centers and Providers Society of General Internal Medicine	M_    N
Society of Thoracic Surgeons	NA 🗆
3c. Distinctive or Additive Value	
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-	
endorsed measures:	3c
	C
5.1 If this measure is similar to measure(s) already endersed by NOE (i.e., on the same tonic and the	P
5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:	M□ N□
5 Francisco, Francisco	NA 🗌
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	
,	3

Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C P M
	N□
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. ( <a href="evaluation criteria">evaluation criteria</a> )	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	
4a.1-2 How are the data elements that are needed to compute measure scores generated?  Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C   P   M   N   N
4b. Electronic Sources	
4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) Yes 4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	4b C   P   M   N
4c. Exclusions	
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?	4c C   P   M   N
4c.2 If yes, provide justification.	NA 🗌
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results. This measure may be susceptible to human error (i.e., recording the measure inaccurately or not at all).	
When data collection on this measure is done through participation in the STS Adult Cardiac Surgery Database, an auditing strategy is in place.	
Both STS and the Duke Clinical Research Institute have a list of database participants making participation in the STS Adult Cardiac Surgery Database easy to track.	
Each participant is responsible for the quality and accuracy of the data they submit to the database. The participant agrees to the following quality control measures in the participation agreement: i) Participant hereby warrants that all data submitted for inclusion in the STS National Database will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the independent data warehouse service provider and agrees to cooperate with and assist STS and its designees in connection with the performance of any independent audit.	
ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the STS National Database, including but not limited to apprising the Director of the STS National Database and the independent data warehouse service provider about any other Participation Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named.	4d C P M N

STS audited for these potential problems during testing. Please see IFMC audit results.	
4e. Data Collection Strategy/Implementation	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): Data Collection: There are no direct costs to collect the data for this measure. Costs to develop the measure included volunteer cardiothoracic surgeon time, STS staff time, and DCRI statistician and project management time.	
Other fees: STS Adult Cardiac Surgery Database participants (single cardiothoracic surgeons or a group of surgeons) pay annual participant fees of \$2,950 or \$3,700, depending on whether participants are STS members (or whether the majority of surgeons in a group are STS members). As a benefit of STS membership, STS members are charged the lesser of the two fees.	40
4e.3 Evidence for costs:  4e.4 Business case documentation:	4e C   P   M   N
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i> ?	
,	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C   P   M   N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement? Comments:	Y D
	A
CONTACT INFORMATION	A
Co.1 Measure Steward (Intellectual Property Owner)	A
	A
Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization	A
Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611  Co.2 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856- Measure Developer If different from Measure Steward	A
Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611  Co.2 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	A

Co.5 Submitter If different from Measure Steward POC

Jane, Han, MSW, jhan@sts.org, 312-202-5856-, Society of Thoracic Surgeons

Co.6 Additional organizations that sponsored/participated in measure development

#### ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Members of the STS Task Force on Quality Initiatives provide clinical expertise as needed. The STS Workforce on National Databases meets at the STS Annual Meeting and reviews the measures on a yearly basis. Changes or updates to the measure will be at the recommendation of the Workforce.

Ad.2 If adapted, provide name of original measure:

Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released: 2004

Ad.7 Month and Year of most recent revision: 12, 2010

Ad.8 What is your frequency for review/update of this measure? annually

Ad.9 When is the next scheduled review/update for this measure? 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment 0129 Sections 2a.14, 1b.2, 2b.3, 2f.3, 3a.6.pdf

Date of Submission (MM/DD/YY): 01/12/2011

# **2a.14. Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method)

The risk adjusted model is a hierarchical logistic regression model with participant level intercept. logit(outcome)  $\sim X\beta + (\gamma | participant)$ 

where X is the patient's risk factors,  $\theta$  is the regression coefficients of patient-level risk factors and  $\gamma$  is the participant level regression coefficient.

#### **Inclusion Criteria**

The patient level risk adjusted model was developed using a population of patients undergoing isolated CABG procedure in the time period January 2002 – December 2006. For this measurement we re-fit the patient-level model using the latest two and a half years of data (January 2008 – June 2010) from the STS Adult Cardiac Surgery Database.

#### Variable Definitions and Selection

All variables for consideration are listed in the table below.

#### Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	= max (age–50, 0)
Age function 2	= max (age-60, 0)
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	= (BSA function 1) <sup>2</sup>
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
Insufficiency, tricuspid	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI >6 and <24 hours prior to surgery, = 0 otherwise
MI ≤ 6 hours	= 1 if history of MI ≤ 6 hours prior to surgery, = 0 otherwise

No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
PCI ≤ 6 hours	= 1 if patient had PCI ≤ 6 hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, 2 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwise
-	

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

The final patient-level model was built by backward selection method with several variables forced into the model. For the final patient-level model, please see the attachment.

# **1b.2.** Summary of Measure Results Demonstrating Performance Gap (Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.)

The summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. A high OR is undesirable and we define the percentiles with decreasing OR. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile" below.

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	1.0
1 <sup>st</sup>	2.2
5 <sup>th</sup>	1.7
10 <sup>th</sup>	1.5
25 <sup>th</sup>	1.2
Median	1.0
75 <sup>th</sup>	0.8
90 <sup>th</sup>	0.7
95 <sup>th</sup>	0.6
99 <sup>th</sup>	0.5
Outlier	35 (5.5)
High	7
Low	28

Also provided is the distribution of the risk adjusted event rate (see below). The risk adjusted rate is an estimate of the participant's event rate if, hypothetically, the case-mix of the patients treated by the participants is the same as the overall STS case-mix. It is calculated by the OR of the participant, other patient level parameter estimates from the hierarchical logistic model, and the overall STS event rate, by:

STS event rate \* (Participant's Expected Event Rate) / (Participant's Expected Event Rate Assuming Its Performance = STS Average Performance)

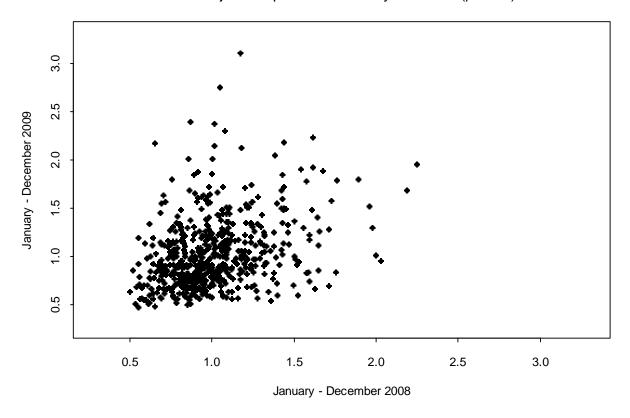
In the above equation, "Participant's Expected Event Rate" is calculated with the participant's actual OR, and "Participant's Expected Event Rate Assuming Its Performance = STS Average Performance" is calculated by assuming the participant's OR = 1 (i.e. no difference in performance from the STS average).

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	2.0
1 <sup>st</sup>	1.1
5 <sup>th</sup>	1.2
10 <sup>th</sup>	1.3
25 <sup>th</sup>	1.5
Median	1.9
75 <sup>th</sup>	2.3
90 <sup>th</sup>	2.8
95 <sup>th</sup>	3.2
99 <sup>th</sup>	4.1

Measurement	Risk-Adjusted Operative Mortality for CABG
Outlier	35 (5.5)
High	33 (3.3) 7
Low	28

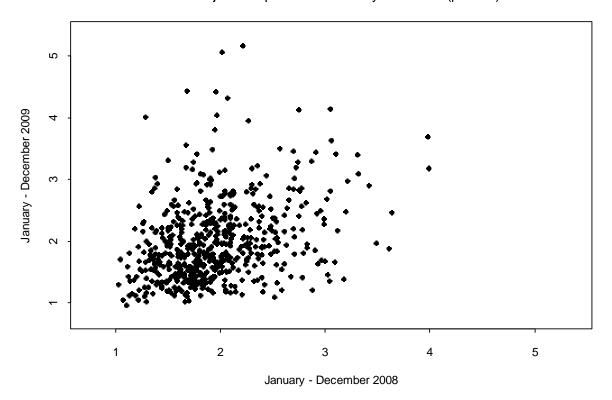
Testing results:  $\rho = 0.34$ 

Risk-Adjusted Operative Mortatility for CABG (ρ=0.34)



Risk Adjusted Rate:

Risk-Adjusted Operative Mortatility for CABG (ρ=0.34)



Results below are from January 1, 2009-December 31, 2009. Sample contains 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months.

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	1.0
1 <sup>st</sup>	2.2
5 <sup>th</sup>	1.7
10 <sup>th</sup>	1.5
25 <sup>th</sup>	1.2
Median	1.0
75 <sup>th</sup>	0.8
90 <sup>th</sup>	0.7
95 <sup>th</sup>	0.6
99 <sup>th</sup>	0.5
Outlier†	35 (5.5)
High	7
Low	28

#### Risk Adjusted Rate:

Measurement	Risk-Adjusted Operative Mortality for CABG
N	640
Mean	2.0
1 <sup>st</sup>	1.1
5 <sup>th</sup>	1.2
10 <sup>th</sup>	1.3
25 <sup>th</sup>	1.5
Median	1.9
75 <sup>th</sup>	2.3
90 <sup>th</sup>	2.8
95 <sup>th</sup>	3.2
99 <sup>th</sup>	4.1
Outlier†	35 (5.5)
High	7
Low	28

<sup>†</sup>Represents the number of participants that are outliers according to two-sided 95% confidence interval of odds ratio.

#### **3a.6. Results** (Qualitative or quantitative results and conclusions)

Although formal testing of interpretability has not been performed, this measure has been used and reported for STS Adult Cardiac Surgery database participants since 2007. Current report presentation and interpretation manuals are presented below. These materials are updated as needed based upon feedback from database participants.

#### 1) Report Overview and Interpretation Manual:

#### **The NQF Measures Report**

#### a. Organization

This report section is separated into three areas corresponding to: 1) NQF volume measures, 2) NQF process measures, and 3) NQF outcomes measures, in that order. The header at the top of each page references the report section for that page. Each NQF measure is presented on a single row in the section. Tabular data are on the left-hand side of each page and a standard graphic representation is shown on the right-hand side.

#### b. Statistical Calculation and Details – NQF Measures

**Time period:** This report section contains information on the individual STS participant and overall STS performance for the <u>most recent 12 months for volume</u>, <u>process and CABG outcomes measures and the most recent 60 months for Valve and Valve + CABG outcomes</u>. The 5 years (60 months) of <u>performance for outcomes involving Valve procedures is necessary due to smaller sample sizes</u>.

**Volume Measures:** The NQF report provides average annual case volumes data for three surgery categories: i) Isolated CABG, ii) Valve without CABG, and iii) combined CABG + Valve. Definitions of the three surgery categories are provided in Table 2 of this NQF Report Overview. For each type of surgery, the <u>participant's annualized volume</u> is calculated as:

Participant Annualized Volume = 12 x (# of surgeries) / (# of months)

where (# of surgeries) denotes the number of surgeries of the specified type performed by the participant during the specified time period, and (# of months) is the number of months during the specified time period for which the participant submitted at least one cardiac surgery of any type. The intent of calculating "annualized" volumes is to adjust for participants who participated in the database for fewer months than the time period specified. For participants who participated in the database and submitted cases every month during 2006, the annualized volume for 2006 is simply the total number of cases.

The <u>STS Average Annualized Volume</u> is the average value of all of the participant annualized volumes across the entire population of STS participants. The <u>Participant Percentile</u> indicates the percent of STS participants whose annualized volumes are less than, or equal to, your own. Higher percentiles indicate higher volumes in relation to other STS participant sites. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant annualized volumes across all database participants. For example, 90% of participants have annualized volumes less than or equal to the value marked "90<sup>th</sup> percentile." Confidence intervals are not provided for volume measures, as volume is known with certainty and is not estimated.

**Process Measures:** The NQF process measures provide data on the frequency of usage of five therapies among subsets of Isolated CABG patients. The therapies are: i) preoperative beta blockade therapy, ii) use of IMA, iii) discharge anti-platelet medication, iv) discharge beta blockade therapy, and v) discharge anti-lipid medication. The patient population for each measure differs, in accordance with the NQF specifications (see Table 2 of this NQF Report Overview for details). The number of <u>Eligible</u>

Procedures is the number of cases performed by the participant during the specified time period who meet the eligibility requirements to be included in the calculations when summarizing the participant's data. Beginning with the 2008 Harvest 3 report (covering the procedure time period through 6/30/2008), STS implementation of NQF medication process measures using data version 2.61 excludes records for which the medication was contraindicated/not indicated from the eligible population. The main summary statistic, Participant Usage, is the percent of eligible Isolated CABG cases during the specified time period for which the patient received the specified therapy. The Overall STS Usage is the percent of all eligible patients in the entire STS population during the specified time period who received the specified therapy. In calculating these percentages, missing data are treated as a "No", emphasizing the importance of having complete data in these fields.

The <u>Participant Percentile</u> indicates the percent of STS participants who applied the therapy in their respective populations less frequently than or as frequently as did your institution. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant usage across all participants in the database. For example, 90% of participants use the therapy less frequently than the amount indicated by the "90<sup>th</sup> percentile". A bar identified as "Participant" indicates the point estimate and limits of a 95% Confidence Interval (CI) for the participant's usage of therapy. The underlying parameter being estimated is the long-run usage rate that would be observed in a large sample of patients. The 95% CI indicates the range of usage rates that are consistent with the data in light of sampling variability.

Outcomes Measures: The NQF outcomes data provide risk-adjusted analyses of mortality and morbidity for Isolated CABG surgery as well as risk-adjusted operative mortality for Isolated AVR, Isolated MVR, AVR+CABG, and MVR+CABG. The main summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. The interpretation is similar to that of an O/E ratio (see the Risk-Adjusted Results: Overview portion of the General Report Overview for details on STS risk adjustment). An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. Each measure is calculated among patients undergoing surgery of the type specified during the time period specified who additionally meet certain eligibility requirements. The column labeled Eligible Procedures indicates the number of patients who met the inclusion criteria to be included in the analysis for the indicated measure. The Participant Percentile is the percent of STS participants who have an estimated OR that is greater than or equal to your estimated OR. Note that this is different than performance percentiles for process measures, where the percentile indicates the percentage of STS participants with performance that is less than the specified number. This simply reflects the fact that high process compliance is desirable, whereas a high OR is undesirable.

The <u>Observed Participant Rate</u> is the percent of eligible patients who experienced the specified outcome. Unlike the participant estimated OR, the observed participant rate is not risk-adjusted. The estimated OR is the main summary statistic for summarizing the NQF measure in this report.

The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of estimated Odds Ratios across all STS participants. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile." The line that extends to the left and right of the Participant Value indicates the lower and upper limits of a 95% Confidence Interval (CI) surrounding the participant's estimated OR.

#### c. Technical Notes

**Calculation of Percentiles for the Distribution of Participant Values:** The graph provided for each measure contains information about the distribution of the value of the measure across all STS

participants, namely the minimum, maximum,  $10^{th}$  percentile,  $50^{th}$  percentile, and 90th percentile. The " $X^{th}$ " percentile, denoted  $P_x$ , is loosely defined as the number having the property that X% of the participant values are less than  $P_x$ , and (100 - X)% of the participant values are greater than  $P_x$ . For process measures, participants with greater than 5% missing data were excluded when calculating percentiles of the STS distribution and do not have a calculated participant percentile. For participants having less than 5% missing data on a process measure, the missing values on the process measure were converted to "No" before calculating percentiles. For outcomes measures, all participants submitting at least one eligible case were included when calculating percentiles of the STS distribution. Missing data on outcomes variables were treated as "No."

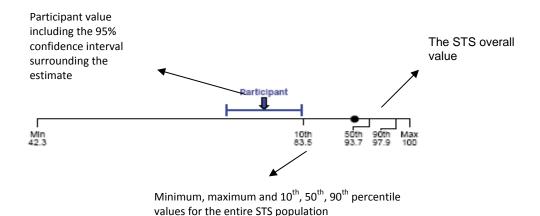
NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion criteria, and rules for handling missing data in the NQF section versus the rest of the report. Definitions used in the NQF report were designed to match current NQF specifications as closely as possible. It is expected that these differences will eventually disappear as the NQF measures are refined. Some important differences are:

Case Volumes – The NQF report section presents "annualized" volumes. These are case volumes that have been adjusted for the number of months that a participant was an active contributor to the database. Elsewhere in the STS report, total case volumes are presented without adjustment for the length of participation.

Eligible Cases - The NQF report also presents the number of "eligible cases" for each measure. Separate inclusion criteria are applied to each measure, and these inclusion criteria do not always match the definitions used elsewhere in the STS report. Please refer to the footnotes in each section for specific details.

#### **Interpretation Manual**

In addition to the statistics provided for each of the STS Composite Quality Domains and NQF measures, a figure representing the distribution of values for the entire STS population is provided.



The figure allows participants to quickly judge their performance relative to the overall STS. The scale of the figure is set up such that the right side of the distribution represents the <u>most</u> favorable performance and the left side represents the <u>least</u> favorable performance (Note that in some cases smaller numbers will be on the left; in other instances, smaller numbers will be on the right. For example, for the Pre-operative Beta Blockade Therapy measure, the far left side of the distribution will contain the *lowest* percentage Beta Blockade Therapy for an STS participant – this corresponds to least

favorable performance. Alternatively, for the Operative Mortality Measure, the far left side of the distribution will contain the *highest* Estimated Odds Ratio – this also corresponds to least favorable performance). If a participant's value for a given measure is to the left of the STS overall value, the participant is performing worse on that measure than the overall STS. Conversely, if the participant's value for a given measure is located to the right of the overall STS value, the participant is performing better than the overall STS.

**NOTE!** Care should be given to reading these figures. In some instances, the various percentiles presented cluster very close together in the data. In such cases, the label for the percentile is not necessarily located immediately at the point on the distribution where the percentile occurs. An example of this is apparent in the figure above: The 50<sup>th</sup> percentile corresponds to a value of 93.7 and looks to align fairly closely with the STS overall value as represented by the large black dot. However, the expandable figure marking actually points to a place somewhere to the right of the STS overall value for the 50<sup>th</sup> percentile marking. So the STS overall value would be some amount less than 93.7.

Also, please note that in some cases, small sample sizes preclude valid comparisons between the participant and the STS overall. Such instances are clearly noted in the report output.

#### a. NQF Measures Interpretation Example

Sample CABG Operative Mortality results – tabular and figure representation.

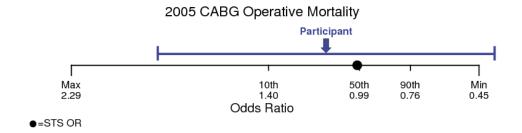
NQF	Eligible	Participant	Participant	Participant
Measure	Procedures	Estimated OR	Percentile	Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

Eligible Procedures: 74 patients met the inclusion criteria for the indicated measure.

Participant Estimated OR (Odds Ratio): The main summary statistic measuring the impact that a participant's performance has on a patient's probability of experiencing an adverse outcome has a value of 1.14 indicating worse than expected performance.

Participant Percentile: 26.3% of STS participants had an estimated OR greater than or equal to your estimated OR. In other words, 26.3% had the same or worse performance.

Participant Observed Rate: 5.4% of the 74 eligible patients experienced the specified outcome.



#### 2) Sample page from section of the report that contains NQF measure results:



## NQF Measures Process Measures Participant 99999 STS Period Ending 12/31/2008



NQF Measure	Eligible Procedures	Participant Usage (95% CI)	Participant Percentile	Overall STS Usage	Distribution of Participant Values
Jan 2008 - Dec 2008 Preoperative Beta Blockade Therapy <sup>1</sup>	541	89.3% (86.4 , 91.8)	69.9	82.1%	Participant    Min   10th   50th   90th   Max   95.6   100
Jan 2008 - Dec 2008 Use of IMA <sup>2</sup>	536	96.5% (94.5 , 97.9)	63.3	94.2%	Participant  Min 10th 50th 90th Max 53.2 87.8 85.2 98.9 100
Jan 2008 - Dec 2008 Discharge Anti-Platelet Medication <sup>3</sup>	536	98.7% (97.3 , 99.5)	68.7	96.1%	Participant  Min 10th 50th 90th Max 18.7 92.1 97.5 100 100
Jan 2008 - Dec 2008 Discharge Beta Blockade Therapy <sup>4</sup>	538	96.1% (94.1 , 97.6)	53.4	93.7%	Participant  Min 10th 50th 80th Max 15.1 85.3 85.7 100 100
Jan 2008 - Dec 2008 Discharge Anti-Lipid Treatment⁴	535	91.8% (89.1 , 94.0)	40.7	91.4%	Participant

Excludes v2.61 contranindicated / not indicated records.

Excludes patients with prior CABG surgery

Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

Excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

# The Society of Thoracic Surgeons 2008 Cardiac Surgery Risk Models: Part 1—Coronary Artery Bypass Grafting Surgery

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Background. The first version of The Society of Thoracic Surgeons National Adult Cardiac Surgery Database (STS NCD) was developed nearly 2 decades ago. Since its inception, the number of participants has grown dramatically, patient acuity has increased, and overall outcomes have consistently improved. To adjust for these and other changes, all STS risk models have undergone periodic revisions. This report provides a detailed description of the 2008 STS risk model for coronary artery bypass grafting surgery (CABG).

Methods. The study population consisted of 774,881 isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2002, and December 31, 2006, at 819 STS NCD participating centers. This cohort was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. The validation sample was used to assess model calibration and discrimination. Model outcomes included operative mortality, renal failure, stroke, reoperation for any cause, prolonged ventilation, deep sternal wound infection, composite major morbidity or mortality, prolonged length of stay (> 14 days), and short length of stay (< 6 days and alive). Candidate predictor variables were selected based on their availability in versions 2.35, 2.41, and 2.52.1 of the STS NCD and their presence in (or ability to be mapped to) version 2.61. Potential predictor

variables were screened for overall prevalence in the study population, missing data frequency, coding concerns, bivariate relationships with outcomes, and their presence in previous STS or other CABG risk models. Supervised backwards selection was then performed with input from an expert panel of cardiac surgeons and biostatisticians. After successfully validating the fit of the models, the development and validation samples were subsequently combined, and the final regression coefficients were estimated using the overall combined (development plus validation) sample.

Results. The c-index for the mortality model was 0.812, and the c-indices for other endpoints ranged from 0.653 for reoperation to 0.793 for renal failure in the validation sample. Plots of observed versus predicted event rates revealed acceptable calibration in the overall population and in numerous subgroups. When patients were grouped into categories of predicted risk, the absolute difference between the observed and expected event rates was less than 1.5% for each endpoint. The final model intercept and coefficients are provided.

Conclusions. New STS risk models have been developed for CABG mortality and eight other endpoints. Detailed descriptions of model development and testing are provided, together with the final algorithm. Overall model performance is excellent.

(Ann Thorac Surg 2009;88:S2-22) © 2009 by The Society of Thoracic Surgeons

In 1986, The Society of Thoracic Surgeons (STS) convened an Ad Hoc Committee on Risk Factors for Coronary Artery Bypass Graft Surgery (CABG) [1] and an

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Ad Hoc Committee to Develop a National Database for Cardiothoracic Surgery [2]. This was prompted by the

Drs Shahian, O'Brien, Filardo, Ferraris, Haan, Rich, Normand, DeLong, Shewan, Peterson, Edwards, Anderson, and Ms Dokholyan have no conflicts of interest to declare regarding this work.

#### Abbreviations and Acronyms

BSA = body surface area

CABG = coronary artery bypass graft surgery

CHF = congestive heart failure

EF = ejection fraction

GFR = glomerular filtration rate

HCFA = Health Care Financing Administration

IABP = intra-aortic balloon pump NYHA = New York Heart Association NCD = National Adult Cardiac Surgery Database

O/E = observed to expected ratio

QMTF = Quality Measurement Task Force STS = The Society of Thoracic Surgeons

release earlier that year of inadequately risk-adjusted hospital mortality data by the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services. Although the HCFA analytical methodology was widely criticized, STS leadership recognized that the underlying principle of collecting and analyzing data to improve patient outcomes was valid, particularly for complex and costly procedures such as coronary artery bypass grafting surgery (CABG). They believed that it was the responsibility of professional organizations to develop credible clinical data registries for their own specialties, and that risk models derived from such registries would circumvent many of the concerns resulting from the use of unadjusted administrative data. Such clinical registries would be used as credible data sources for quality assessment and improvement activities as well as for research.

These early activities ultimately led to the development of the STS National Adult Cardiac Surgery Database (NCD) [3, 4]. Since its release to members in 1990, the STS NCD has evolved to become one of the largest specialty-specific clinical data registries in the world. It currently has more than 950 participants enrolled, representing just under 90% of the cardiac surgery providers in the United States, with data on more than 3.6 million procedures. Similar STS data registries have now been developed for congenital heart surgery and general thoracic surgery, and future plans include the development of specialty modules (eg, quality metrics, atrial fibrillation surgery, thoracic aortic surgery). Recent enhancements, including the addition of unique physician and patient identifiers, will facilitate linkages with other registries and greatly expand the potential of the STS NCD for longitudinal follow-up, comparative effectiveness, and cost efficiency studies.

In addition to the development of the STS NCD as a comprehensive, nationally representative data registry, the second major goal of the STS was to assure that analyses derived from this registry would be appropriately adjusted for preoperative patient severity, a major deficiency of the HCFA reports that were initially published in 1986. This was accomplished by first identifying

risk factors for specific procedures and outcomes, beginning with isolated CABG, then using these predictor variables to develop risk models. With statistical risk models, which are most often based on logistic regression, the expected outcome for a patient with a given set of risk factors can be determined, and that can be compared with the observed outcome. The observed (O) and expected (E) outcomes are summed over all patients of a particular surgeon or hospital to yield the risk-standardized mortality ratio (O/E), which can then be multiplied by the average rate in the reference population to calculate risk-standardized mortality rates [5–7].

STS CABG risk models have undergone periodic updates and revisions, the most recent of which was based upon 2000 to 2002 STS NCD data. In 2007, the STS Database Modernization Task Force completed a major specification upgrade of the STS NCD data collection instrument from version 2.52.1 to version 2.61. This included refinement, modification, consolidation, or elimination of some data elements, as well as an attempt to harmonize definitions with those of the American College of Cardiology National Cardiovascular Data Registry whenever possible. Given these changes, as well as the number of years since the last risk model update, the STS Quality Measurement Task Force (QMTF) was asked to develop new risk models for isolated CABG, isolated valve repair or replacement, and combined CABG plus valve procedures. The authors of this report include the QMTF members who participated in this initiative.

Implementation of these new models in January 2008 coincided with the release of STS NCD version 2.61. This report, Part 1 of 3, describes the development of the new mortality and morbidity models for isolated CABG surgery.

#### **Study Purpose**

The primary goal of this study was to develop risk-prediction algorithms for patients undergoing isolated CABG surgery. As the major intended use of these algorithms was to compare participant outcomes to the overall STS national experience, risk factors were generally restricted to patient and clinical characteristics present preoperatively.

#### Risk Model Development and Transparency

The availability of user-friendly statistical software programs and the exponential increase in computing speed have greatly facilitated statistical analyses such as logistic regression, the basis for many risk models. However, despite these technological advances, clinical judgment, experience, intuition, and practicality still play a critical role in risk model development. There are many points in model development at which legitimate differences in approach may lead to substantial differences in the resulting statistical models and the inferences derived from them [8].

We believe the degree of transparency provided in this report regarding the development of the STS CABG risk models is essential in today's health care environment. In an era when society demands full transparency regarding health care performance, the methodologies used to evaluate that performance should be just as transparent [9, 10]. This fundamental principle is among the standards established by the American Heart Association and American College of Cardiology for statistical models used for public reporting [11].

#### Study Population and Endpoints

All isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2000, and December 31, 2006, were initially considered for inclusion, although the final development and validation samples were derived from 2002 to 2006 data. Patients missing data on sex (n = 195) were excluded, as these patients are not included in STS performance feedback reports to database participants. That left a study population of 774,881 surgical procedures from 819 database participants. Patients on dialysis preoperatively (n = 12,415) were excluded when developing the risk model for postoperative renal failure.

#### Training and Validation Samples

The study population was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. Data from the validation sample were used to assess model fit, discrimination, and calibration. After choosing variables and assessing model fit, the development and validation samples were subsequently combined, and the final model coefficients were estimated using the combined (development plus validation) data.

#### **Endpoints**

Risk models were developed for the nine endpoints listed below. Only mortality was recorded beyond the index hospitalization. Morbidity data included only in-hospital complications, although beginning in STS NCD version 2.61, sternal infections will be recorded for up to 30 days postoperatively. The nine endpoints are as follows: (1) operative mortality: death during the same hospitalization as surgery, regardless of timing, or within 30 days of surgery regardless of venue; (2) permanent stroke (cerebrovascular accident): a central neurologic deficit persisting longer than 72 hours; (3) renal failure: a new requirement for dialysis or an increase of the serum creatinine to more than 2.0 mg/dL and double the most recent preoperative creatinine level; (4) prolonged ventilation (longer than 24 hours); (5) deep sternal wound infection; (6) reoperation for any reason; (7) major morbidity or mortality: a composite defined as the occurrence of any of the above endpoints; (8) prolonged postoperative length of stay (PLOS): length of stay (LOS) more than 14 days (alive or dead); and (9) short postoperative LOS (SLOS): LOS less than 6 days and patient alive at discharge (this SLOS definition differs from the previous STS risk models, which did not exclude patients who died in-hospital; patients who died within 5 days of surgery are

included in the new models but are treated as not having a short stay).

Table 1 summarizes the frequencies of these endpoints in the study population for each predictor variable category (ie, the bivariate relationships).

#### Selection of Candidate Predictor Variables

Initial Data Screening of Candidate Predictor Variables

We began by considering all possible candidate variables from the development set (Table 2). Because the primary goal of the STS risk models is to adjust surgical outcomes, in general only preoperative patient variables are included. However, because these models are also used for other purposes such as individual patient prediction and counseling, there were a few modifications (which are discussed in the relevant sections) in the application of this general principle.

As there were a large number of procedures and endpoints available, we were not statistically constrained to highly parsimonious models, nor is such an approach generally favored in regression modeling [12–14]. Discarding valid data elements can waste valuable information that has been collected at substantial effort and cost. Furthermore, although much of the discrimination of a predictive model may be contained in a relatively small number of variables [15, 16], some predictor variables that add only modestly to discrimination may still be important predictors of outcomes at the patient level [17, 18].

# Expert Panel Review for Clinical Relevance and Face Validity

All candidate variables available in version 2.61 were individually discussed by a panel of cardiac surgeons and health policy experts to assure that clinical relevance as well as multiple aspects of validity (face, construct, and content) had been considered.

#### Data Version for Model Development

Although these new risk models were to be introduced in conjunction with the release of STS NCD version 2.61, they were developed with data collected under the three previous data versions (2.35, 2.41, and 2.52.1) because no 2.61 data were yet available. The QMTF began its predictor selection process with two caveats. First, any candidate variable had to be collected consistently across the three previous data versions. Second, it had to also be available in version 2.61 or have the ability to be mapped to this new version. For example, history of smoking and renal failure were not candidate variables as they were either not included in, or were unable to be mapped to, version 2.61. Renal function is now assessed by the last preoperative serum creatinine value, which is collected in all data versions. Because the definition of hypercholesterolemia has changed substantially over successive STS data versions, and because counterintuitive results have been observed in some previous analyses of hyper-

Table 1. Distribution of Risk Factors and Frequency of Adverse Outcomes in Overall Study Population, Isolated Coronary Artery Bypass Graft Surgery (2002–2006)

	Numl Pati				Perce	nt of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Overall											
Total	774,881	100.0	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Age, years											
< 55	137,318	17.72	1.0	0.5	1.7	7.1	0.3	3.7	10.0	2.7	67.1
55–64	221,697	28.61	1.3	0.9	2.4	7.8	0.4	4.2	11.4	3.8	59.4
65–74	245,132	31.63	2.4	1.6	3.9	10.0	0.5	5.5	14.9	5.9	47.7
≥ 75	170,734	22.03	4.7	2.3	6.4	13.9	0.5	7.5	20.9	9.6	33.0
Sex											
Male	560,006	72.27	2.0	1.2	3.4	8.7	0.4	5.1	13.4	4.9	55.0
Female	214,875	27.73	3.4	1.9	4.1	12.2	0.5	5.6	17.0	7.2	41.5
Race											
Caucasian	665,941	85.94	2.3	1.3	3.5	9.3	0.4	5.1	13.9	5.3	52.2
Black	44,405	5.73	2.7	2.0	5.2	13.5	0.7	6.3	19.0	8.2	41.3
Hispanic	25,103	3.24	2.6	1.5	4.3	11.3	0.5	5.6	16.1	6.1	48.4
Asian	12,509	1.61	2.7	1.9	3.8	12.6	0.3	7.2	17.4	7.0	45.2
Other	21,222	2.74	2.3	1.3	3.6	10.4	0.5	5.5	14.8	6.0	48.7
Missing	5,701	0.74	2.3	1.4	4.1	9.4	0.4	5.2	14.5	6.1	48.9
Body surface area (m <sup>2</sup> )	-,						**-				
< 1.50	14,339	1.85	6.2	2.4	4.6	16.2	0.3	8.3	22.1	9.8	36.5
1.50–1.74	111,458	14.38	3.8	2.0	4.0	12.6	0.3	6.5	17.7	7.4	42.5
1.75–1.99	280,677	36.22	2.4	1.5	3.5	9.6	0.4	5.4	14.4	5.6	50.7
≥ 2.00	363,817	46.95	1.7	1.0	3.6	8.6	0.5	4.6	13.1	4.8	55.0
Missing	4,590	0.59	3.7	1.4	4.0	7.6	0.3	4.7	13.9	6.8	46.0
Body mass index (kg/m²)	4,070	0.07	0.7	1.1	1.0	7.0	0.0	1.7	10.7	0.0	10.0
< 25	169,091	21.82	3.3	1.7	3.5	11.0	0.3	6.7	16.3	6.7	47.6
25–29	303,371	39.15	2.1	1.3	3.1	8.6	0.3	4.9	13.1	4.8	54.2
30–34	186,148	24.02	1.8	1.2	3.6	9.0	0.5	4.5	13.4	5.0	53.1
≥ 35	110,213	14.22	2.3	1.2	5.2	12.0	0.8	4.9	16.8	6.8	45.7
Missing	6,058	0.78	3.7	1.4	4.2	8.6	0.3	4.8	14.5	6.7	47.2
Diabetes mellitus	0,030	0.70	0.7	1.1	1.4	0.0	0.0	1.0	14.5	0.7	17.2
No diabetes	492,800	63.60	2.1	1.2	2.8	8.8	0.3	5.0	13.0	4.7	54.8
Diabetes–noninsulin	195,421	25.22	2.3	1.6	4.3	10.1	0.5	5.2	15.2	6.0	48.2
Diabetes-insulin	84,406	10.89	3.6	1.8	7.1	13.9	1.0	6.5	20.6	9.7	37.5
Diabetes-missing treatment	1,439	0.19	3.1	2.2	4.6	11.1	0.7	4.6	15.7	8.8	41.9
Missing	815	0.13	3.8	0.7	2.6	8.8	0.5	4.5	12.3	6.9	43.7
Hypertension	013	0.11	3.0	0.7	2.0	0.0	0.5	4.5	12.5	0.9	43.7
No	167,260	21.59	1.9	0.9	2.2	8.1	0.3	4.6	11.7	4.2	58.2
Yes	606,813	78.31	2.5	1.5	4.0	10.1	0.5	5.4	15.1	5.9	49.3
Missing	808	0.10	3.8	0.7	2.4	9.3	0.5	5.2	12.7	6.7	43.9
Hypercholesterolemia	808	0.10	3.0	0.7	2.4	9.3	0.5	3.2	12.7	0.7	43.9
No	199,894	25.80	3.0	1.6	3.9	11.0	0.5	5.8	16.1	6.5	48.7
Yes	573,257	73.98	2.1	1.3	3.5	9.2	0.3	5.0	13.8	5.2	52.1
Missing	1,730	0.22	4.1	1.6	3.5	10.3	0.4	4.7	13.9	7.3	47.5
9	1,730	0.22	4.1	1.0	3.3	10.5	0.3	4.7	13.9	7.3	47.3
Past or present smoker No	295,999	38.20	2.4	1.4	3.7	9.0	0.4	E 1	13.9	E 2	50.1
			2.4	1.4			0.4	5.1		5.3	
Yes	477,911	61.68	2.3	1.3	3.6	10.1	0.5	5.3	14.7	5.7	51.9
Missing	971	0.13	3.4	0.7	3.1	9.9	0.4	5.3	13.5	9.1	41.0
Chronic lung disease	(10.011	70.01	2.0	1.0	2.2	0.4	0.2	4.0	12.0	4 7	F2 F
None	612,211	79.01	2.0	1.3	3.3	8.4	0.3	4.9	13.0	4.7	53.7
Mild	85,005	10.97	2.8	1.5	4.2	12.0	0.6	5.8	16.9	7.0	45.7
Moderate	47,745	6.16	3.8	1.6	5.3	15.8	0.8	6.8	20.8	9.6	39.5
Severe	22,302	2.88	7.0	2.0	7.7	22.8	1.1	9.5	29.0	15.3	29.2
Missing	7,618	0.98	2.6	1.4	3.2	8.2	0.2	3.9	12.6	5.7	53.4

Table 1. Continued

	Numb Patie		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Peripheral vascular disease											
No	653,260	84.30	2.0	1.2	3.2	8.8	0.4	4.8	13.1	4.8	53.5
Yes	120,480	15.55	4.4	2.3	6.1	14.4	0.7	7.5	21.2	9.6	38.7
Missing	1,141	0.15	3.9	1.1	3.1	11.8	0.3	5.5	14.4	7.4	43.9
Cerebrovascular disease											
No	668,073	86.22	2.1	1.1	3.3	9.0	0.4	4.9	13.4	5.0	53.4
Yes	105,792	13.65	4.0	2.9	5.8	14.0	0.6	7.2	20.7	9.3	37.7
Missing	1,016	0.13	3.2	0.6	2.4	8.9	0.3	4.2	11.4	6.8	43.2
CVA											
No CVA	717,721	92.62	2.2	1.2	3.4	9.3	0.4	5.1	13.8	5.2	52.5
Remote CVA (> 2 weeks)	53,341	6.88	4.2	3.1	6.1	15.3	0.7	7.4	22.0	10.3	35.5
Recent CVA ( $\leq$ 2 weeks)	1,763	0.23	5.0	4.9	6.5	18.8	0.9	8.7	25.4	13.0	32.5
CVA-missing timing	745	0.10	3.8	3.5	6.9	14.0	0.5	5.9	21.7	10.7	34.2
Missing	1,311	0.17	3.3	1.0	2.6	7.4	0.2	4.3	11.4	5.9	47.8
Endocarditis											
No endocarditis	773,002	99.76	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Treated endocarditis	472	0.06	4.4	0.8	5.3	15.3	0.6	8.5	19.9	8.9	33.7
Active endocarditis	110	0.01	2.7	1.8	6.3	20.0	1.8	11.8	24.5	20.0	41.8
Endocarditis-missing type	90	0.01	4.4	4.4	5.8	11.1	1.1	3.3	15.6	2.2	55.6
Missing	1,207	0.16	4.1	1.0	3.5	9.0	0.2	4.6	12.8	7.0	46.2
Renal failure											
No	731,626	94.42	2.1	1.3	3.2	9.0	0.4	5.0	13.4	5.0	52.8
Yes	42,153	5.44	7.2	2.7	14.7	22.5	1.0	9.9	31.9	15.8	23.4
Missing	1,102	0.14	3.1	0.8	2.8	7.4	0.3	3.4	10.8	6.4	46.6
Renal function											
Creatinine < 1.00 mg/dL	274,197	35.39	1.6	1.1	1.5	8.0	0.3	4.4	11.2	4.0	55.6
Creatinine 1-1.49 mg/dL	398,833	51.47	2.0	1.3	3.4	8.9	0.4	5.0	13.5	4.9	53.1
Creatinine 1.5-1.99 mg/dL	57,779	7.46	4.5	2.3	10.8	16.1	0.7	7.8	25.2	10.6	34.5
Creatinine 2.0-2.49 mg/dL	12,463	1.61	6.9	2.9	14.3	21.3	0.9	9.4	31.5	15.3	24.7
Creatinine $\geq 2.5 \text{ mg/dL}$	7,906	1.02	8.2	3.2	20.4	23.4	0.9	11.1	37.9	18.6	20.4
Dialysis	12,415	1.60	8.4	2.7	*NA	25.3	1.2	10.5	31.5	16.4	19.6
Missing	11,288	1.46	3.3	1.2	3.1	7.6	0.3	4.3	12.9	5.9	50.1
Immunosuppressive treatment											
No	758,368	97.87	2.3	1.4	3.6	9.6	0.4	5.2	14.2	5.4	51.5
Yes	14,976	1.93	5.4	1.8	6.3	15.6	0.8	8.7	22.5	10.8	37.0
Missing	1,537	0.20	3.3	0.8	2.8	6.5	0.4	4.6	11.4	6.1	46.8
Prior CABG Surgery											
No	735,033	94.86	2.2	1.4	3.5	9.4	0.4	5.1	14.1	5.4	51.7
Yes	36,693	4.74	5.3	1.6	5.8	14.7	0.5	7.5	20.9	7.8	42.6
Missing	3,155	0.41	2.7	1.1	3.3	8.9	0.5	4.8	12.9	6.8	48.9
Prior valve surgery											
No	769,434	99.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.3
Yes	2,280	0.29	5.9	1.9	6.8	15.3	0.7	8.6	22.5	11.1	32.0
Missing	3,167	0.41	2.9	1.2	3.5	8.6	0.5	4.4	12.7	6.3	50.0
Prior other cardiac surgery											
No	755,653	97.52	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.3
Yes	15,218	1.96	3.9	1.5	4.9	13.1	0.6	6.6	18.6	7.6	45.5
Missing	4,010	0.52	2.8	1.0	2.9	8.5	0.4	4.4	12.2	5.9	50.5
Number of previous CV surgeries											
No previous CV surgery	723,623	93.39	2.2	1.4	3.5	9.4	0.4	5.1	14.0	5.4	51.7
One prior CV surgery	40,474	5.22	4.7	1.6	5.4	13.8	0.5	7.3	19.9	7.7	44.1
Two or more prior CV Surgeries	4,840	0.62	6.2	1.4	5.6	14.7	0.6	8.0	22.0	8.4	41.5
Missing	5,944	0.77	2.9	1.1	3.2	9.8	0.6	5.5	14.3	6.1	51.2

Table 1. Continued

	Numb Patie		Percent of Patients Experiencing Endpoint									
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS	
Prior PCI												
No PCI	606,824	78.31	2.3	1.4	3.6	9.5	0.4	5.1	14.2	5.6	51.1	
$PCI \le 6 \text{ hours}$	7,373	0.95	8.9	2.1	7.4	25.8	0.6	10.5	32.6	11.3	35.5	
PCI > 6 hours	155,161	20.02	2.3	1.2	3.5	9.6	0.4	5.4	14.3	5.1	52.4	
PCI-missing timing	2,456	0.32	3.0	0.6	3.3	8.0	0.8	5.1	13.4	6.8	48.9	
Missing	3,067	0.40	3.3	1.0	3.0	9.8	0.5	4.7	13.7	6.2	47.3	
Acuity status												
Elective	381,116	49.18	1.5	1.1	2.9	6.6	0.4	4.3	11.1	4.1	55.6	
Urgent	356,287	45.98	2.4	1.5	3.9	10.8	0.5	5.6	15.7	6.2	48.5	
Emergent	34,513	4.45	8.1	2.6	8.3	29.6	0.7	10.4	34.1	13.3	33.2	
Emergent salvage	1,967	0.25	38.6	4.9	17.4	52.7	0.7	18.4	70.0	23.5	12.6	
Missing	998	0.13	3.2	1.3	3.6	9.2	0.5	4.8	13.7	6.5	43.6	
MI												
No prior MI	424,599	54.80	1.5	1.1	2.8	6.9	0.3	4.5	11.3	4.1	55.4	
MI > 21 days	137,522	17.75	2.1	1.3	3.5	8.9	0.5	5.2	13.9	5.4	50.4	
MI 8–21 days	26,205	3.38	4.0	1.8	6.0	14.4	0.8	7.5	20.7	10.2	38.1	
MI 1–7 days	148,659	19.18	3.4	1.8	4.8	14.0	0.5	6.1	18.9	7.5	45.7	
MI > 6 and < 24 hours	21,044	2.72	6.0	2.4	6.7	23.6	0.5	8.1	28.1	10.4	39.1	
$MI \le 6 \text{ hours}$	11,539	1.49	10.4	2.6	8.6	31.2	0.6	10.6	36.8	13.3	33.5	
MI-missing timing	4,064	0.52	3.6	1.6	4.6	11.3	0.5	5.6	17.5	7.2	43.9	
Missing	1,249	0.16	2.1	1.1	2.4	6.6	0.2	3.8	10.2	6.7	49.4	
Angina												
No	130,143	16.80	2.5	1.4	3.8	9.5	0.4	5.6	14.7	6.2	48.5	
Yes	643,815	83.09	2.3	1.3	3.6	9.7	0.4	5.2	14.3	5.4	51.8	
Missing	923	0.12	2.3	1.0	2.6	8.8	0.5	4.0	11.2	8.2	43.9	
Cardiogenic shock												
No	758,766	97.92	2.0	1.3	3.4	8.9	0.4	5.0	13.6	5.2	51.9	
Yes	14,919	1.93	18.0	3.6	14.6	49.6	1.0	15.3	55.7	23.1	18.3	
Missing	1,196	0.15	2.7	1.1	3.2	8.0	0.4	4.4	12.0	7.4	44.7	
Resuscitation	,											
No	766,674	98.94	2.2	1.3	3.5	9.4	0.4	5.1	14.1	5.4	51.5	
Yes	6,939	0.90	17.1	3.0	11.4	37.5	0.9	14.0	46.1	18.2	24.3	
Missing	1,268	0.16	2.2	0.8	3.4	8.0	0.6	3.9	11.5	7.3	45.0	
Arrhythmia	,											
No arrhythmia	706,709	91.20	2.0	1.3	3.3	8.9	0.4	4.9	13.4	5.0	53.1	
AFib/flutter	39,125	5.05	5.4	2.3	7.1	16.4	0.7	8.5	23.8	11.9	29.4	
Heart block	10,026	1.29	5.8	1.9	6.8	16.8	0.6	9.2	24.2	9.4	36.4	
Sustained VT/VF	14,336	1.85	8.2	2.0	6.8	23.8	0.6	11.1	31.5	12.0	33.0	
Arrhythmia–other	1,853	0.24	3.8	1.6	5.3	12.9	0.6	6.5	19.1	7.3	39.2	
Arrhythmia–missing type	1,344	0.17	3.9	1.7	4.4	11.9	0.7	7.3	17.5	8.3	37.9	
Missing	1,488	0.19	2.7	1.0	3.0	7.1	0.5	3.8	11.1	6.5	45.5	
Preoperative IABP	1,100	0.13	,	110	0.0	,,,	0.0	0.0	1111	0.0	10.0	
No	714,824	92.25	2.0	1.3	3.3	8.0	0.4	4.9	12.8	4.9	52.8	
Yes	58,134	7.50	6.9	2.2	7.7	30.8	0.6	9.6	34.4	12.9	32.0	
Missing	1,923	0.25	4.2	1.7	4.3	10.9	0.6	5.8	16.0	7.2	45.7	
NYHA class	1,720	0.20	1.2	1.7	1.0	10.7	0.0	3.0	10.0	7.2	10.7	
I	97,812	12.62	1.5	1.1	2.5	6.3	0.3	4.4	10.6	3.9	57.0	
II	187,947	24.25	1.3	1.1	2.6	6.5	0.3	4.2	10.7	3.8	56.5	
III	287,760	37.14	2.0	1.3	3.6	9.0	0.3	5.0	13.9	5.4	51.3	
IV	165,325	21.34	4.5	1.9	5.5	16.6	0.4	7.1	21.9	8.8	42.5	
Missing	36,037	4.65	4.5 2.4	1.9	3.6	8.9	0.6	5.3	13.6	5.8	42.5 47.7	
9	30,037	4.03	4.4	1.4	3.0	0.7	0.3	5.5	13.0	5.0	4/./	
Congestive heart failure	666 E00	86.02	10	1.2	2.0	7.0	0.2	47	12.2	4.2	E4 7	
No Voc	666,592 106,700	86.03	1.8	1.2	2.9	7.9	0.3	4.7	12.2	4.3	54.7	
Yes	106,700	13.77	5.9	2.4	8.5	21.0	0.9	8.7	28.0	13.2	29.5	
Missing	1,589	0.21	3.3	1.4	3.1	9.2	0.4	4.5	13.0	7.4	49.6	

Table 1. Continued

	Numb Patie				Percer	nt of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Number of diseased coronary vessels											
None	2,012	0.26	2.3	0.4	2.8	8.9	0.4	4.6	12.6	5.5	53.1
One	32,311	4.17	1.5	0.6	1.9	6.1	0.2	4.4	9.8	3.1	66.3
Two	150,881	19.47	1.8	1.0	2.7	8.0	0.4	4.5	12.0	4.5	56.3
Three	586,658	75.71	2.5	1.5	4.0	10.4	0.4	5.5	15.3	6.0	49.1
Missing	3,019	0.39	2.6	0.6	1.8	5.5	0.2	4.5	10.8	5.9	54.2
Left main disease $\geq 50\%$											
No	554,355	71.54	2.1	1.3	3.4	8.8	0.4	5.0	13.5	5.1	52.7
Yes	217,548	28.08	3.0	1.5	4.3	11.9	0.5	5.9	16.8	6.6	47.6
Missing	2,978	0.38	2.3	1.4	2.7	6.3	0.3	5.5	11.9	5.9	45.4
Ejection fraction (%)											
< 25	25,323	3.27	7.2	2.2	8.0	25.2	0.8	10.5	31.9	13.7	27.8
25–34	57,460	7.42	4.6	2.1	6.1	17.6	0.6	7.6	23.8	10.3	36.8
35–44	108,623	14.02	3.0	1.7	4.7	12.4	0.6	6.0	17.5	7.2	45.7
45–54	189,478	24.45	1.9	1.3	3.4	8.7	0.4	4.8	13.2	5.0	53.1
≥ 55	351,455	45.36	1.5	1.1	2.7	6.8	0.3	4.4	11.1	3.9	56.1
Missing	42,542	5.49	3.4	1.4	4.1	10.8	0.4	5.6	16.0	6.1	50.0
Mitral stenosis											
No	756,609	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Yes	2,703	0.35	5.5	2.4	6.4	17.0	0.7	7.5	22.9	10.5	35.7
Missing	15,569	2.01	2.1	1.3	3.4	8.3	0.4	4.6	13.1	5.0	53.1
Aortic stenosis	,										
No	750,185	96.81	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.4
Yes	11,386	1.47	4.7	2.1	6.5	14.8	0.7	7.9	21.5	9.7	36.6
Missing	13,310	1.72	2.3	1.3	3.3	8.5	0.4	4.7	13.1	5.0	52.5
Tricuspid stenosis	,										
No	756,574	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	597	0.08	3.4	2.3	6.6	14.9	0.7	6.0	20.9	10.1	43.6
Missing	17,710	2.29	2.1	1.3	3.6	8.5	0.4	4.7	13.4	5.0	53.2
Pulmonic stenosis	,										
No	753,975	97.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	445	0.06	3.4	2.2	3.9	12.6	0.0	6.3	20.2	6.3	49.4
Missing	20,461	2.64	2.2	1.4	3.8	8.7	0.4	5.0	13.9	5.3	52.5
Mitral insufficiency	,										
None	622,173	80.29	2.1	1.2	3.3	8.9	0.4	4.9	13.4	5.0	53.2
Trivial	49,152	6.34	2.4	1.6	4.2	10.5	0.4	5.7	15.7	6.2	47.9
Mild	60,811	7.85	3.7	2.0	5.7	14.3	0.5	6.9	20.3	8.6	40.3
Moderate	16,723	2.16	6.7	2.7	7.9	20.1	0.7	9.6	28.0	12.5	30.3
Severe	2,143	0.28	8.7	3.1	8.9	24.1	0.6	11.0	32.6	15.1	28.2
Missing	23,879	3.08	2.1	1.2	3.0	7.5	0.4	4.7	12.0	5.2	51.5
Aortic insufficiency	20,017	0.00			0.0	7.0	0.1	2.,,	12.0	J	01.0
None	705,771	91.08	2.3	1.3	3.5	9.5	0.4	5.1	14.1	5.4	51.9
Trivial	17,988	2.32	3.6	2.1	5.6	13.4	0.5	7.0	19.4	8.3	40.9
Mild	18,571	2.40	4.1	2.2	5.9	14.3	0.4	7.3	20.8	9.0	37.9
Moderate	3,576	0.46	5.3	2.6	7.0	16.2	0.5	7.9	23.2	10.2	32.8
Severe	411	0.05	7.1	1.9	6.7	15.6	0.7	9.5	25.8	10.9	37.2
Missing	28,564	3.69	2.1	1.2	3.2	7.9	0.4	4.6	12.5	5.3	51.4
Tricuspid insufficiency	_0,004	0.07	4.1	1.4	0.2	1.7	01	4.0	12.0	0.0	01.7
None	675,778	87.21	2.2	1.3	3.4	9.4	0.4	5.1	13.9	5.3	52.1
Trivial	32,856	4.24	2.5	1.6	4.5	9. <del>4</del> 11.1	0.4	6.1	16.6	6.7	47.4
Mild	29,611	3.82	3.9	2.2	5.9	14.7	0.4	7.4	21.0	9.1	39.3
Moderate	5,753	0.74	7.6	3.0	9.0	22.7	0.5	9.8	30.2	13.7	26.9
Severe	728	0.09	9.1	2.9	10.5	24.2	0.4	10.9	33.0	17.2	26.2
Missing	30,155	3.89	2.2	1.2	3.2	7.9	0.4	4.6	12.6	5.2	51.7

Table 1. Continued

	Numb Patie		Percent of Patients Experiencing Endpoint										
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS		
Pulmonic insufficiency													
None	724,258	93.47	2.3	1.4	3.6	9.7	0.4	5.2	14.3	5.5	51.4		
Trivial	10,726	1.38	2.8	1.5	4.3	12.3	0.5	6.5	17.3	7.3	44.8		
Mild	4,867	0.63	3.8	2.1	5.6	14.1	0.4	7.4	21.0	9.1	39.7		
Moderate	546	0.07	6.6	3.1	7.8	17.6	0.2	7.9	24.4	11.5	29.7		
Severe	217	0.03	5.1	0.5	5.1	9.7	0.5	6.5	15.7	8.8	50.7		
Missing	34,267	4.42	2.2	1.3	3.5	8.3	0.4	4.8	13.2	5.5	50.7		

CABG = coronary artery bypass graft surgery; Comp = composite adverse outcome (any); DSWI = deep sternal wound infection; IABP = intra-aortic balloon pump; CVA = cerebrovascular accident (stroke); MI = mvocardial Mort = mortality; Na = not applicable; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; Reop = reoperation; RF = renal failure; PLOS = prolonged length of stay; SLOS = short length of stay; Vent = prolonged ventila-VT = ventricular tachycardia. VF = ventricular fibrillation;

cholesterolemia, a decision was made not to include this variable in the new models.

#### Predictor Frequency

For each variable, the QMTF explored the overall prevalence and missing data frequency per year. Predictor variables that are rarely present in the development sample are difficult to model. For this reason, mitral (0.35%), tricuspid (0.08%), and pulmonic stenosis (0.06%), pulmonic insufficiency (0.10%), and endocarditis (0.09%) were not considered as variables in the new isolated CABG models.

## Inconsistently Coded Variables

A few variables have been collected inconsistently or with questionable reliability, often for clinically unavoidable reasons. For example, pulmonary artery mean pressure data were missing for 70% of patients during 2002 to 2006. Furthermore, the value of this continuous variable may vary substantially depending on the clinical state and volume-loading status of the patient when the measurement is obtained. Because of these concerns, pulmonary artery pressure was not included in the models.

#### Derived or Redundant Variables

Several derived variables were considered for inclusion in the models. For example, body mass index (BMI) is a useful measure of overall body habitus. However, because BMI is highly correlated with body surface area (BSA), the more commonly used anthropometric measure in most previous STS models, the latter was retained in the new models. Similarly, there is a theoretical superiority to inclusion of glomerular filtration rate (GFR) rather than serum creatinine as a measure of renal function. However, the Modification of Diet in Renal Disease formula for estimating GFR is a complex function of creatinine, race, sex, and age, and not all laboratories perform this calculation automatically. Furthermore, as age, sex, and race are already model covariates, using GFR would complicate the interpretation of their regression coefficients. Some of the prognostic value of GFR

comes from these variables that are already included in the model. Finally, previous studies suggest that various measures of renal function used in CABG mortality risk models have similar performance [19]. For all these reasons, serum creatinine was retained as the measure of renal function.

#### Controversial Variables

RACE. Several variables raised particular clinical, statistical, or health policy issues. For example, race was an obvious candidate variable because it was a significant predictor (p < 0.001) of each endpoint except mortality and because the proportion of nonwhite patients varied substantially across institutions. In exploratory analyses, the association between race and outcomes persisted after adjusting for hospital identity, suggesting that this association is not explained by differences in hospital quality.

However, general principles of risk model development complicated the decision as to whether or not to include race in the models. When the dominant purpose of a risk model is adjustment of provider results, it is advisable to include only biological and clinical patient variables that are present before a patient's first contact with the provider. In this context, race is clearly a fixed biological characteristic, but its impact on patient outcomes may be mediated through other mechanisms. It is possible that certain racial and ethnic groups have worse outcomes not because of inherent biological characteristics but because of differences in the quality of care delivered to them. In this case, including race and ethnicity in a risk model could essentially select out or obscure the very disparity issues that society wishes to identify and correct. Inclusion of race and ethnicity in a risk model would say, in effect, that we expect nonwhites to have inferior results and would make an allowance for providers who care for such patients, just as we would for providers who care for patients in cardiogenic shock.

After deliberation regarding the pros and cons, the QMTF ultimately elected to retain race and ethnicity in the new models because of their impact on outcomes,

## Table 2. Initial List of Potential Candidate Variables

#### Demographics

- 1. Age
- 2. Sex
- 3. Race (black, Caucasian, Hispanic, Asian, Native American, other)

Note: Data collection changed in v2.61. New version allows for multiple races (check all that apply). Added Hawaiian/Pacific Islander category. Hispanic ethnicity is a separate variable.

#### Anthropometric

- 4. Height
- 5. Weight

#### Status

- 6. Status (elective, urgent, emergent, salvage)
- 7. Shock
- 8. Resuscitation

#### Cardiac variables

9. Angina, angina type (STS categories are unstable, stable, no angina)

Note: Angina was removed on v2.61 data collection form. The new form has a variable called "cardiac presentation on admission." Angina is one of possible response categories to that field.

10. New York Heart Association functional class

Note: In v2.61, NYHA class is only collected if patient has congestive heart failure.

- 11. Arrhythmia and arrhythmia type (sustained VT/VF; heart block; AFib/flutter, None)
- 12. Myocardial infarction timing: ( $\leq 6$ , > 6 and < 24 hours; 1–7, 8–21, > 21 days)

#### Hemodynamic/catheterization variables

- 13. Ejection fraction
- 14. Number of diseased vessels (0, 1, 2, 3)
- 15. Left main disease
- 16. Pulmonary artery mean pressure
- 17. Mitral stenosis
- 18. Aortic stenosis
- 19. Tricuspid stenosis
- 20. Pulmonic stenosis
- 21. Mitral insufficiency (none, trivial, mild, moderate, severe)
- 22. Aortic insufficiency (none, trivial, mild, moderate, severe)
- 23. Tricuspid insufficiency (none, trivial, mild, moderate, severe)
- 24. Pulmonic insufficiency (none, trivial, mild, moderate, severe)

#### Comorbidities

- 25. Serum creatinine
- 26. Dialysis
- 27. Renal failure

Note: This variable was removed in v2.61.

- 28. Endocarditis (active, treated, none)
- 29. Diabetes and treatment (insulin, oral, diet, untreated, no diabetes)
- 30. Chronic lung disease (none, mild, moderate, severe)
- 31. Congestive heart failure
- 32. Peripheral vascular disease
- 33. Cerebrovascular disease
- 34. CVA and CVA timing (recent, remote, none)

Note: CVA is a child field of cerebrovascular disease in v2.61.

35. Hypercholesterolemia (v2.35, v2.41) and Dyslipidemia (v2.52)

Note: Data from all 3 versions were merged and analyzed under the variable name "hypercholesterolemia."

- 36. Hypertension
- 37. Smoker

Note: Major definition change in v2.61.

#### Preoperative interventions

- 38. Preoperative intra-aortic balloon pump
- 39. Preoperative inotropes
- 40. Immunosuppressive treatment
- 41. Prior percutaneous coronary intervention and timing ( $\leq$  6 hours, > 6 hours, none)

#### **Previous Interventions**

- 42. Prior coronary artery bypass graft surgery
- 43. Prior valve surgery
- 44. Prior other cardiac surgery
- 45. Number of previous cardiovascular surgeries

while recognizing the potential limitations of this decision.

PREOPERATIVE INTRA-AORTIC BALLOON PUMP. Preoperative intra-aortic balloon pump (IABP) is a proxy for more serious preoperative status of the patient (eg, unstable angina, ventricular dysfunction). It captures information that may not be present in other data elements, and it is associated with higher risk of postoperative morbidity and mortality. For these reasons, most CABG risk models include preoperative IABP as a risk predictor. However, placement of an IABP is also a highly discretionary care process the frequency of which varies widely among participating institutions. Indications are subjective and are often dictated by the cardiologist before even referring the patient for cardiac surgery. Based on CABG risk models, an institution that liberally utilizes IABPs will have a higher expected risk of morbidity and mortality (according to the model) compared with another institution with a similar case-mix but a more restrictive IABP policy. That would impact their relative O/E ratios and risk-adjusted outcomes.

Despite its discretionary nature (and the potential for gaming), the QMTF decided to retain IABP use in the models because it is such an important predictor. Ultimately, it was elected to model preoperative IABP as a joint variable with preoperative inotrope use as an overall measure of preoperative acuity/severity.

#### Review of External Sources

The QMTF also reviewed multiple external resources to aid in the selection of potential candidate variables [15, 16, 20]. First, all previous versions of the STS CABG risk models were reviewed. The QMTF also examined other CABG risk models including the European System for Cardiac Operative Risk Evaluation (EuroSCORE) [21], the New York Cardiac Surgery Reporting System [22], the Veterans Affairs Administration cardiac surgery models [23, 24], and the Northern New England Cardiovascular Disease Study Group model [25, 26]. We particularly wanted to identify variables that were found in some form across all the risk models. Subject to the constraints of version 2.61 data specifications, we made a special effort to include such variables in the new STS risk models, in some instances requiring us to "force" them into the models, as described in the section on the final variable selection procedure.

#### Missing Data

Missing data in the STS NCD are rare, having a frequency of less than 1% for most variables. Candidate predictor variables missing most commonly were ejection fraction (5.5%), New York Heart Association (NYHA) class (4.7%), tricuspid insufficiency (3.9%), aortic insufficiency (3.7%), mitral insufficiency (3.1%), aortic stenosis (1.7%), and creatinine/dialysis (1.5%).

Missing predictor values in the STS NCD were managed using imputation. Multiple imputation is the generally preferred statistical method [27], but single imputation was also considered based on the following

practical considerations: (a) the fraction of missing data in the STS NCD was small and, hence, single and multiple imputation would likely give similar point estimates; (b) a slight adjustment to the standard errors would not impact the study conclusions or the published risk algorithms; (c) the large sample size would make multiple imputation less practical to implement because of long computational times.

Prior to selecting an imputation strategy, exploratory analyses were performed using CABG data from 2002 to 2003 to compare single versus multiple imputation results for predicting mortality. These analyses confirmed that the choice between single versus multiple imputation would have only a slight impact on regression coefficients. For example, the estimated odds ratio for a 5-unit increase in ejection fraction was 0.90 (with a 95% confidence interval extending from 0.83 to 0.97) under single imputation and was 0.92 (with a confidence interval extending from 0.85 to 0.99) under multiple imputation. Other variables were missing less frequently than ejection fraction and were even less sensitive to the choice between single versus multiple imputation. Additional analyses of missing data consisted of reestimating the final model coefficients using single versus multiple imputation and comparing results. A summary of these investigations, as well as model coefficients and covariance matrices, are available at www.sts.org/riskmodels. For most patients, if risk were calculated using the multiple imputation model instead of single imputation, the relative change in their risk estimate would only be 1% to 2% (eg, 5% to 5.1% is a 2% change).

Based on the considerations described above, single imputation was used with the following specific rules: (1) binary (yes/no) risk factors were modeled as yes versus no or missing. Missing data for such variables usually implies their absence, and for most binary variables the composite event rates were similar for "no" and "missing" categories; (2) missing data on categorical predictor variables were imputed to the lowest risk value, which, in most instances, was the mode. In most instances, composite event rates for patients with missing data were among the lowest. It is the policy of the STS Data Warehouse and Analysis Center to discourage missing data through this default coding practice; and (3) missing data on continuous predictor variables were imputed to the conditional median. For ejection fraction, we conditioned on congestive heart failure (CHF) and sex. For BSA, we conditioned on sex. For serum creatinine, we conditioned on renal failure (although this approach will be modified when the model is ultimately applied to version 2.61 data, as renal failure has been removed).

For model endpoints (eg, mortality), missing data were handled by modeling yes versus no or missing. Thus, cases with missing data for an endpoint were analyzed as if the endpoint did not occur. Complete case analysis was not used because "missing" was not considered to be consistently coded for these variables. For example, some STS data managers have reported that they set complications to "no" unless there is explicit documentation in the medical record that the complication occurred. Other

data managers may leave the field missing unless there is explicit documentation that the complication did not occur. Thus, missing data may reflect differences in coding practices rather than truly unknown or missing data.

# Preliminary Analyses for Ordinal Categorical Variables and Continuous Variables

The QMTF conducted preliminary analyses to determine how best to model ordinal categorical variables and continuous variables. Categorical variables were entered into a logistic regression model by including a separate parameter for each category. Continuous variables were entered as piecewise linear functions (splines) with several changes of slope (knots). Terms were then removed one at a time using backward selection based on the Wald statistic. At each iteration, either two adjacent categories were collapsed into a single category or else two adjacent line segments were collapsed into a single line with no change of slope. The backward selection terminated when all adjacent categories and slopes were statistically different from one another at p < 0.001. This variable selection routine was performed separately for each endpoint. An expert panel determined the final coding based on the results of the backwards selection algorithm, supplemented by their clinical judgment and practical considerations. Table 3 summarizes these coding decisions.

#### **Specific Coding Decisions**

RACE AND ETHNICITY. In versions 2.35, 2.41, and 2.52.1, race was collected by choosing one of the following mutually exclusive response categories: Caucasian, black, Hispanic, Asian, Native American, and other. In version 2.61, the data collection form was modified to conform to standards adopted by the US Census Bureau. It allows for selecting one or more races per patient (ie, select all that apply), and treats ethnicity (Hispanic versus non-Hispanic) as a separate variable. Because of these differences, the mapping of race among data versions is not straightforward.

Ultimately, the QMTF decided to model race as black, Asian, Hispanic, and Caucasian/other (collapsed). Initially, these categories will be mapped to version 2.61 as follows: (1) black will include all black patients, regardless of ethnicity or additional races; (2) Hispanic will include all nonblack Hispanic patients; (3) Asian will include all Asian patients who are not also identified as black or Hispanic; and (4) all remaining patients will be placed in the Caucasian/other category. The validity of this mapping will be assessed once 2.61 data become available and future versions could employ race "bridging" methodologies.

BODY SURFACE AREA. Height and weight were replaced by BSA, which was modeled as a quadratic trend to allow for a possible U-shaped relationship with outcomes (eg, extreme obesity and cachexia). This quadratic polynomial was modeled separately for males and females. Any BSA values below 1.4 or above 2.6 were mapped to these

values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

ANGINA. Version 2.61 of the data collection form eliminates angina and substitutes a new variable called "cardiac presentation on admission," within which unstable angina is one of the possible response categories. The QMTF believed that unstable angina would be coded more consistently than any other angina class, and also that this was the most important type of angina presentation to include in the models. Angina coding was therefore restricted in the new risk models to "unstable angina without MI < 7 days (yes/no)." It was necessary to exclude patients with myocardial infarction less than 7 days because the new version 2.61 does not permit simultaneous coding of angina and acute myocardial infarction.

REOPERATIVE STATUS. The most important consideration with regard to reoperative status is the number of prior sternotomies, irrespective of the specific type of procedure performed. The revised models replaced prior CABG, prior valve, and prior "other" cardiac surgery with simply the number of previous cardiovascular surgeries.

ACUITY STATUS. The new models combine resuscitation with salvage status. By definition, all salvage patients should have resuscitation coded "yes."

NUMBER OF DISEASED CORONARY VESSELS. Outcomes are modeled using the number of diseased vessels (grouped as 0 or 1 versus 2 versus 3), as a linear effect across the three categories. This approach is consistent with the previous STS CABG models and was supported by the data.

NYHA CLASS. Version 2.61 uses NYHA class as a subfield of CHF. The grouping of NYHA IV versus less than IV (I–III) classes is consistent with all existing STS models. The final categories were no CHF, CHF not NYHA IV, and CHF plus NYHA IV.

AGE. Age was modeled as a linear spline with knots at ages 50 and 60 years.

EJECTION FRACTION. Ejection fraction (EF) was modeled linearly, and EFs below 10% and above 50% were mapped to these values respectively. Only 0.03% of patients have EFs lower than 10%; such values are considered invalid and are treated like missing data. The coding decision regarding EF values above 50% was based on preliminary analyses in which the data were used to suggest the functional form of continuous variables.

CREATININE. Creatinine was modeled as a linear spline with knots at 1.0 and 1.5. Creatinine levels less than 0.5 or greater than 5.0 were mapped to these values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

MORTALITY AND LENGTH OF STAY. The QMTF changed the previous STS definition of the "short postoperative length of stay (SLOS)" endpoint. The original definition did not specifically exclude early postoperative deaths, and such patients could have been inappropriately included with the remaining SLOS patients who had a particularly short and uncomplicated postoperative course. In the new models, patients who die within 5 days of surgery are included in the analysis but are not counted as a short stay.

Table 3. Final List of Candidate Variables and Coding For STS Risk Models

Candidate Variables	Coding
Continuous variables	
Age <sup>a</sup>	Linear spline with knots at 50 and 60.
Ejection fraction <sup>a</sup>	Linear; values $>$ 50 are mapped to 50. Only 0.03% of patients have ejection fraction $<$ 10, and that is presumed to be a data entry error these values are considered invalid and are treated like missing data. The decision to consolidate values $>$ 50 was based on initial exploratory analyses in which data were used to suggest the functional form of continuous variables.
Body surface area <sup>a</sup>	Quadratic polynomial modeled separately for males and females. Note: body surface areas $< 1.4$ and $> 2.6$ were mapped to these values, respectively. <sup>c</sup>
Creatinine <sup>a</sup>	Linear spline with knots at 1.0 and 1.5. (Only for patients not on dialysis.) Note: Creatinine values < 0.5 and > 5.0 were mapped to these values, respectively. <sup>d</sup>
Time trend <sup>a</sup>	Ordinal categorical variable with separate category for each 6-month harvest interval.
Binary variables	
Dialysis <sup>a</sup>	Yes/no
Preoperative atrial fibrillation <sup>b</sup>	Yes/no
Shock	Yes/no
Female <sup>a</sup>	Yes/no
Hypertension	Yes/no
Immunosuppressive treatment	Yes/no
Percutaneous coronary intervention $\leq$ 6 hours	Yes/no
Preoperative intra-aortic balloon pump or inotropes	Yes/no
Peripheral vascular disease	Yes/no
Unstable angina (no myocardial infarction < 7 days)	Yes/no
Left main disease	Yes/no
Aortic stenosis	Yes/no
Aortic insufficiency	Defined as at least moderate (yes/no)
Mitral insufficiency	Defined as at least moderate (yes/no)
Tricuspid insufficiency	Defined as at least moderate (yes/no)
Categorical variables	· ·
Chronic lung disease	4 groups: (1) none, (2) mild, (3) moderate, (4) severe
CVD/CVA	3 groups: (1) no CVD, (2) CVD no CVA, (3) CVD + CVA
Diabetes mellitus	3 groups: (1) insulin diabetes, (2) noninsulin diabetes, (3) other or no diabetes
Number diseased coronary vessels	3 groups: (1) fewer than 2 diseased vessels, (2) 2 disease vessels, (3) 3 diseased vessels; modeled as linear across the categories.
Myocardial infarction	4 groups: (1) $\leq$ 6 hours, (2) $>$ 6 and $<$ 24 hours, (3) 1 to 21 days, (4) $>$ 21 days or no myocardial infarction.
Race	4 groups: (1) black, (2) Asian, (3) Hispanic, (4) other, including Caucasian
Status	4 groups: (1) elective, (2) urgent, (3) emergent, no resuscitation, (4) salvage or emergent with resuscitation
Previous cardiovascular operations	3 groups: 0 previous, 1 previous, 2 or more previous
CHF and NYHA class	3 groups: no CHF, CHF not NYHA IV, CHF + NYHA IV
Interactions	
Age by reoperation <sup>a</sup>	
Age by emergent status <sup>a</sup>	

<sup>&</sup>lt;sup>a</sup> These variables were forced into each model. <sup>b</sup> Preoperative atrial fibrillation was forced into the model for stroke. <sup>c</sup> These are the approximate 1st and 99th percentiles of the empirical distribution. Values less than 1.4 were mapped to 1.4. Values greater than 2.6 were mapped to 2.6. Estimates in the extreme tails of the body surface area distribution are highly influenced by data from other regions of the body surface area distribution (owing to use of a parametric, quadratic model) and may not be reliable. <sup>d</sup> These are approximately the 1st and 99th percentiles of the empirical distribution. Although we used a flexible spline model, linear splines can have unreliable extreme results in the tails due to the assumption that the effect is linear above the largest knot and below the smallest knot.

Table 4. Discrimination of Models (C-Index)

New STS	models—devel	opment sample	(C-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.810	0.716	0.795	0.756	0.706	0.657	0.724	0.769	0.727
New STS	models—valida	ntion sample (C	-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.812	0.720	0.793	0.754	0.689	0.653	0.725	0.767	0.726
Old STS r	nodels—validat	tion sample (C-	index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.807	0.713	0.750	0.742	0.672	0.645	0.711	0.754	0.713
		outcom a (amy).	CVAt1	DCMI — 1		stion. Most – se	t-lit DI OC	

 $\begin{array}{lll} Comp = composite \ adverse \ outcome \ (any); & CVA = stroke; \\ length \ of \ stay; & Reop = reoperation; & RF = renal \ failure; \\ prolonged \ ventilation. & \end{array}$ 

 $\begin{aligned} DSWI &= \text{deep sternal wound infection;} &\quad Mort &= \text{mortality;} &\quad PLOS &= \text{prolonged} \\ SLOS &= \text{short length of stay;} &\quad STS &= \text{The Society of Thoracic Surgeons;} &\quad Vent &= \end{aligned}$ 

#### Final Variable Selection Procedure

#### Backward Selection

Using the remaining candidate variables and the coding schemes described previously, a supervised backward selection approach was then performed. Initial variable selection used the Wald  $\chi^2$  statistic with a significance criterion of 0.001. This high level of significance was chosen because of the very large sample size that resulted in quite small p values. An expert panel of cardiothoracic surgeons and biostatisticians then reviewed the selected variables and made several modifications. Measures of model performance (discrimination and calibration) were similar when all variables were retained in the models regardless of statistical significance or expert panel review.

#### Forced Variables

Several variables were included in the models regardless of statistical significance. These included all of the continuous variables (age, BSA, date of surgery [in 6-month intervals], creatinine, ejection fraction), plus sex and dialysis. In addition, atrial fibrillation was included a priori in the model for permanent stroke.

The rationale for including surgery date, a nonmodifiable variable of no intrinsic interest, was to adjust for changes in the frequency of adverse outcomes over the 5-year study period. We adjusted for surgery date to reduce potential confounding by time trends when estimating regression coefficients for variables that are of primary interest, such as preoperative clinical characteristics. For example, temporal changes in the frequency of coding for dyslipidemia, if they occur coincidentally with a secular declining trend in mortality rates, may lead to the unwarranted causal inferences unless there is adjustment for surgery date.

Date of surgery was categorized by 6-month intervals (corresponding to STS data harvests) and modeled as a linear trend across the ordinal categories. Surgery date is not included in the final risk algorithm and a patient's predicted risk is not dependent upon it. The intercept

parameter published in the Appendix has been adjusted to incorporate the time trend, and it reflects the baseline risk for a reference period of July to December 2006.

#### Interaction Terms

These models focused on main effects, and the final models included only four sets of preselected variable interactions: (1) sex by BSA; (2) sex by BSA squared; (3) age by reoperation; (4) age by emergent status. More extensive investigation for interactions was considered, including nonlinear, machine-learning approaches. However, the incremental value of such approaches remains uncertain [28], and interpretability can also become more problematic with numerous interaction terms.

Although multiple terms were allotted for modeling the main effects of age and reoperation, only a single degree of freedom was allotted for their interaction. The models defined a single variable interaction term for age and reoperation. It was equal to the patient's age minus 50 if the patient was at least 50 years old and had a previous CV surgery; otherwise it was equal to zero. This term represents the difference in the change of the slope of age at age 50 for patients who have had at least one previous CV surgery compared with patients who have not had a previous CV surgery. Similarly, only one degree of freedom was allotted for the interaction between age and status. The interaction represents the difference in the change of the slope of age at age 50 for patients with emergent or salvage status compared with patients with elective or urgent status. Although these interaction terms complicate the interpretation of other model variables, this was considered to be acceptable because the main focus of the analysis was prediction, not effect estimation.

## Results

#### Model Performance

Table 4 presents the discrimination of each of the isolated CABG models as well as a comparison with the previous

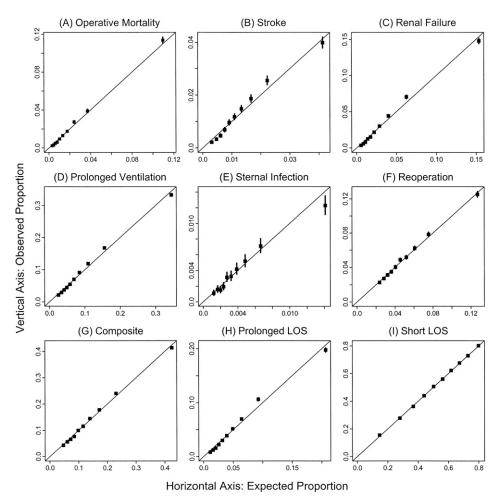


Fig 1. Plots of observed (O) versus expected (E) in validation sample

STS CABG risk models. For the new CABG models, discrimination ranged from 0.657 to 0.810 in the development sample and from 0.653 to 0.812 in the validation sample. The close agreement between c-indices from the development and validation samples reflects the large sample size and suggests that the models did not overfit the data. When the discrimination of the new and previous STS models were compared using the validation sample, the c-index of the new model was larger for each endpoint.

The Hosmer-Lemeshow test is not reported as an overall measure of calibration for these models because of its sensitivity to sample size. With samples as large as those used to develop these models, the null hypothesis will inevitably be proven false, given that all such models are only approximations [29]. As an alternative to such global measures of calibration, Figure 1 shows plots of observed versus expected event proportions within deciles of predicted risk for a variety of endpoints. For each endpoint, the absolute difference between the observed and expected proportions was less than 1.5% in each decile category. Additional analyses of model fit and discrimination are available online at www.sts.org/riskmodels.

#### Final Models

After calculating these measures of model performance, the final regression coefficients were estimated from the combined training and validation samples. Odds ratios for each predictor variable and model endpoint are summarized in Table 5. "Not applicable" indicates that the specific predictor was not included in a particular risk model. These final models were estimated using generalized estimating equations with empirical (sandwich) standard error estimates to account for clustering of patients within institutions [30]. An independence working correlation matrix was used to apply the generalized estimating equations method. With this approach, the estimated regression coefficients were identical to those obtained using ordinary logistic regression, but the standard errors were adjusted to account for correlated observations within hospitals.

#### Final Model Intercept and Coefficients

The Appendix contains the algorithm, intercept and coefficients for the final STS 2008 CABG risk models. The variance/covariance matrix is available on the web at www.sts.org/riskmodels. An on-line risk calculator is available at http://209.220.160.181/STSWebRiskCalc261/.

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Table 5. Estimated Odds Ratios for CABG Mortality, Morbidity, and Length of Stay Models

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50 (no reoperation, elective)	1.36 (1.24, 1.49)	1.78 (1.58, 1.99)	1.24 (1.16, 1.33)	1.06 (1.02, 1.10)	1.43 (1.23, 1.67)	1.14 (1.09, 1.19)	1.08 (1.05, 1.11)	1.35 (1.27, 1.43)	0.77 (0.75, 0.78)
Age 70 versus 50 (no reoperation, elective)	2.53 (2.31, 2.76)	2.43 (2.19, 2.71)	1.93 (1.81, 2.07)	1.42 (1.37, 1.47)	1.70 (1.47, 1.97)	1.45 (1.39, 1.51)	1.49 (1.44, 1.53)	2.17 (2.05, 2.29)	0.44 (0.43, 0.45)
Age 80 versus 50 (no reoperation, elective)	4.70 (4.29, 5.15)	3.34 (2.99, 3.72)	3.01 (2.80, 3.24)	1.90 (1.82, 1.99)	2.02 (1.73, 2.36)	1.85 (1.76, 1.94)	2.05 (1.98, 2.12)	3.48 (3.28, 3.69)	0.25 (0.24, 0.26)
BSA 1.6 versus 2.0 among females	1.26 (1.19, 1.32)	1.15 (1.08, 1.23)	0.84 (0.80, 0.89)	1.03 (1.00, 1.06)	0.49 (0.43, 0.57)	1.23 (1.18, 1.28)	1.03 (1.01, 1.06)	0.94 (0.90, 0.97)	1.17 (1.14, 1.20)
BSA 1.6 versus 2.0 among males	1.75 (1.64, 1.86)	1.19 (1.08, 1.31)	1.24 (1.17, 1.32)	1.40 (1.34, 1.46)	0.77 (0.63, 0.93)	1.40 (1.33, 1.46)	1.35 (1.30, 1.40)	1.43 (1.36, 1.50)	0.79 (0.77, 0.82)
BSA 1.8 versus 2.0 among females	1.02 (0.99, 1.05)	1.07 (1.03, 1.11)	0.86 (0.84, 0.88)	0.95 (0.94, 0.97)	0.67 (0.63, 0.71)	1.06 (1.04, 1.08)	0.96 (0.94, 0.97)	0.90 (0.88, 0.92)	1.14 (1.13, 1.16)
BSA 1.8 versus 2.0 among males	1.20 (1.17, 1.23)	1.09 (1.05, 1.13)	1.02 (1.00, 1.04)	1.09 (1.07, 1.10)	0.85 (0.79, 0.91)	1.13 (1.11, 1.15)	1.08 (1.07, 1.09)	1.10 (1.08, 1.12)	0.96 (0.95, 0.97)
BSA 2.2 versus 2.0 among females	1.20 (1.14, 1.27)	0.95 (0.88, 1.02)	1.32 (1.27, 1.37)	1.18 (1.15, 1.22)	1.62 (1.51, 1.74)	1.03 (1.00, 1.07)	1.19 (1.16, 1.21)	1.28 (1.24, 1.32)	0.78 (0.77, 0.80)
BSA 2.2 versus 2.0 among males	1.01 (0.99, 1.03)	0.92 (0.90, 0.95)	1.17 (1.15, 1.19)	1.10 (1.08, 1.11)	1.27 (1.22, 1.32)	0.97 (0.96, 0.99)	1.07 (1.06, 1.08)	1.08 (1.07, 1.10)	0.90 (0.89, 0.91)
Creatinine 1.5 versus 1.0	1.66 (1.57, 1.76)	1.39 (1.30, 1.49)	3.36 (3.16, 3.58)	1.56 (1.51, 1.62)	1.44 (1.28, 1.62)	1.33 (1.28, 1.38)	1.76 (1.70, 1.82)	1.65 (1.59, 1.72)	0.69 (0.67, 0.71)
Creatinine 2.0 versus 1.0	1.94 (1.84, 2.04)	1.49 (1.39, 1.58)	4.06 (3.83, 4.31)	1.73 (1.68, 1.79)	1.47 (1.30, 1.65)	1.44 (1.40, 1.49)	2.05 (1.98, 2.11)	1.92 (1.86, 2.00)	0.55 (0.53, 0.57)
Creatinine 2.5 versus 1.0	2.26 (2.14, 2.39)	1.59 (1.47, 1.71)	4.90 (4.61, 5.21)	1.92 (1.85, 1.99)	1.50 (1.30, 1.72)	1.57 (1.51, 1.64)	2.39 (2.30, 2.48)	2.24 (2.15, 2.34)	0.44 (0.42, 0.46)
Dialysis versus no dialysis and creatinine = 1.0	3.84 (3.54, 4.16)	1.67 (1.48, 1.88)	NA	2.85 (2.68, 3.03)	2.13 (1.78, 2.56)	1.86 (1.73, 2.00)	2.46 (2.33, 2.60)	2.80 (2.63, 2.98)	0.27 (0.25, 0.29)
EF per 10-unit decrease	1.19 (1.17, 1.22)	1.14 (1.11, 1.16)	1.08 (1.06, 1.10)	1.18 (1.16, 1.20)	1.11 (1.07, 1.16)	1.11 (1.09, 1.13)	1.16 (1.15, 1.18)	1.17 (1.15, 1.19)	0.84 (0.83, 0.85)
Preoperative atrial fibrillation	1.36 (1.28, 1.44)	1.21 (1.12, 1.30)	1.24 (1.18, 1.30)	1.20 (1.16, 1.24)	NA	1.26 (1.21, 1.31)	1.24 (1.21, 1.28)	1.42 (1.37, 1.48)	0.61 (0.59, 0.63)
CHF not NYHA IV	1.21 (1.15, 1.28)	NA	1.36 (1.30, 1.43)	1.31 (1.26, 1.35)	1.33 (1.19, 1.48)	1.16 (1.11, 1.21)	1.27 (1.23, 1.31)	1.43 (1.38, 1.48)	0.72 (0.70, 0.75)
CHF NYHA IV	1.39 (1.31, 1.47)	NA	1.35 (1.28, 1.42)	1.52 (1.45, 1.59)	1.45 (1.25, 1.67)	1.26 (1.20, 1.32)	1.48 (1.42, 1.54)	1.50 (1.44, 1.57)	0.65 (0.61, 0.68)
Chronic lung disease, mild	1.22 (1.16, 1.29)	NA	1.14 (1.08, 1.21)	1.36 (1.31, 1.41)	1.56 (1.40, 1.73)	1.11 (1.07, 1.15)	1.23 (1.19, 1.27)	1.34 (1.29, 1.39)	0.79 (0.76, 0.82)
Chronic lung disease, moderate	1.40 (1.32, 1.49)	NA	1.25 (1.18, 1.33)	1.65 (1.57, 1.73)	1.80 (1.58, 2.06)	1.20 (1.14, 1.26)	1.42 (1.36, 1.47)	1.65 (1.58, 1.73)	0.68 (0.65, 0.71)
Chronic lung disease, severe	2.35 (2.19, 2.52)	NA	1.66 (1.54, 1.79)	2.37 (2.24, 2.51)	2.40 (2.06, 2.79)	1.54 (1.44, 1.64)	1.98 (1.90, 2.07)	2.46 (2.34, 2.60)	0.48 (0.45, 0.51)
CVD with CVA	1.31 (1.24, 1.38)	2.09 (1.96, 2.22)	1.18 (1.12, 1.23)	1.35 (1.31, 1.39)	NA	1.21 (1.17, 1.26)	1.32 (1.29, 1.36)	1.45 (1.40, 1.51)	0.70 (0.68, 0.72)

Table 5. Continued

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
CVD without CVA	1.14 (1.08, 1.20)	1.65 (1.54, 1.75)	1.11 (1.06, 1.17)	1.15 (1.11, 1.18)	NA	1.12 (1.08, 1.17)	1.17 (1.14, 1.20)	1.14 (1.10, 1.18)	0.85 (0.81, 0.89)
Diabetes, insulin dependent	1.30 (1.24, 1.37)	1.19 (1.12, 1.27)	1.80 (1.72, 1.87)	1.22 (1.18, 1.26)	2.24 (2.02, 2.48)	1.14 (1.10, 1.18)	1.30 (1.27, 1.34)	1.59 (1.53, 1.64)	0.64 (0.62, 0.66)
Diabetes, noninsulin dependent	1.01 (0.97, 1.06)	1.16 (1.11, 1.22)	1.32 (1.28, 1.36)	1.04 (1.02, 1.07)	1.38 (1.27, 1.49)	0.98 (0.96, 1.01)	1.08 (1.06, 1.10)	1.15 (1.12, 1.17)	0.87 (0.86, 0.88)
Diseased vessels (2 versus 1, or 3 versus 2)	1.17 (1.12, 1.23)	1.35 (1.29, 1.42)	1.23 (1.19, 1.27)	1.19 (1.16, 1.22)	1.15 (1.07, 1.24)	1.07 (1.05, 1.10)	1.16 (1.14, 1.18)	1.15 (1.11, 1.18)	0.81 (0.80, 0.82)
Preoperative IABP/ inotropes	1.41 (1.33, 1.49)	NA	1.43 (1.36, 1.51)	2.56 (2.42, 2.72)	NA	1.37 (1.31, 1.43)	1.96 (1.86, 2.06)	1.60 (1.53, 1.67)	0.60 (0.57, 0.63)
Shock	2.29 (2.12, 2.47)	1.38 (1.23, 1.55)	1.65 (1.54, 1.77)	2.08 (1.96, 2.21)	NA	1.43 (1.34, 1.52)	2.10 (1.99, 2.23)	1.73 (1.62, 1.84)	0.58 (0.54, 0.62)
Female versus male (at BSA = 1.8)	1.31 (1.25, 1.36)	1.32 (1.24, 1.39)	1.25 (1.21, 1.31)	1.33 (1.29, 1.36)	1.19 (1.06, 1.35)	0.90 (0.87, 0.93)	1.18 (1.15, 1.21)	1.24 (1.20, 1.28)	0.65 (0.63, 0.66)
Hypertension	NA	1.29 (1.22, 1.37)	1.25 (1.20, 1.30)	1.10 (1.08, 1.13)	NA	NA	1.12 (1.10, 1.15)	1.07 (1.04, 1.11)	0.92 (0.90, 0.94)
Immunosuppressive treatment	1.48 (1.37, 1.60)	NA	1.21 (1.12, 1.31)	1.11 (1.05, 1.18)	NA	1.32 (1.24, 1.41)	1.20 (1.14, 1.26)	1.28 (1.20, 1.37)	0.80 (0.76, 0.84)
Aortic insufficiency, moderate/severe	NA	0.82 (0.75, 0.89)							
Mitral insufficiency, moderate/severe	1.31 (1.21, 1.41)	NA	NA	1.12 (1.06, 1.18)	NA	1.24 (1.16, 1.32)	1.20 (1.15, 1.26)	1.15 (1.09, 1.22)	0.85 (0.80, 0.91)
Tricuspid insufficiency, moderate/severe	NA	NA	1.31 (1.17, 1.45)	1.28 (1.18, 1.39)	NA	NA	1.24 (1.16, 1.33)	NA	0.78 (0.71, 0.87)
$PCI \le 6 \text{ hours}$	1.37 (1.24, 1.50)	NA	1.29 (1.16, 1.43)	1.21 (1.13, 1.29)	NA	1.30 (1.19, 1.42)	1.31 (1.23, 1.39)	1.17 (1.07, 1.27)	0.79 (0.74, 0.84)
Peripheral vascular disease	1.42 (1.36, 1.48)	1.32 (1.26, 1.39)	1.21 (1.17, 1.26)	1.22 (1.19, 1.26)	1.36 (1.24, 1.48)	1.24 (1.20, 1.28)	1.25 (1.22, 1.28)	1.31 (1.28, 1.35)	0.82 (0.81, 0.84)
Aortic stenosis	NA	NA	NA	1.18 (1.11, 1.26)	NA	NA	1.16 (1.10, 1.22)	1.15 (1.07, 1.23)	0.87 (0.82, 0.92)
Left main disease	NA	NA	NA	1.07 (1.04, 1.09)	NA	NA	1.04 (1.02, 1.06)	NA	NA
MI 1–21 days	1.37 (1.32, 1.44)	1.31 (1.25, 1.37)	1.27 (1.22, 1.32)	1.34 (1.29, 1.38)	NA	NA	1.23 (1.20, 1.25)	1.22 (1.18, 1.25)	0.88 (0.86, 0.90)
MI > 6 and < 24 hours	1.59 (1.46, 1.74)	1.59 (1.43, 1.76)	1.48 (1.36, 1.60)	1.59 (1.49, 1.68)	NA	NA	1.43 (1.37, 1.50)	1.31 (1.24, 1.39)	0.80 (0.76, 0.84)
$MI \leq 6 \text{ hours}$	1.70 (1.53, 1.89)	1.49 (1.31, 1.68)	1.43 (1.29, 1.57)	1.56 (1.45, 1.67)	NA	NA	1.44 (1.35, 1.53)	1.30 (1.21, 1.40)	0.82 (0.77, 0.87)
Time trend, per 6- month harvest interval	0.97 (0.97, 0.98)	0.97 (0.96, 0.98)	1.01 (1.00, 1.02)	1.01 (1.01, 1.02)	0.97 (0.95, 0.99)	0.99 (0.99, 1.00)	1.00 (1.00, 1.01)	1.00 (0.99, 1.01)	0.99 (0.98, 1.00)
Race Asian	NA	1.33 (1.14, 1.55)	1.08 (0.96, 1.22)	1.33 (1.21, 1.47)	1.00 (0.66, 1.51)	1.31 (1.17, 1.46)	1.23 (1.15, 1.31)	1.26 (1.13, 1.40)	0.70 (0.61, 0.81)
Race black	NA	1.41 (1.30, 1.54)	1.24 (1.16, 1.33)	1.37 (1.27, 1.48)	1.30 (1.13, 1.51)	1.21 (1.14, 1.30)	1.31 (1.24, 1.38)	1.43 (1.34, 1.51)	0.69 (0.65, 0.73)
Race Hispanic	NA	1.12 (0.98, 1.27)	1.24 (1.11, 1.39)	1.16 (1.07, 1.26)	1.30 (1.07, 1.58)	1.05 (0.97, 1.13)	1.12 (1.05, 1.19)	1.09 (0.99, 1.20)	0.85 (0.77, 0.94)

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SCIS
Reoperation, 1 previous operation <sup>a</sup>	3.13 (2.74, 3.57)	NA	1.52 (1.35, 1.71)	.52 (1.35, 1.71) 1.72 (1.58, 1.86)	NA	1.57 (1.43, 1.74)	1.57 (1.43, 1.74) 1.61 (1.50, 1.72) 1.62 (1.47, 1.80) 0.72 (0.67, 0.78)	1.62 (1.47, 1.80)	0.72 (0.67, 0.78)
Reoperation, $\geq 2$ previous operations <sup>a</sup>	4.19 (3.45, 5.09)	NA	1.58 (1.33, 1.87)	.58 (1.33, 1.87) 1.86 (1.62, 2.14)	NA	1.71 (1.44, 2.03)	1.71 (1.44, 2.03) 1.84 (1.65, 2.05)	1.79 (1.53, 2.08)	0.64 (0.56, 0.73)
Status urgent <sup>a</sup>	1.16 (1.10, 1.22)	1.11 (1.06, 1.17)	1.12 (1.05, 1.19)	1.24 (1.18, 1.31)	1.20 (1.10, 1.32)	1.18 (1.13, 1.23)	1.18 (1.14, 1.22)	1.20 (1.15, 1.25)	0.86 (0.83, 0.90)
Status emergent, no resuscitation <sup>a</sup>	2.83 (2.52, 3.18)	2.12 (1.82, 2.48)	1.68 (1.49, 1.89)	2.14 (1.96, 2.34)	1.87 (1.46, 2.40)	1.83 (1.68, 1.99)	1.77 (1.64, 1.91)	2.12 (1.93, 2.32)	0.62 (0.58, 0.67)
Status emergent with resuscitation or salvage <sup>a</sup>	8.00 (6.91, 9.26)	8.00 (6.91, 9.26) 2.51 (1.98, 3.18)	2.16 (1.82, 2.55)	3.01 (2.68, 3.38)	2.09 (1.45, 3.01)	2.34 (2.06, 2.65) 3.65 (3.26, 4.09)	3.65 (3.26, 4.09)	2.39 (2.10, 2.72) 0.34 (0.30, 0.38)	0.34 (0.30, 0.38)
Unstable angina	1.12 (1.07, 1.17)	NA	1.11 (1.05, 1.17)	.11 (1.05, 1.17) 1.05 (1.01, 1.10)	NA	NA	NA	NA	NA

<sup>a</sup> Variable interacts with age. Reported odds ratio represents effect of risk factor for patients aged 50 years old.

CVD = cerebrovascular disease; = renal failure; NA = not applicable; = cerebrovascular accident, or stroke; Mort = mortality; = peripheral vascular disease; Comp = composite adverse outcome (any); .BP = intra-aortic balloon pump; MI = r = intra-aortic balloon pump; N PLOS = prolonged length of stay; BSA = body surface area; CH = deep sternal wound infection; Heart Association; short length of stay; Previously, the STS risk models were completely upgraded every 3 years, with annual recalibration in the interim to assure that the benchmark O/E ratio is always 1. In the near future, annual upgrades of the models are planned.

## Limitations

Regardless of sample size or degree of statistical sophistication, all risk models are imperfect representations of reality. Although the STS risk models are based upon excellent clinical data and large sample sizes, there are some risk factors that are rare in the overall population but, when present, may be important predictors of outcome for specific patients. Some such variables, such as liver disease, are not included in the risk models, and the mortality risk for patients with these risk factors may be underestimated. Addition of a number of such variables will be considered at the next major specification upgrade.

There are other variables whose specifications undergo small but important changes over time, often in response to comments from STS database participants. These refinements are discussed on regular biweekly conference calls open to database participants, and suggested changes are regularly communicated to participants through a variety of means including FAQ's. With each major specification upgrade, they are incorporated into the new software specifications.

Audit is extremely important to assure the accuracy of any data registry. For the STS database and the risk models derived from it, robust audit is particularly critical as this registry is increasingly used for public reporting of outcomes and pay for performance. Studies suggest that the accuracy of the STS database is high for most important variables [31-35], although these audits are currently restricted to a limited number of sites annually because of budgetary constraints. In these audits, one of the most problematic variables has been 30-day mortality status (as opposed to in-hospital mortality). This is often a difficult endpoint to ascertain and may require more substantial investment of time and effort by participants, particularly for patients referred from outside their own institutions. Analysis of STS data suggests that approximately 90% of 30-day deaths occur in-hospital. Thus, if some patients recorded as being alive at 30 days have actually had their status ascertained only during the index hospitalization, the impact of this misclassification on the risk models should be negligible. This hypothesis was confirmed by comparing the odds ratios of all model variables for in-hospital versus 30-day mortality. Differences between the two were quite small, and these data are available on the web at www. sts.org/riskmodels. A new risk model for in-hospital mortality has been developed and placed on the same STS website. Furthermore, an aggressive program is in place to further enhance the accuracy of 30-day follow-up. In 2009, STS instituted a requirement that participants maintain documentation of the method by which they ascertained 30-day status, and that has become part of our routine audit. Linkage of the STS database with external death registries, such as the Social Security Death Master File, will

further support this capability. Finally, plans are being developed to expand the audit of certain key variables such as 30-day mortality to a significantly greater number of sites annually.

#### **Conclusions**

Risk-adjustment models account for the effect of patient comorbidities on outcomes. STS risk models are based upon clinical data from the STS NCD, one of the oldest and largest of all specialty registries. The value of such clinical registries is particularly evident in today's health care environment, where accreditation, regulatory compliance, reimbursement, and referrals are increasingly based upon objective data. Organizations such as the AQA and the National Quality Forum that evaluate and endorse performance measures strongly advocate the use of risk-adjusted outcomes measures.

STS believes that clinical data are superior to those derived from administrative sources. Furthermore, given the substantial implications of risk-adjusted outcomes, we believe that all risk models used for profiling quality of care should be transparent to permit comprehensive peer review and to foster credibility among stakeholders.

We present a detailed exposition of the development and validation of the 2008 STS CABG risk model. This describes not only the statistical considerations but, just as importantly, the many clinical and pragmatic judgments that are always necessary in risk model development.

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# **Appendix**

Regression Coefficients and Variable Definitions for STS 2008 CABG Models

For each endpoint, the formula for calculating a patient's predicted risk of the endpoint has the form:

Predicted Risk = 
$$\frac{e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}{1+e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}$$

where  $x_1, x_2, \ldots, x_n$  denote patient preoperative risk factors (eg, quantitative variables such as age, and comorbidities coded as 1 = present, 0 = absent), and  $\beta_0, \beta_1, \ldots, \beta_n$  denote regression coefficients (numerical constants). Regression coefficients for each endpoint are presented in Appendix Table 1. The variables  $x_1, x_2, \ldots, x_n$  are the same for each endpoint and are defined in Appendix Table 2. The regression coefficient for the time trend is not presented. Instead, the intercept has been adjusted to incorporate the time trend. This adjusted intercept reflects the baseline risk for a reference period of July to December 2006.

Appendix Table 1. Regression Coefficients

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Intercept	-6.34090	-7.18174	-7.94605	-4.15175	-6.75378	-3.84861	-3.71671	-5.35975	2.84959
Atrial fibrillation	0.30830	0.18935	0.21351	0.17871	0.00000	0.23031	0.21565	0.35322	-0.49309
Age	-0.00259	0.00996	0.00678	0.00170	-0.00665	-0.00013	0.00247	0.00914	-0.01781
Age function 1	0.03325	0.04742	0.01496	0.00393	0.04270	0.01305	0.00515	0.02085	-0.00895
Age function 2	0.03140	-0.02582	0.02249	0.02366	-0.01895	0.01133	0.02441	0.01734	-0.02904
Age by reoperation function	-0.01714	-0.00098	-0.00291	-0.00459	0.00304	-0.00720	-0.00444	-0.00809	0.00449
Age by status function	-0.01366	-0.01363	-0.00022	-0.00106	-0.00352	-0.00435	0.00270	-0.00833	-0.00266
BSA function 1	-1.39342	-0.44041	-0.53672	-0.83950	0.65513	-0.83758	-0.75006	-0.89037	0.57952
BSA function 2	2.41303	0.06122	2.19879	2.15647	0.90025	1.16543	1.81770	2.15270	-1.83776
CHF but not NYHA IV	0.19229	0.00000	0.30971	0.26853	0.28272	0.14692	0.23695	0.35623	-0.32350
CHF and NYHA IV	0.32663	0.00000	0.30013	0.41599	0.36909	0.22846	0.39005	0.40757	-0.43827
Chronic lung disease mild	0.20273	0.00000	0.13488	0.30473	0.44371	0.10432	0.20878	0.29051	-0.23600
Chronic lung disease moderate	0.33843	0.00000	0.22530	0.50235	0.59021	0.18071	0.34720	0.50246	-0.39085
Chronic lung disease severe	0.85513	0.00000	0.50645	0.86175	0.87366	0.43034	0.68538	0.90211	-0.73862
Creatinine function 1	0.19353	0.02822	1.91934	-0.02712	-0.37465	0.01583	0.13361	-0.09060	0.00773
Creatinine function 2	0.82140	0.63174	0.50685	0.92120	1.09976	0.55107	0.99190	1.09571	-0.75781
Creatinine function 3	-0.70646	-0.52856	-2.04970	-0.68907	-0.68466	-0.39956	-0.81791	-0.70069	0.30449
CVD without prior CVA	0.13177	0.49807	0.10637	0.13792	0.00000	0.11403	0.15561	0.13271	-0.16385
CVD and prior CVA	0.26877	0.73600	0.16135	0.29946	0.00000	0.19208	0.28099	0.37248	-0.35706
Diabetes noninsulin dependent	0.01375	0.14992	0.27443	0.04283	0.31888	-0.01929	0.07453	0.13541	-0.13813
Diabetes insulin dependent	0.26312	0.14332	0.58581	0.19735	0.80627	0.12930	0.26525	0.46226	-0.44725
Dialysis	1.53777	0.54158	0.00000	1.01943	0.38312	0.63691	1.03466	0.93792	-1.30294
Ejection fraction function	0.01765	0.01274	0.00754	0.01669	0.01081	0.03091	0.01496	0.93792	-0.01756
Female	0.26801	0.01274	0.00754	0.28338	0.01081	-0.10270	0.01436	0.01342	-0.01750 $-0.43658$
Female by BSA function 1	0.82285	0.08974	0.96428	0.76954	1.11546	0.31901	0.66663	1.05623	-0.96846
Female by BSA function 2	0.05606	0.06490	-0.61086	-0.62558	0.17399	-0.02390	-0.25077	-0.35160	0.46088
Hypertension	0.00000	0.25718	0.22126	0.09930	0.00000	0.00000	0.11674	0.07200	-0.08155
IABP or inotropes	0.34193	0.00000	0.36023	0.94050	0.00000	0.31326	0.67253	0.47092	-0.51444
Immunosuppressive treatment	0.39159	0.00000	0.18881	0.10686	0.00000	0.27802	0.18030	0.24833	-0.22718
Insufficiency, aortic	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.19889
Insufficiency, mitral	0.26631	0.00000	0.00000	0.11169	0.00000	0.21170	0.18225	0.14174	-0.15962
Insufficiency, tricuspid	0.00000	0.00000	0.26729	0.24834	0.00000	0.00000	0.21893	0.00000	-0.24548
Left main disease	0.00000	0.00000	0.00000	0.06629	0.00000	0.00000	0.03570	0.00000	0.00000
MI 1 to 21 days	0.31810	0.27134	0.23962	0.28925	0.00000	0.00000	0.20524	0.19517	-0.12752
MI > 6 and < 24 hours	0.46614	0.46063	0.38917	0.46158	0.00000	0.00000	0.35859	0.27109	-0.22557
$MI \le 6 \text{ hours}$	0.53242	0.39601	0.35421	0.44230	0.00000	0.00000	0.36337	0.26311	-0.19946
No. diseased vessel function	0.16120	0.30339	0.20729	0.17622	0.13869	0.06895	0.15075	0.13589	-0.21043
PCI ≤ 6 hours	0.31149	0.00000	0.25189	0.18695	0.00000	0.26256	0.26774	0.15633	-0.23860
Peripheral vascular disease	0.34951	0.27985	0.19308	0.20240	0.30529	0.21306	0.22277	0.27380	-0.19321
Race black	0.00000	0.34423	0.21696	0.31563	0.26572	0.19456	0.26634	0.35426	-0.37515
Race Hispanic	0.00000	0.11002	0.21645	0.14802	0.26330	0.04798	0.11289	0.08968	-0.16091
Race Asian	0.00000	0.28567	0.07579	0.28561	-0.00145	0.26855	0.20484	0.23064	-0.35049
Reop, 1 previous operation	1.13997	0.00000	0.41962	0.53987	0.00000	0.45372	0.47614	0.48534	-0.32375
Reop, $\geq$ 2 previous operations	1.43250	0.00000	0.45592	0.62211	0.00000	0.53695	0.61014	0.57945	-0.44745
Shock	0.82667	0.32434	0.50003	0.73290	0.00000	0.35800	0.74320	0.54575	-0.54475
Status urgent	0.14608	0.10671	0.11226	0.21738	0.18496	0.16500	0.16492	0.18202	-0.14608
Status emergent	1.04010	0.75216	0.51857	0.76090	0.62665	0.60549	0.56983	0.75083	-0.47745
Status salvage	2.07934	0.91950	0.76808	1.10085	0.73651	0.84873	1.29422	0.87072	-1.08265
Stenosis aortic	0.00000	0.00000	0.00000	0.16529	0.00000	0.00000	0.14706	0.13988	-0.14173
Unstable angina	0.11217	0.00000	0.10287	0.05060	0.00000	0.00000	0.00000	0.00000	0.00000

 $BSA = body \ surface \ area; \ CHF = congestive \ heart \ failure; \ Comp = composite \ adverse \ event \ (any); \ CVA = cerebrovascular \ accident \ (stroke); \ CVD = cerebrovascular \ disease; \ DSWI = deep \ sternal \ wound \ infection; \ IABP = intra-aortic \ balloon \ pump; \ MI = myocardial \ infarction; \ Mort = mortality; \ NYHA = New \ York \ Heart \ Association; \ PCI = percutaneous \ coronary \ intervention; \ PLOS = prolonged \ length \ of \ stay; \ Reop = reoperation; \ RF = renal \ failure; \ SLOS = short \ length \ of \ stay; \ Vent = prolonged \ ventilation.$ 

# Appendix Table 2. Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	$= \max(age-50, 0)$
Age function 2	$= \max(age-60, 0)$
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	$= (BSA \text{ function } 1)^2$
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
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Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral Insufficiency, tricuspid	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
, I	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI > 6 and <24 hours prior to surgery, = 0 otherwise
$MI \le 6 \text{ hours}$	= 1 if history of MI $\leq$ 6 hours prior to surgery, = 0 otherwise
No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
$PCI \leq 6 \text{ hours}$	= 1 if patient had $PCI \le 6$ hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, ≥ 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwis

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

# NATIONAL QUALITY FORUM

# Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

#### Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 0131	NQF Project: Surgery Endorsement Maintenance 2010
MEA	ASURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Risk-Adjusted Stroke/	Cerebrovascular Accident
(without pre-existing neurologic deficit) wl	tho have a postoperative stroke (i.e., any confirmed neurological deficit blood supply to the brain) that did not resolve within 24 hours
1.1-2 Type of Measure: Outcome De.3 If included in a composite or paired OT1-013-09 - The STS CABG Composite Sco	with another measure, please identify composite or paired measure re
De.4 National Priority Partners Priority A De.5 IOM Quality Domain: Safety De.6 Consumer Care Need: Getting bette	•

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission	A
<b>A.4 Measure Steward Agreement attached:</b> STS Measure Steward Agreement. Fully Executed-634267360663143330.pdf	Y□ N□

update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	Y □
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  ▶ Purpose: Public reporting, Internal quality improvement	C Y N
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.  D.1Testing: Yes, fully developed and tested  D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes	D Y□ N□
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
1. IMI CREATE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	Eval Rating
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality	

artery bypass grafting: report and collective review. Heart Surg Forum. 1999;2(3):242-245.  Inoue K, Luth JU, Pottkamper D, et al. Incidence and risk factors of perioperative cerebral complications: heart transplantation compared to coronary artery bypass grafting and valve surgery. J Cardiovasc Surg. 1998;39(2):201-208.	
Likosky DS, Leavitt BJ, Marrin CA, et al. Intra- and postoperative predictors of stroke after coronary artery bypass grafting. Ann Thorac Surg. 2003;76(2):428-434.  Mangano DT. Aspirin and mortality from coronary bypass surgery. N Engl J Med. 2002; 347(17):1309-	
1317.  Puskas JD, Winston AD, Wright CE, et al. Stroke after coronary artery operation: incidence, correlates, outcome and cost. Ann Thorac Surg. 2000:69(4):1053-1056.	
- Shroyer 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 Welke 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.  Speir AM, Kasirajan V, Barnett SD, Fonner E Jr. Additive costs of postoperative complications for	
isolated coronary artery bypass grafting patients in Virginia. Ann Thorac Surg. 2009 Jul;88(1):40-5; discussion 45-6. PubMed PMID: 19559186.  Brown PP, Kugelmass AD, Cohen DJ, Reynolds MR, Culler SD, Dee AD, Simon AW. The frequency and	
cost of complications associated with coronary artery bypass grafting surgery: results from the United States Medicare program. Ann Thorac Surg. 2008 Jun;85(6):1980-6. PubMed PMID: 18498806.  Naylor AR. Does the risk of post-CABG stroke merit staged or synchronous reconstruction in patients	
with symptomatic or asymptomatic carotid disease? J Cardiovasc Surg (Torino). 2009 Feb;50(1):71-81.  1b. Opportunity for Improvement	
<b>1b.1 Benefits (improvements in quality) envisioned by use of this measure:</b> Reductions of the rates of post-CABG stroke have occurred with the implementation of operative strategies to decrease manipulation of the heart and aorta, measures to maintain blood pressure and perfusion, glycemic control, avoidance of atrial fibrillation, anticoagulation protocols, and avoidance of combined carotid and CABG surgery in certain settings. Implementation of these modalities is highly variable among CABG performing groups, and stroke rates are significantly variable. Many opportunities exist to decrease stroke rates by increasing implementation of evidence based strategies.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: Please see attachment	
1b.3 Citations for data on performance gap: Dates: January 1, 2009-December 31, 2009	
Analysis includes 597 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data (not restricted to this measure) to the STS Adult Cardiac Surgery Database for all 12 months.	
1b.4 Summary of Data on disparities by population group:	1b C□
1b.5 Citations for data on Disparities:	P
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Post operative Stroke/Cerebrovascular Accident produces significant short- and long-term often devastating effects to patients and their families. It is associated with significant increases in death, respiratory failure, renal	1c C□
failure, length of stay, and cost of care.  1c.2-3. Type of Evidence: Observational study, Expert opinion, Systematic synthesis of research, Other	P

Clinical results from approximately 90% of cardiac surgery centers in the US

**1c.4 Summary of Evidence** (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):

Reductions of the rates of stroke post-CABG have occurred with the implementation of operative strategies to decrease manipulation of the heart and aorta, measures to maintain blood pressure and perfusion, glycemic control, avoidance of atrial fibrillation, anticoagulation protocols, and avoidance of combined carotid and CABG surgery in certain settings. Implementation of these modalities is highly variable among CABG performing groups, and stroke rates are significantly variable. Many opportunities exist to decrease stroke rates by increasing implementation of evidence based strategies.

**1c.5** Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):

#### 1c.6 Method for rating evidence:

## 1c.7 Summary of Controversy/Contradictory Evidence:

- **1c.8 Citations for Evidence (***other than guidelines***):** Amory DW, Grigore A, Amory JK, et al. Neuroprotection is associated with beta-adrenergic receptor antagonists during cardiac surgery: evidence from 1,575 patients. J Cardiothorac Vasc Anesth. 2002;16(3):270-277.
- Bucerius J, Gummert JF, Borger MA, et al. Predictors of delirium after cardiac surgery delirium: effect of beating-heart (off-pump) surgery. J Thorac Cardiovasc Surg. 2004;127(1):57-64.
- Eagle KA, Guyton RA, Davidoff R, Ewy GA, Fonger J, Gardner TJ, Gott JP, Hermann HC, Marlow RA, Nugent W, O'Connor GT, Orszulak TA, Rieselbach RE, Winters WL, Yusuf S. 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.
- Engelman DT, Cohn LH, Rizzo RJ. Incidence and predictors of TIAs and strokes following coronary artery bypass grafting: report and collective review. Heart Surg Forum. 1999;2(3):242-245.
- Inoue K, Luth JU, Pottkamper D, et al. Incidence and risk factors of perioperative cerebral complications: heart transplantation compared to coronary artery bypass grafting and valve surgery. J Cardiovasc Surg. 1998;39(2):201-208.
- Likosky DS, Leavitt BJ, Marrin CA, et al. Intra- and postoperative predictors of stroke after coronary artery bypass grafting. Ann Thorac Surg. 2003;76(2):428-434.
- Mangano DT. Aspirin and mortality from coronary bypass surgery. N Engl J Med. 2002; 347(17):1309-1317.
- Puskas JD, Winston AD, Wright CE, et al. Stroke after coronary artery operation: incidence, correlates, outcome and cost. Ann Thorac Surg. 2000:69(4):1053-1056.
- Shroyer 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.
- Welke 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.
- Speir AM, Kasirajan V, Barnett SD, Fonner E Jr. Additive costs of postoperative complications for isolated coronary artery bypass grafting patients in Virginia. Ann Thorac Surg. 2009 Jul;88(1):40-5; discussion 45-6. PubMed PMID: 19559186.
- Brown PP, Kugelmass AD, Cohen DJ, Reynolds MR, Culler SD, Dee AD, Simon AW. The frequency and cost of complications associated with coronary artery bypass grafting surgery: results from the United States Medicare program. Ann Thorac Surg. 2008 Jun;85(6):1980-6. PubMed PMID: 18498806.
- Naylor AR. Does the risk of post-CABG stroke merit staged or synchronous reconstruction in patients with symptomatic or asymptomatic carotid disease? J Cardiovasc Surg (Torino). 2009 Feb;50(1):71-81.
- 1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):
- 1c.10 Clinical Practice Guideline Citation:
- 1c.11 National Guideline Clearinghouse or other URL:

1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):	
1c.13 <b>Method for rating strength of recommendation</b> ( <i>If different from USPSTF system</i> , also describe rating and how it relates to USPSTF):	
1c.14 Rationale for using this guideline over others:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report?</i>	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y□ N□
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ( <u>evaluation criteria</u> )	Eval Rating
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:	
2a. Precisely Specified	
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):  Number of patients undergoing isolated CABG who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours	
2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):	
2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):  Number of isolated CABG procedures in which postoperative stroke [CNStrokP (STS Adult Cardiac Surgery Database Version 2.73)] is marked "yes"	
2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured): All patients undergoing isolated CABG	
2a.5 Target population gender: Female, Male 2a.6 Target population age range: 18 and older	
2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator): 12 months	2a-
<b>2a.8 Denominator Details</b> (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):  Number of isolated CABG procedures	specs C P M N

Isolated CABG is determined as a procedure for which all of the following apply:

- OpCAB is marked "Yes"
- (VADProc is marked "No" or "Missing") or (VADProc is marked "Yes, Implanted" and UnplVAD is marked "yes")
- OCarASDTy is marked "PFO" or "missing"
- OCarAFibAProc is marked "primarily epicardial" or "missing" and
- OpValve, VSAV, VSAVPr, ResectSubA, VSMV, VSMVPr, OpTricus, OpPulm, OpONCard, OCarLVA, OCarVSD, OCarSVR, OCarCong, OCarTrma, OCarCrTx, OCAoProcType, EndoProc, OCTumor, OCPulThromDis, OCarOthr are all marked "no" or "missing"
- **2a.9 Denominator Exclusions** (Brief text description of exclusions from the target population): Patients with prior CVA
- **2a.10 Denominator Exclusion Details (**All information required to collect exclusions to the denominator, including all codes, logic, and definitions):

Isolated CABG procedures in which prior CVA (CVA) is marked "yes"

**2a.11 Stratification Details/Variables** (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):

N/A

2a.12-13 Risk Adjustment Type: Case-mix adjustment

**2a.14 Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

Please see attachment

2a.15-17 Detailed risk model available Web page URL or attachment: Attachment 2a.15 Detailed Risk Model-634267362265581794.pdf

2a.18-19 Type of Score: Rate/proportion

2a.20 Interpretation of Score: Better quality = Lower score

**2a.21 Calculation Algorithm** (Describe the calculation of the measure as a flowchart or series of steps): N/A

2a.22 Describe the method for discriminating performance (e.g., significance testing):

Participant specific OR and their 95% CI were estimated in the hierarchical model. These model-based estimates were used to control variation due to random statistical fluctuations while estimating true signal variation. A 95% CI excluding zero indicates the participant's performance is significantly lower or higher than an "average" STS participant.

**2a.23 Sampling (Survey) Methodology** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A

**2a.24 Data Source (**Check the source(s) for which the measure is specified and tested) Registry data

**2a.25** Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):

STS Adult Cardiac Surgery Database - Version 2.73

**2a.26-28** Data source/data collection instrument reference web page URL or attachment: URL Data Collection Form (an updated version will be made available on the STS Website in mid-December of 2010)---http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataCollectionForm2\_7\_Annotated\_20101021.pdf

**2a.29-31 Data dictionary/code table web page URL or attachment:** URL http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataSpecificationsV2\_7\_20101021.pdf -- an updated version will be made available on the STS Website in mid-December of 2010

**2a.32-35 Level of Measurement/Analysis** (Check the level(s) for which the measure is specified and tested)

Clinicians: Group, Facility/Agency, Population: national, Population: regional/network, Population: states, Population: counties or cities	
2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested) Hospital	
2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)	
TESTING/ANALYSIS	
2b. Reliability testing	
<b>2b.1 Data/sample</b> (description of data/sample and size): STS Adult Cardiac Surgery Database - Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009.	
<b>2b.2 Analytic Method</b> (type of reliability & rationale, method for testing): Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009. Excluded from analysis are participants that did not submit results for both time periods. Because database participants can change their underlying care processes at any time, we would not expect perfect correlation between two sets of results from even proximate time periods.	2b C□
<b>2b.3 Testing Results</b> (reliability statistics, assessment of adequacy in the context of norms for the test conducted):  Please see attachment	P
2c. Validity testing	
2c.1 Data/sample (description of data/sample and size): STS Adult Cardiac Surgery Database	
Audits conducted in 2010, all cases performed in 2009; N = 40 randomly selected sites participating in the STS Adult Cardiac Surgery Database	
<b>2c.2 Analytic Method</b> (type of validity & rationale, method for testing): Participating sites are randomly selected for participation in STS Adult Cardiac Surgery Database Audit, which is designed to evaluate the accuracy, consistency, and comprehensiveness of data collection and ultimately validate the integrity of the data contained in the database. The lowa Foundation for Medical Care (IFMC), the quality improvement organization for lowa and Illinois, has conducted audits on behalf of STS since 2006.	
Each year, the IFMC conducts audits at randomly selected sites throughout the country and tracks the individual agreement rates by variable and by year. More specifically, for each site, agreement rates are calculated for 73 individual elements. In addition, aggregate agreement rates for each element, variable category (e.g., pre-operative risk factors, previous interventions, etc), and overall for all categories are calculated for all sites. While this is not region specific, it is data point specific and comparison agreement rates confirm the improvement over time as well as the consistency.	2c
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): Post Operative Stroke: 99.8% agreement rate	C   P   M   N
2d. Exclusions Justified	
2d.1 Summary of Evidence supporting exclusion(s):	2d C□
2d.2 Citations for Evidence:	P   M   N

<b>2d.3 Data/sample</b> (description of data/sample and size): January 1, 2009-December 31, 2009; 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure (before the exclusion is applied). Patients with prior CVA are excluded from this NQF measure.	
2d.4 Analytic Method (type analysis & rationale):	
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): Please see attachment	
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size): Please see Risk Adjustment Type section above	
2e.2 Analytic Method (type of risk adjustment, analysis, & rationale): Detailed information regarding the risk adjustment model can be found in the attachment:	
Shahian DM, O'Brien SM, Filardo G, Ferraris VA, Haan CK, Rich JB, Normand SL, DeLong ER, Shewan CM, Dokholyan RS, Peterson ED, Edwards FH, Anderson RP. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 1coronary artery bypass grafting surgery. Ann Thorac Surg. 2009 Jul;88(1 Suppl):S2-22.	2e C□
2e.3 Testing Results (risk model performance metrics):	P   M   N
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	NA.
2f. Identification of Meaningful Differences in Performance	
2f.1 Data/sample from Testing or Current Use (description of data/sample and size): 597 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months. January 1, 2009-December 31, 2009	
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):  We calculated the risk adjusted event rate with the participant's Odds Ratio (OR) estimate and the overall STS event rate. Therefore, the risk adjusted rate is closely related to OR estimate. If OR > 1, then the participant's risk adjusted rate will be greater than the overall STS event rate; if OR < 1, then the participant's risk adjusted rate will be smaller than the overall STS event rate. The statistical significance is defined by the 95% confidence interval (CI) or the OR estimate. If the 95% CI for a participant's OR includes the null value 1.0, then we cannot distinguish this participant's performance from the STS average - either the participant's performance was close to average or else the participant's sample size was too small to make a reliable inference. Otherwise, if the 95% CI falls to the right of 1.0, then the participant's performance is considered significantly lower than the average STS results; if the 95% CI falls to the left of 1.0, then the participant's performance is considered significantly higher than the average STS results.	2f
<b>2f.3 Provide Measure Scores from Testing or Current Use</b> (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  Please see attachment	C   P   M   N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size):	
2g.2 Analytic Method (type of analysis & rationale):	2g C P M
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	N_ NA

2h. Disparities in Care	2h
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts):	C□
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	P   M   NA   NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?	2
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met? Rationale:	2 C P M N
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information	
3a.1 Current Use: In use	
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org	
Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily participate in this initiative.	
3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):  CMS Physician Quality Reporting Initiative (PQRI), www.cms.hhs.gov/pqri	
Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)  3a.4 Data/sample (description of data/sample and size): See 3a.6 below	
3a.5 Methods (e.g., focus group, survey, QI project):	3a C□
3a.6 Results (qualitative and/or quantitative results and conclusions): Please see attachment	M N
3b/3c. Relation to other NQF-endorsed measures	
3b.1 NQF # and Title of similar or related measures: OT1-013-09 - The STS CABG Composite Score; Component measures: 0114 Risk-Adjusted Post-Operative Renal Failure, 0115 Risk-Adjusted Surgical Re-exploration, 0116 Anti-Platelet Medication at Discharge, 0117 Beta Blockade at Discharge, 0118 Anti-Lipid Treatment at Discharge, 0119 Risk-Adjusted Operative Mortality for CABG, 0127 Pre-Operative Beta Blockade, 0129 Risk-Adjusted Prolonged Intubation (ventilation), 0130 Risk-Adjusted Deep Sternal Wound Infection Rate, 0131 Risk-Adjusted Stroke/Cerebrovascular Accident, 0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	

3b. Harmonization If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why? N/A; however, data definitions and key elements have been established by a multi-societal writing committee called the "ACCF/AHA Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards" with representatives from each of the following organizations:	
Agency for Healthcare Research and Quality American College of Cardiology American College of Chest Physicians American College of Emergency Physicians American College of Physicians American College of Preventative Medicine American Heart Association American Medical Association Centers for Disease Control and Prevention Emergency Nurses Association Food and Drug Administration Joint Commission on Accreditation of Healthcare Organizations National Association of Emergency Medical Technicians National Association of EMS Physicians	
National Heart, Lung, and Blood Institute Preventive Cardiovascular Nurses Association Society for Academic Emergency Medicine Society of Chest Pain Centers and Providers Society of General Internal Medicine Society of Thoracic Surgeons	3b C P M N NA
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF- endorsed measures:  5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:	3c C P M N NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C   P   M   N
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	
<b>4a.1-2</b> How are the data elements that are needed to compute measure scores generated?  Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C   P   M   N
4b. Electronic Sources	4b C□

NQF #0131

<b>4b.1 Are all the data elements available electronically?</b> (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) Yes	P
4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	
4c. Exclusions	_
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?	4c C   P   M   N
4c.2 If yes, provide justification.	NA.
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.  This measure may be susceptible to human error (i.e., recording the measure inaccurately or not at all).	
When data collection on this measure is done through participation in the STS Adult Cardiac Surgery Database, an auditing strategy is in place.	
Both STS and the Duke Clinical Research Institute have a list of database participants making participation in the STS Adult Cardiac Surgery Database easy to track.	
Each participant is responsible for the quality and accuracy of the data they submit to the database. The participant agrees to the following quality control measures in the participation agreement: i) Participant hereby warrants that all data submitted for inclusion in the STS National Database will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the independent data warehouse service provider and agrees to cooperate with and assist STS and its designees in connection with the performance of any independent audit.	
ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the STS National Database, including but not limited to apprising the Director of the STS National Database and the independent data warehouse service provider about any other Participation Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named.	4d C□ P□
STS audited for these potential problems during testing. Please see IFMC audit results.	N□
4e. Data Collection Strategy/Implementation	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:	
4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary measures): Data Collection: There are no direct costs to collect the data for this measure. Costs to develop the measure included volunteer cardiothoracic surgeon time, STS staff time, and DCRI statistician and project management time.	4e C□
Other fees: STS Adult Cardiac Surgery Database participants (single cardiothoracic surgeons or a group of surgeons) pay	P

	_
annual participant fees of \$2,950 or \$3,700, depending on whether participants are STS members (or whether the majority of surgeons in a group are STS members). As a benefit of STS membership, STS members are charged the lesser of the two fees.	
4e.3 Evidence for costs:	
4e.4 Business case documentation:	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C   P   M   N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement? Comments:	Y □ N □ A □
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611 Co.2 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Measure Developer If different from Measure Steward  Co.3 Organization  Society of Thoracic Surgeons, 633 North Saint Clair Street, Suite 2320, Chicago, Illinois, 60611	
Co.4 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Co.5 Submitter If different from Measure Steward POC Jane, Han, MSW, jhan@sts.org, 312-202-5856-, Society of Thoracic Surgeons	
Co.6 Additional organizations that sponsored/participated in measure development	
ADDITIONAL INFORMATION	
Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations.  Describe the members' role in measure development.  Members of the STS Task Force on Quality Initiatives provide clinical expertise as needed. The STS Workforce National Databases meets at the STS Annual Meeting and reviews the measures on a yearly basis. Changes or updates to the measure will be at the recommendation of the Workforce.	e on
Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment	
Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 Year the measure was first released: 2004 Ad.7 Month and Year of most recent revision: 12, 2010	

Ad.8 What is your frequency for review/update of this measure? annually Ad.9 When is the next scheduled review/update for this measure? 2011

Ad.10 Copyright statement/disclaimers:

Ad.11 -13 Additional Information web page URL or attachment: Attachment 0131 Sections 2a.14, 1b.2, 2b.3, 2d.5, 2f.3, 3a.6.pdf

Date of Submission (MM/DD/YY): 01/12/2011

# **2a.14. Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method)

The risk adjusted model is a hierarchical logistic regression model with participant level intercept. logit(outcome)  $\sim X\beta + (\gamma | participant)$ 

where X is the patient's risk factors,  $\theta$  is the regression coefficients of patient-level risk factors and  $\gamma$  is the participant level regression coefficient.

# **Inclusion Criteria**

The patient level risk adjusted model was developed using a population of patients undergoing isolated CABG procedure in the time period January 2002 – December 2006. For this measurement we re-fit the patient-level model using the latest two and a half years of data (January 2008 – June 2010) from the STS Adult Cardiac Surgery Database.

# Variable Definitions and Selection

All variables for consideration are listed in the table below.

# Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	= max (age–50, 0)
Age function 2	= max (age-60, 0)
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	= (BSA function 1) <sup>2</sup>
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
Insufficiency, tricuspid	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI >6 and <24 hours prior to surgery, = 0 otherwise
MI ≤ 6 hours	= 1 if history of MI ≤ 6 hours prior to surgery, = 0 otherwise

No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
PCI ≤ 6 hours	= 1 if patient had PCI ≤ 6 hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, 2 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwise
-	·

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

The final patient-level model was built by backward selection method with several variables forced into the model. For the final patient-level model, please see the attachment.

# **1b.2.** Summary of Measure Results Demonstrating Performance Gap (Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.)

The summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. A high OR is undesirable and we define the percentiles with decreasing OR. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile" below.

Management	Stroke	
Measurement	Cerebrovascular Accident	
N	597	
Mean	1.0	
1 <sup>st</sup>	2.1	
5 <sup>th</sup>	1.6	
10 <sup>th</sup>	1.4	
25 <sup>th</sup>	1.2	
Median	1.0	
75 <sup>th</sup>	0.8	
90 <sup>th</sup>	0.7	
95 <sup>th</sup>	0.7	
99 <sup>th</sup>	0.6	
Outlier	13 (2.2)	
High	1	
Low	12	

Also provided is the distribution of the risk adjusted event rate (see below). The risk adjusted rate is an estimate of the participant's event rate if, hypothetically, the case-mix of the patients treated by the participants is the same as the overall STS case-mix. It is calculated by the OR of the participant, other patient level parameter estimates from the hierarchical logistic model, and the overall STS event rate, by:

STS event rate \* (Participant's Expected Event Rate) / (Participant's Expected Event Rate Assuming Its Performance = STS Average Performance)

In the above equation, "Participant's Expected Event Rate" is calculated with the participant's actual OR, and "Participant's Expected Event Rate Assuming Its Performance = STS Average Performance" is calculated by assuming the participant's OR = 1 (i.e. no difference in performance from the STS average).

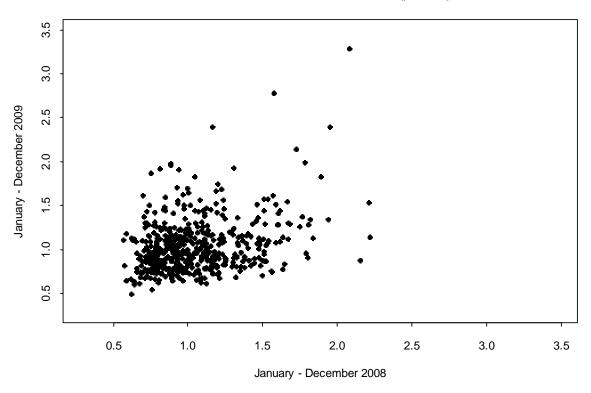
Measurement	Stroke Cerebrovascular Accident	
N	597	
Mean	1.1	
1 <sup>st</sup>	0.7	
5 <sup>th</sup>	0.8	
10 <sup>th</sup>	0.8	
25 <sup>th</sup>	0.9	
Median	1.0	

Measurement	Stroke Cerebrovascular Accident
75 <sup>th</sup>	1.2
90 <sup>th</sup>	1.5
95 <sup>th</sup>	1.7
99 <sup>th</sup>	2.3
Outlier	13 (2.2)
High	1
Low	12

**2b.3. Testing Results** (Reliability statistics, assessment of adequacy in the context of norms for the test conducted)

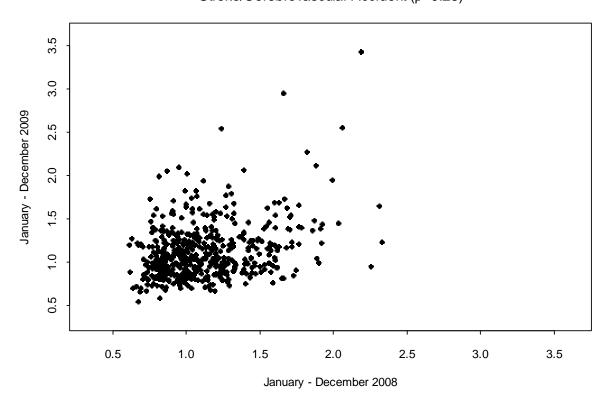
Testing results:  $\rho = 0.26$ 

Stroke/Cerebrovascular Accident (p=0.26)



Risk Adjusted Rate

Stroke/Cerebrovascular Accident (p=0.26)

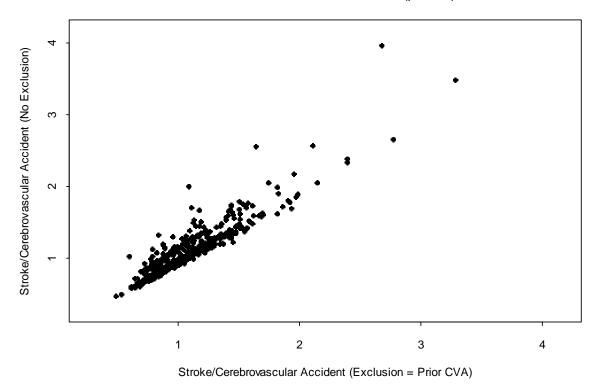


## **2d.5. Testing Results** (E.g., frequency, variability, sensitivity analyses)

Stroke Cerebrovascular Accident							
# of Patients 144060							
# excluded	9695						
% excluded	0.07						

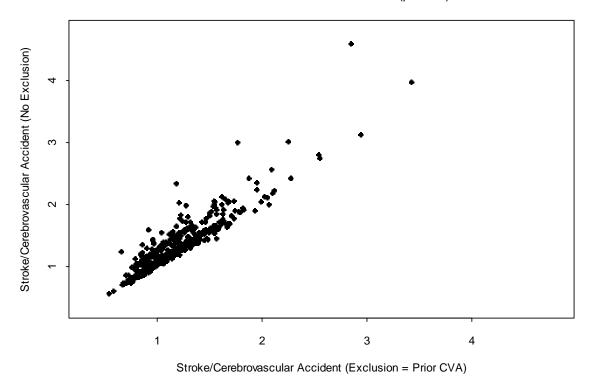
## **Odds Ratio**

## Stroke/Cerebrovascular Accident ( $\rho$ =0.92)



Risk Adjusted Rate

## Stroke/Cerebrovascular Accident (ρ=0.92)



# **2f.3. Measure Scores from Testing or Current Use** (Description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)

Results below are from January 1, 2009-December 31, 2009. Sample contains 597 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months.

	Stroke
Measurement	Cerebrovascular Accident
N	597
Mean	1.0
L <sup>st</sup>	2.1
th	1.6
LO <sup>th</sup>	1.4
25 <sup>th</sup>	1.2
Лedian	1.0
<sup>7</sup> 5 <sup>th</sup>	0.8
00 <sup>th</sup>	0.7
5 <sup>th</sup>	0.7
99 <sup>th</sup>	0.6
Outlier†	13 (2.2)
High	1
.ow	12

### Risk Adjusted Rate:

	Stroke
Measurement	Cerebrovascular Accident
N	597
Mean	1.1
1 <sup>st</sup>	0.7
5 <sup>th</sup>	0.8
10 <sup>th</sup>	0.8
25 <sup>th</sup>	0.9
Median	1.0
75 <sup>th</sup>	1.2
90 <sup>th</sup>	1.5
95 <sup>th</sup>	1.7
99 <sup>th</sup>	2.3
Outlier†	13 (2.2)
High	1

	Stroke
Measurement	Cerebrovascular Accident
Low	12

†Represents the number of participants that are outliers according to two-sided 95% confidence interval of odds ratio.

#### **3a.6. Results** (Qualitative or quantitative results and conclusions)

Although formal testing of interpretability has not been performed, this measure has been used and reported for STS Adult Cardiac Surgery database participants since 2007. Current report presentation and interpretation manuals are presented below. These materials are updated as needed based upon feedback from database participants.

#### 1) Report Overview and Interpretation Manual:

#### **The NQF Measures Report**

#### a. Organization

This report section is separated into three areas corresponding to: 1) NQF volume measures, 2) NQF process measures, and 3) NQF outcomes measures, in that order. The header at the top of each page references the report section for that page. Each NQF measure is presented on a single row in the section. Tabular data are on the left-hand side of each page and a standard graphic representation is shown on the right-hand side.

#### b. Statistical Calculation and Details – NQF Measures

**Time period:** This report section contains information on the individual STS participant and overall STS performance for the <u>most recent 12 months for volume, process and CABG outcomes measures and the most recent 60 months for Valve and Valve + CABG outcomes. The 5 years (60 months) of performance for outcomes involving Valve procedures is necessary due to smaller sample sizes.</u>

**Volume Measures:** The NQF report provides average annual case volumes data for three surgery categories: i) Isolated CABG, ii) Valve without CABG, and iii) combined CABG + Valve. Definitions of the three surgery categories are provided in Table 2 of this NQF Report Overview. For each type of surgery, the <u>participant's annualized volume</u> is calculated as:

Participant Annualized Volume = 12 x (# of surgeries) / (# of months)

where (# of surgeries) denotes the number of surgeries of the specified type performed by the participant during the specified time period, and (# of months) is the number of months during the specified time period for which the participant submitted at least one cardiac surgery of any type. The intent of calculating "annualized" volumes is to adjust for participants who participated in the database for fewer months than the time period specified. For participants who participated in the database and submitted cases every month during 2006, the annualized volume for 2006 is simply the total number of cases.

The <u>STS</u> Average Annualized Volume is the average value of all of the participant annualized volumes across the entire population of STS participants. The <u>Participant Percentile</u> indicates the percent of STS participants whose annualized volumes are less than, or equal to, your own. Higher percentiles indicate higher volumes in relation to other STS participant sites. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant annualized volumes across all database participants. For example, 90% of participants have annualized volumes less than or equal to the value marked "90<sup>th</sup> percentile." Confidence intervals are not provided for volume measures, as volume is known with certainty and is not estimated.

**Process Measures:** The NQF process measures provide data on the frequency of usage of five therapies among subsets of Isolated CABG patients. The therapies are: i) preoperative beta blockade therapy, ii) use of IMA, iii) discharge anti-platelet medication, iv) discharge beta blockade therapy, and v) discharge anti-lipid medication. The patient population for each measure differs, in accordance with the NQF specifications (see Table 2 of this NQF Report Overview for details). The number of <u>Eligible</u>

Procedures is the number of cases performed by the participant during the specified time period who meet the eligibility requirements to be included in the calculations when summarizing the participant's data. Beginning with the 2008 Harvest 3 report (covering the procedure time period through 6/30/2008), STS implementation of NQF medication process measures using data version 2.61 excludes records for which the medication was contraindicated/not indicated from the eligible population. The main summary statistic, Participant Usage, is the percent of eligible Isolated CABG cases during the specified time period for which the patient received the specified therapy. The Overall STS Usage is the percent of all eligible patients in the entire STS population during the specified time period who received the specified therapy. In calculating these percentages, missing data are treated as a "No", emphasizing the importance of having complete data in these fields.

The <u>Participant Percentile</u> indicates the percent of STS participants who applied the therapy in their respective populations less frequently than or as frequently as did your institution. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant usage across all participants in the database. For example, 90% of participants use the therapy less frequently than the amount indicated by the "90<sup>th</sup> percentile". A bar identified as "Participant" indicates the point estimate and limits of a 95% Confidence Interval (CI) for the participant's usage of therapy. The underlying parameter being estimated is the long-run usage rate that would be observed in a large sample of patients. The 95% CI indicates the range of usage rates that are consistent with the data in light of sampling variability.

Outcomes Measures: The NQF outcomes data provide risk-adjusted analyses of mortality and morbidity for Isolated CABG surgery as well as risk-adjusted operative mortality for Isolated AVR, Isolated MVR, AVR+CABG, and MVR+CABG. The main summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. The interpretation is similar to that of an O/E ratio (see the Risk-Adjusted Results: Overview portion of the General Report Overview for details on STS risk adjustment). An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. Each measure is calculated among patients undergoing surgery of the type specified during the time period specified who additionally meet certain eligibility requirements. The column labeled Eligible Procedures indicates the number of patients who met the inclusion criteria to be included in the analysis for the indicated measure. The Participant Percentile is the percent of STS participants who have an estimated OR that is greater than or equal to your estimated OR. Note that this is different than performance percentiles for process measures, where the percentile indicates the percentage of STS participants with performance that is less than the specified number. This simply reflects the fact that high process compliance is desirable, whereas a high OR is undesirable.

The <u>Observed Participant Rate</u> is the percent of eligible patients who experienced the specified outcome. Unlike the participant estimated OR, the observed participant rate is not risk-adjusted. The estimated OR is the main summary statistic for summarizing the NQF measure in this report.

The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of estimated Odds Ratios across all STS participants. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile." The line that extends to the left and right of the Participant Value indicates the lower and upper limits of a 95% Confidence Interval (CI) surrounding the participant's estimated OR.

#### c. Technical Notes

**Calculation of Percentiles for the Distribution of Participant Values:** The graph provided for each measure contains information about the distribution of the value of the measure across all STS

participants, namely the minimum, maximum,  $10^{th}$  percentile,  $50^{th}$  percentile, and 90th percentile. The " $X^{th}$ " percentile, denoted  $P_x$ , is loosely defined as the number having the property that X% of the participant values are less than  $P_x$ , and (100 - X)% of the participant values are greater than  $P_x$ . For process measures, participants with greater than 5% missing data were excluded when calculating percentiles of the STS distribution and do not have a calculated participant percentile. For participants having less than 5% missing data on a process measure, the missing values on the process measure were converted to "No" before calculating percentiles. For outcomes measures, all participants submitting at least one eligible case were included when calculating percentiles of the STS distribution. Missing data on outcomes variables were treated as "No."

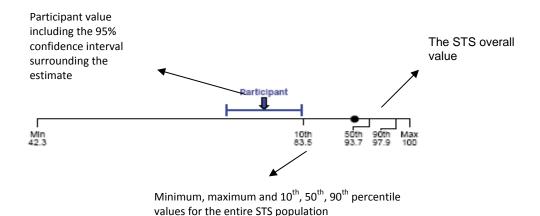
NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion criteria, and rules for handling missing data in the NQF section versus the rest of the report. Definitions used in the NQF report were designed to match current NQF specifications as closely as possible. It is expected that these differences will eventually disappear as the NQF measures are refined. Some important differences are:

Case Volumes – The NQF report section presents "annualized" volumes. These are case volumes that have been adjusted for the number of months that a participant was an active contributor to the database. Elsewhere in the STS report, total case volumes are presented without adjustment for the length of participation.

Eligible Cases - The NQF report also presents the number of "eligible cases" for each measure. Separate inclusion criteria are applied to each measure, and these inclusion criteria do not always match the definitions used elsewhere in the STS report. Please refer to the footnotes in each section for specific details.

#### **Interpretation Manual**

In addition to the statistics provided for each of the STS Composite Quality Domains and NQF measures, a figure representing the distribution of values for the entire STS population is provided.



The figure allows participants to quickly judge their performance relative to the overall STS. The scale of the figure is set up such that the right side of the distribution represents the <u>most</u> favorable performance and the left side represents the <u>least</u> favorable performance (Note that in some cases smaller numbers will be on the left; in other instances, smaller numbers will be on the right. For example, for the Pre-operative Beta Blockade Therapy measure, the far left side of the distribution will contain the *lowest* percentage Beta Blockade Therapy for an STS participant – this corresponds to least

favorable performance. Alternatively, for the Operative Mortality Measure, the far left side of the distribution will contain the *highest* Estimated Odds Ratio – this also corresponds to least favorable performance). If a participant's value for a given measure is to the left of the STS overall value, the participant is performing worse on that measure than the overall STS. Conversely, if the participant's value for a given measure is located to the right of the overall STS value, the participant is performing better than the overall STS.

**NOTE!** Care should be given to reading these figures. In some instances, the various percentiles presented cluster very close together in the data. In such cases, the label for the percentile is not necessarily located immediately at the point on the distribution where the percentile occurs. An example of this is apparent in the figure above: The 50<sup>th</sup> percentile corresponds to a value of 93.7 and looks to align fairly closely with the STS overall value as represented by the large black dot. However, the expandable figure marking actually points to a place somewhere to the right of the STS overall value for the 50<sup>th</sup> percentile marking. So the STS overall value would be some amount less than 93.7.

Also, please note that in some cases, small sample sizes preclude valid comparisons between the participant and the STS overall. Such instances are clearly noted in the report output.

#### a. NQF Measures Interpretation Example

Sample CABG Operative Mortality results – tabular and figure representation.

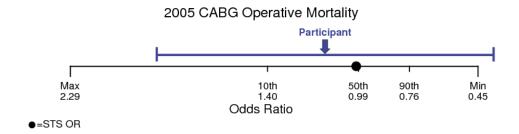
NQF	Eligible	Participant	Participant	Participant
Measure	Procedures	Estimated OR	Percentile	Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

Eligible Procedures: 74 patients met the inclusion criteria for the indicated measure.

Participant Estimated OR (Odds Ratio): The main summary statistic measuring the impact that a participant's performance has on a patient's probability of experiencing an adverse outcome has a value of 1.14 indicating worse than expected performance.

Participant Percentile: 26.3% of STS participants had an estimated OR greater than or equal to your estimated OR. In other words, 26.3% had the same or worse performance.

Participant Observed Rate: 5.4% of the 74 eligible patients experienced the specified outcome.



The highest OR among all STS participants = 2.29 The lowest OR among all STS participants = 0.45 The STS average OR is 1.00

## 2) Sample page from section of the report that contains NQF measure results:



# NQF Measures Process Measures Participant 99999 STS Period Ending 12/31/2008



NQF Measure	Eligible Procedures	Participant Usage (95% CI)	Participant Percentile	Overall STS Usage	Distribution of Participant Values
Jan 2008 - Dec 2008 Preoperative Beta Blockade Therapy <sup>1</sup>	541	89.3% (86.4 , 91.8)	69.9	82.1%	Participant    Min   10th   50th   90th   Max   95.6   100
Jan 2008 - Dec 2008 Use of IMA <sup>2</sup>	536	96.5% (94.5 , 97.9)	63.3	94.2%	Participant  Min 10th 50th 90th Max 53.2 87.8 85.2 98.9 100
Jan 2008 - Dec 2008 Discharge Anti-Platelet Medication <sup>3</sup>	536	98.7% (97.3 , 99.5)	68.7	96.1%	Participant  Min 10th 50th 90th Max 18.7 92.1 97.5 100 100
Jan 2008 - Dec 2008 Discharge Beta Blockade Therapy <sup>4</sup>	538	96.1% (94.1 , 97.6)	53.4	93.7%	Participant  Min 10th 50th 80th Max 15.1 85.3 85.7 100 100
Jan 2008 - Dec 2008 Discharge Anti-Lipid Treatment⁴	535	91.8% (89.1 , 94.0)	40.7	91.4%	Participant

Excludes v2.61 contranindicated / not indicated records.

Excludes patients with prior CABG surgery

Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

Excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

# The Society of Thoracic Surgeons 2008 Cardiac Surgery Risk Models: Part 1—Coronary Artery Bypass Grafting Surgery

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Background. The first version of The Society of Thoracic Surgeons National Adult Cardiac Surgery Database (STS NCD) was developed nearly 2 decades ago. Since its inception, the number of participants has grown dramatically, patient acuity has increased, and overall outcomes have consistently improved. To adjust for these and other changes, all STS risk models have undergone periodic revisions. This report provides a detailed description of the 2008 STS risk model for coronary artery bypass grafting surgery (CABG).

Methods. The study population consisted of 774,881 isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2002, and December 31, 2006, at 819 STS NCD participating centers. This cohort was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. The validation sample was used to assess model calibration and discrimination. Model outcomes included operative mortality, renal failure, stroke, reoperation for any cause, prolonged ventilation, deep sternal wound infection, composite major morbidity or mortality, prolonged length of stay (> 14 days), and short length of stay (< 6 days and alive). Candidate predictor variables were selected based on their availability in versions 2.35, 2.41, and 2.52.1 of the STS NCD and their presence in (or ability to be mapped to) version 2.61. Potential predictor

variables were screened for overall prevalence in the study population, missing data frequency, coding concerns, bivariate relationships with outcomes, and their presence in previous STS or other CABG risk models. Supervised backwards selection was then performed with input from an expert panel of cardiac surgeons and biostatisticians. After successfully validating the fit of the models, the development and validation samples were subsequently combined, and the final regression coefficients were estimated using the overall combined (development plus validation) sample.

Results. The c-index for the mortality model was 0.812, and the c-indices for other endpoints ranged from 0.653 for reoperation to 0.793 for renal failure in the validation sample. Plots of observed versus predicted event rates revealed acceptable calibration in the overall population and in numerous subgroups. When patients were grouped into categories of predicted risk, the absolute difference between the observed and expected event rates was less than 1.5% for each endpoint. The final model intercept and coefficients are provided.

Conclusions. New STS risk models have been developed for CABG mortality and eight other endpoints. Detailed descriptions of model development and testing are provided, together with the final algorithm. Overall model performance is excellent.

(Ann Thorac Surg 2009;88:S2-22) © 2009 by The Society of Thoracic Surgeons

In 1986, The Society of Thoracic Surgeons (STS) convened an Ad Hoc Committee on Risk Factors for Coronary Artery Bypass Graft Surgery (CABG) [1] and an

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Ad Hoc Committee to Develop a National Database for Cardiothoracic Surgery [2]. This was prompted by the

Drs Shahian, O'Brien, Filardo, Ferraris, Haan, Rich, Normand, DeLong, Shewan, Peterson, Edwards, Anderson, and Ms Dokholyan have no conflicts of interest to declare regarding this work.

#### Abbreviations and Acronyms

BSA = body surface area

CABG = coronary artery bypass graft surgery

CHF = congestive heart failure

EF = ejection fraction

GFR = glomerular filtration rate

HCFA = Health Care Financing Administration

IABP = intra-aortic balloon pump NYHA = New York Heart Association NCD = National Adult Cardiac Surgery Database

O/E = observed to expected ratio

QMTF = Quality Measurement Task Force STS = The Society of Thoracic Surgeons

release earlier that year of inadequately risk-adjusted hospital mortality data by the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid Services. Although the HCFA analytical methodology was widely criticized, STS leadership recognized that the underlying principle of collecting and analyzing data to improve patient outcomes was valid, particularly for complex and costly procedures such as coronary artery bypass grafting surgery (CABG). They believed that it was the responsibility of professional organizations to develop credible clinical data registries for their own specialties, and that risk models derived from such registries would circumvent many of the concerns resulting from the use of unadjusted administrative data. Such clinical registries would be used as credible data sources for quality assessment and improvement activities as well as for research.

These early activities ultimately led to the development of the STS National Adult Cardiac Surgery Database (NCD) [3, 4]. Since its release to members in 1990, the STS NCD has evolved to become one of the largest specialty-specific clinical data registries in the world. It currently has more than 950 participants enrolled, representing just under 90% of the cardiac surgery providers in the United States, with data on more than 3.6 million procedures. Similar STS data registries have now been developed for congenital heart surgery and general thoracic surgery, and future plans include the development of specialty modules (eg, quality metrics, atrial fibrillation surgery, thoracic aortic surgery). Recent enhancements, including the addition of unique physician and patient identifiers, will facilitate linkages with other registries and greatly expand the potential of the STS NCD for longitudinal follow-up, comparative effectiveness, and cost efficiency studies.

In addition to the development of the STS NCD as a comprehensive, nationally representative data registry, the second major goal of the STS was to assure that analyses derived from this registry would be appropriately adjusted for preoperative patient severity, a major deficiency of the HCFA reports that were initially published in 1986. This was accomplished by first identifying

risk factors for specific procedures and outcomes, beginning with isolated CABG, then using these predictor variables to develop risk models. With statistical risk models, which are most often based on logistic regression, the expected outcome for a patient with a given set of risk factors can be determined, and that can be compared with the observed outcome. The observed (O) and expected (E) outcomes are summed over all patients of a particular surgeon or hospital to yield the risk-standardized mortality ratio (O/E), which can then be multiplied by the average rate in the reference population to calculate risk-standardized mortality rates [5–7].

STS CABG risk models have undergone periodic updates and revisions, the most recent of which was based upon 2000 to 2002 STS NCD data. In 2007, the STS Database Modernization Task Force completed a major specification upgrade of the STS NCD data collection instrument from version 2.52.1 to version 2.61. This included refinement, modification, consolidation, or elimination of some data elements, as well as an attempt to harmonize definitions with those of the American College of Cardiology National Cardiovascular Data Registry whenever possible. Given these changes, as well as the number of years since the last risk model update, the STS Quality Measurement Task Force (QMTF) was asked to develop new risk models for isolated CABG, isolated valve repair or replacement, and combined CABG plus valve procedures. The authors of this report include the QMTF members who participated in this initiative.

Implementation of these new models in January 2008 coincided with the release of STS NCD version 2.61. This report, Part 1 of 3, describes the development of the new mortality and morbidity models for isolated CABG surgery.

## **Study Purpose**

The primary goal of this study was to develop risk-prediction algorithms for patients undergoing isolated CABG surgery. As the major intended use of these algorithms was to compare participant outcomes to the overall STS national experience, risk factors were generally restricted to patient and clinical characteristics present preoperatively.

#### Risk Model Development and Transparency

The availability of user-friendly statistical software programs and the exponential increase in computing speed have greatly facilitated statistical analyses such as logistic regression, the basis for many risk models. However, despite these technological advances, clinical judgment, experience, intuition, and practicality still play a critical role in risk model development. There are many points in model development at which legitimate differences in approach may lead to substantial differences in the resulting statistical models and the inferences derived from them [8].

We believe the degree of transparency provided in this report regarding the development of the STS CABG risk models is essential in today's health care environment. In an era when society demands full transparency regarding health care performance, the methodologies used to evaluate that performance should be just as transparent [9, 10]. This fundamental principle is among the standards established by the American Heart Association and American College of Cardiology for statistical models used for public reporting [11].

#### Study Population and Endpoints

All isolated CABG procedures performed on adult patients aged 20 to 100 years between January 1, 2000, and December 31, 2006, were initially considered for inclusion, although the final development and validation samples were derived from 2002 to 2006 data. Patients missing data on sex (n = 195) were excluded, as these patients are not included in STS performance feedback reports to database participants. That left a study population of 774,881 surgical procedures from 819 database participants. Patients on dialysis preoperatively (n = 12,415) were excluded when developing the risk model for postoperative renal failure.

#### Training and Validation Samples

The study population was randomly divided into a 60% training (development) sample and a 40% test (validation) sample. The development sample was used to identify predictor variables and estimate model coefficients. Data from the validation sample were used to assess model fit, discrimination, and calibration. After choosing variables and assessing model fit, the development and validation samples were subsequently combined, and the final model coefficients were estimated using the combined (development plus validation) data.

#### **Endpoints**

Risk models were developed for the nine endpoints listed below. Only mortality was recorded beyond the index hospitalization. Morbidity data included only in-hospital complications, although beginning in STS NCD version 2.61, sternal infections will be recorded for up to 30 days postoperatively. The nine endpoints are as follows: (1) operative mortality: death during the same hospitalization as surgery, regardless of timing, or within 30 days of surgery regardless of venue; (2) permanent stroke (cerebrovascular accident): a central neurologic deficit persisting longer than 72 hours; (3) renal failure: a new requirement for dialysis or an increase of the serum creatinine to more than 2.0 mg/dL and double the most recent preoperative creatinine level; (4) prolonged ventilation (longer than 24 hours); (5) deep sternal wound infection; (6) reoperation for any reason; (7) major morbidity or mortality: a composite defined as the occurrence of any of the above endpoints; (8) prolonged postoperative length of stay (PLOS): length of stay (LOS) more than 14 days (alive or dead); and (9) short postoperative LOS (SLOS): LOS less than 6 days and patient alive at discharge (this SLOS definition differs from the previous STS risk models, which did not exclude patients who died in-hospital; patients who died within 5 days of surgery are

included in the new models but are treated as not having a short stay).

Table 1 summarizes the frequencies of these endpoints in the study population for each predictor variable category (ie, the bivariate relationships).

#### Selection of Candidate Predictor Variables

Initial Data Screening of Candidate Predictor Variables

We began by considering all possible candidate variables from the development set (Table 2). Because the primary goal of the STS risk models is to adjust surgical outcomes, in general only preoperative patient variables are included. However, because these models are also used for other purposes such as individual patient prediction and counseling, there were a few modifications (which are discussed in the relevant sections) in the application of this general principle.

As there were a large number of procedures and endpoints available, we were not statistically constrained to highly parsimonious models, nor is such an approach generally favored in regression modeling [12–14]. Discarding valid data elements can waste valuable information that has been collected at substantial effort and cost. Furthermore, although much of the discrimination of a predictive model may be contained in a relatively small number of variables [15, 16], some predictor variables that add only modestly to discrimination may still be important predictors of outcomes at the patient level [17, 18].

# Expert Panel Review for Clinical Relevance and Face Validity

All candidate variables available in version 2.61 were individually discussed by a panel of cardiac surgeons and health policy experts to assure that clinical relevance as well as multiple aspects of validity (face, construct, and content) had been considered.

#### Data Version for Model Development

Although these new risk models were to be introduced in conjunction with the release of STS NCD version 2.61, they were developed with data collected under the three previous data versions (2.35, 2.41, and 2.52.1) because no 2.61 data were yet available. The QMTF began its predictor selection process with two caveats. First, any candidate variable had to be collected consistently across the three previous data versions. Second, it had to also be available in version 2.61 or have the ability to be mapped to this new version. For example, history of smoking and renal failure were not candidate variables as they were either not included in, or were unable to be mapped to, version 2.61. Renal function is now assessed by the last preoperative serum creatinine value, which is collected in all data versions. Because the definition of hypercholesterolemia has changed substantially over successive STS data versions, and because counterintuitive results have been observed in some previous analyses of hyper-

Table 1. Distribution of Risk Factors and Frequency of Adverse Outcomes in Overall Study Population, Isolated Coronary Artery Bypass Graft Surgery (2002–2006)

	Numl Pati				Perce	nt of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Overall											
Total	774,881	100.0	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Age, years											
< 55	137,318	17.72	1.0	0.5	1.7	7.1	0.3	3.7	10.0	2.7	67.1
55–64	221,697	28.61	1.3	0.9	2.4	7.8	0.4	4.2	11.4	3.8	59.4
65–74	245,132	31.63	2.4	1.6	3.9	10.0	0.5	5.5	14.9	5.9	47.7
≥ 75	170,734	22.03	4.7	2.3	6.4	13.9	0.5	7.5	20.9	9.6	33.0
Sex											
Male	560,006	72.27	2.0	1.2	3.4	8.7	0.4	5.1	13.4	4.9	55.0
Female	214,875	27.73	3.4	1.9	4.1	12.2	0.5	5.6	17.0	7.2	41.5
Race											
Caucasian	665,941	85.94	2.3	1.3	3.5	9.3	0.4	5.1	13.9	5.3	52.2
Black	44,405	5.73	2.7	2.0	5.2	13.5	0.7	6.3	19.0	8.2	41.3
Hispanic	25,103	3.24	2.6	1.5	4.3	11.3	0.5	5.6	16.1	6.1	48.4
Asian	12,509	1.61	2.7	1.9	3.8	12.6	0.3	7.2	17.4	7.0	45.2
Other	21,222	2.74	2.3	1.3	3.6	10.4	0.5	5.5	14.8	6.0	48.7
Missing	5,701	0.74	2.3	1.4	4.1	9.4	0.4	5.2	14.5	6.1	48.9
Body surface area (m <sup>2</sup> )	-,						**-				
< 1.50	14,339	1.85	6.2	2.4	4.6	16.2	0.3	8.3	22.1	9.8	36.5
1.50–1.74	111,458	14.38	3.8	2.0	4.0	12.6	0.3	6.5	17.7	7.4	42.5
1.75–1.99	280,677	36.22	2.4	1.5	3.5	9.6	0.4	5.4	14.4	5.6	50.7
≥ 2.00	363,817	46.95	1.7	1.0	3.6	8.6	0.5	4.6	13.1	4.8	55.0
Missing	4,590	0.59	3.7	1.4	4.0	7.6	0.3	4.7	13.9	6.8	46.0
Body mass index (kg/m²)	4,070	0.07	0.7	1.1	1.0	7.0	0.5	1.7	10.7	0.0	10.0
< 25	169,091	21.82	3.3	1.7	3.5	11.0	0.3	6.7	16.3	6.7	47.6
25–29	303,371	39.15	2.1	1.3	3.1	8.6	0.3	4.9	13.1	4.8	54.2
30–34	186,148	24.02	1.8	1.2	3.6	9.0	0.5	4.5	13.4	5.0	53.1
≥ 35	110,213	14.22	2.3	1.2	5.2	12.0	0.8	4.9	16.8	6.8	45.7
Missing	6,058	0.78	3.7	1.4	4.2	8.6	0.3	4.8	14.5	6.7	47.2
Diabetes mellitus	0,030	0.70	0.7	1.1	1.4	0.0	0.5	1.0	14.5	0.7	17.2
No diabetes	492,800	63.60	2.1	1.2	2.8	8.8	0.3	5.0	13.0	4.7	54.8
Diabetes–noninsulin	195,421	25.22	2.3	1.6	4.3	10.1	0.5	5.2	15.2	6.0	48.2
Diabetes-insulin	84,406	10.89	3.6	1.8	7.1	13.9	1.0	6.5	20.6	9.7	37.5
Diabetes-missing treatment	1,439	0.19	3.1	2.2	4.6	11.1	0.7	4.6	15.7	8.8	41.9
Missing	815	0.13	3.8	0.7	2.6	8.8	0.5	4.5	12.3	6.9	43.7
Hypertension	013	0.11	3.0	0.7	2.0	0.0	0.5	4.5	12.5	0.9	43.7
No	167,260	21.59	1.9	0.9	2.2	8.1	0.3	4.6	11.7	4.2	58.2
Yes	606,813	78.31	2.5	1.5	4.0	10.1	0.5	5.4	15.1	5.9	49.3
Missing	808	0.10	3.8	0.7	2.4	9.3	0.5	5.2	12.7	6.7	43.9
Hypercholesterolemia	808	0.10	3.0	0.7	2.4	9.3	0.5	3.2	12.7	0.7	43.9
No	199,894	25.80	3.0	1.6	3.9	11.0	0.5	5.8	16.1	6.5	48.7
Yes	573,257	73.98	2.1	1.3	3.5	9.2	0.3	5.0	13.8	5.2	52.1
Missing	1,730	0.22	4.1	1.6	3.5	10.3	0.4	4.7	13.9	7.3	47.5
9	1,730	0.22	4.1	1.0	3.3	10.5	0.3	4.7	13.9	7.3	47.3
Past or present smoker No	295,999	38.20	2.4	1.4	3.7	9.0	0.4	E 1	13.9	E 2	50.1
			2.4	1.4			0.4	5.1		5.3	
Yes	477,911	61.68	2.3	1.3	3.6	10.1	0.5	5.3	14.7	5.7	51.9
Missing	971	0.13	3.4	0.7	3.1	9.9	0.4	5.3	13.5	9.1	41.0
Chronic lung disease	(10.011	70.01	2.0	1.0	2.2	0.4	0.2	4.0	12.0	4 7	F2 F
None	612,211	79.01	2.0	1.3	3.3	8.4	0.3	4.9	13.0	4.7	53.7
Mild	85,005	10.97	2.8	1.5	4.2	12.0	0.6	5.8	16.9	7.0	45.7
Moderate	47,745	6.16	3.8	1.6	5.3	15.8	0.8	6.8	20.8	9.6	39.5
Severe	22,302	2.88	7.0	2.0	7.7	22.8	1.1	9.5	29.0	15.3	29.2
Missing	7,618	0.98	2.6	1.4	3.2	8.2	0.2	3.9	12.6	5.7	53.4

Table 1. Continued

	Numb Patie		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Peripheral vascular disease											
No	653,260	84.30	2.0	1.2	3.2	8.8	0.4	4.8	13.1	4.8	53.5
Yes	120,480	15.55	4.4	2.3	6.1	14.4	0.7	7.5	21.2	9.6	38.7
Missing	1,141	0.15	3.9	1.1	3.1	11.8	0.3	5.5	14.4	7.4	43.9
Cerebrovascular disease											
No	668,073	86.22	2.1	1.1	3.3	9.0	0.4	4.9	13.4	5.0	53.4
Yes	105,792	13.65	4.0	2.9	5.8	14.0	0.6	7.2	20.7	9.3	37.7
Missing	1,016	0.13	3.2	0.6	2.4	8.9	0.3	4.2	11.4	6.8	43.2
CVA											
No CVA	717,721	92.62	2.2	1.2	3.4	9.3	0.4	5.1	13.8	5.2	52.5
Remote CVA (> 2 weeks)	53,341	6.88	4.2	3.1	6.1	15.3	0.7	7.4	22.0	10.3	35.5
Recent CVA ( $\leq$ 2 weeks)	1,763	0.23	5.0	4.9	6.5	18.8	0.9	8.7	25.4	13.0	32.5
CVA-missing timing	745	0.10	3.8	3.5	6.9	14.0	0.5	5.9	21.7	10.7	34.2
Missing	1,311	0.17	3.3	1.0	2.6	7.4	0.2	4.3	11.4	5.9	47.8
Endocarditis											
No endocarditis	773,002	99.76	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Treated endocarditis	472	0.06	4.4	0.8	5.3	15.3	0.6	8.5	19.9	8.9	33.7
Active endocarditis	110	0.01	2.7	1.8	6.3	20.0	1.8	11.8	24.5	20.0	41.8
Endocarditis-missing type	90	0.01	4.4	4.4	5.8	11.1	1.1	3.3	15.6	2.2	55.6
Missing	1,207	0.16	4.1	1.0	3.5	9.0	0.2	4.6	12.8	7.0	46.2
Renal failure											
No	731,626	94.42	2.1	1.3	3.2	9.0	0.4	5.0	13.4	5.0	52.8
Yes	42,153	5.44	7.2	2.7	14.7	22.5	1.0	9.9	31.9	15.8	23.4
Missing	1,102	0.14	3.1	0.8	2.8	7.4	0.3	3.4	10.8	6.4	46.6
Renal function											
Creatinine < 1.00 mg/dL	274,197	35.39	1.6	1.1	1.5	8.0	0.3	4.4	11.2	4.0	55.6
Creatinine 1-1.49 mg/dL	398,833	51.47	2.0	1.3	3.4	8.9	0.4	5.0	13.5	4.9	53.1
Creatinine 1.5-1.99 mg/dL	57,779	7.46	4.5	2.3	10.8	16.1	0.7	7.8	25.2	10.6	34.5
Creatinine 2.0-2.49 mg/dL	12,463	1.61	6.9	2.9	14.3	21.3	0.9	9.4	31.5	15.3	24.7
Creatinine $\geq 2.5 \text{ mg/dL}$	7,906	1.02	8.2	3.2	20.4	23.4	0.9	11.1	37.9	18.6	20.4
Dialysis	12,415	1.60	8.4	2.7	*NA	25.3	1.2	10.5	31.5	16.4	19.6
Missing	11,288	1.46	3.3	1.2	3.1	7.6	0.3	4.3	12.9	5.9	50.1
Immunosuppressive treatment											
No	758,368	97.87	2.3	1.4	3.6	9.6	0.4	5.2	14.2	5.4	51.5
Yes	14,976	1.93	5.4	1.8	6.3	15.6	0.8	8.7	22.5	10.8	37.0
Missing	1,537	0.20	3.3	0.8	2.8	6.5	0.4	4.6	11.4	6.1	46.8
Prior CABG Surgery											
No	735,033	94.86	2.2	1.4	3.5	9.4	0.4	5.1	14.1	5.4	51.7
Yes	36,693	4.74	5.3	1.6	5.8	14.7	0.5	7.5	20.9	7.8	42.6
Missing	3,155	0.41	2.7	1.1	3.3	8.9	0.5	4.8	12.9	6.8	48.9
Prior valve surgery											
No	769,434	99.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.3
Yes	2,280	0.29	5.9	1.9	6.8	15.3	0.7	8.6	22.5	11.1	32.0
Missing	3,167	0.41	2.9	1.2	3.5	8.6	0.5	4.4	12.7	6.3	50.0
Prior other cardiac surgery											
No	755,653	97.52	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.3
Yes	15,218	1.96	3.9	1.5	4.9	13.1	0.6	6.6	18.6	7.6	45.5
Missing	4,010	0.52	2.8	1.0	2.9	8.5	0.4	4.4	12.2	5.9	50.5
Number of previous CV surgeries											
No previous CV surgery	723,623	93.39	2.2	1.4	3.5	9.4	0.4	5.1	14.0	5.4	51.7
One prior CV surgery	40,474	5.22	4.7	1.6	5.4	13.8	0.5	7.3	19.9	7.7	44.1
Two or more prior CV Surgeries	4,840	0.62	6.2	1.4	5.6	14.7	0.6	8.0	22.0	8.4	41.5
Missing	5,944	0.77	2.9	1.1	3.2	9.8	0.6	5.5	14.3	6.1	51.2

Table 1. Continued

	Numb Patie				Percer	t of Pat	ients Exp	eriencin	g Endpoint		
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Prior PCI											
No PCI	606,824	78.31	2.3	1.4	3.6	9.5	0.4	5.1	14.2	5.6	51.1
$PCI \le 6 \text{ hours}$	7,373	0.95	8.9	2.1	7.4	25.8	0.6	10.5	32.6	11.3	35.5
PCI > 6 hours	155,161	20.02	2.3	1.2	3.5	9.6	0.4	5.4	14.3	5.1	52.4
PCI-missing timing	2,456	0.32	3.0	0.6	3.3	8.0	0.8	5.1	13.4	6.8	48.9
Missing	3,067	0.40	3.3	1.0	3.0	9.8	0.5	4.7	13.7	6.2	47.3
Acuity status											
Elective	381,116	49.18	1.5	1.1	2.9	6.6	0.4	4.3	11.1	4.1	55.6
Urgent	356,287	45.98	2.4	1.5	3.9	10.8	0.5	5.6	15.7	6.2	48.5
Emergent	34,513	4.45	8.1	2.6	8.3	29.6	0.7	10.4	34.1	13.3	33.2
Emergent salvage	1,967	0.25	38.6	4.9	17.4	52.7	0.7	18.4	70.0	23.5	12.6
Missing	998	0.13	3.2	1.3	3.6	9.2	0.5	4.8	13.7	6.5	43.6
MI											
No prior MI	424,599	54.80	1.5	1.1	2.8	6.9	0.3	4.5	11.3	4.1	55.4
MI > 21 days	137,522	17.75	2.1	1.3	3.5	8.9	0.5	5.2	13.9	5.4	50.4
MI 8–21 days	26,205	3.38	4.0	1.8	6.0	14.4	0.8	7.5	20.7	10.2	38.1
MI 1–7 days	148,659	19.18	3.4	1.8	4.8	14.0	0.5	6.1	18.9	7.5	45.7
MI > 6 and < 24 hours	21,044	2.72	6.0	2.4	6.7	23.6	0.5	8.1	28.1	10.4	39.1
$MI \le 6 \text{ hours}$	11,539	1.49	10.4	2.6	8.6	31.2	0.6	10.6	36.8	13.3	33.5
MI-missing timing	4,064	0.52	3.6	1.6	4.6	11.3	0.5	5.6	17.5	7.2	43.9
Missing	1,249	0.16	2.1	1.1	2.4	6.6	0.2	3.8	10.2	6.7	49.4
Angina											
No	130,143	16.80	2.5	1.4	3.8	9.5	0.4	5.6	14.7	6.2	48.5
Yes	643,815	83.09	2.3	1.3	3.6	9.7	0.4	5.2	14.3	5.4	51.8
Missing	923	0.12	2.3	1.0	2.6	8.8	0.5	4.0	11.2	8.2	43.9
Cardiogenic shock											
No	758,766	97.92	2.0	1.3	3.4	8.9	0.4	5.0	13.6	5.2	51.9
Yes	14,919	1.93	18.0	3.6	14.6	49.6	1.0	15.3	55.7	23.1	18.3
Missing	1,196	0.15	2.7	1.1	3.2	8.0	0.4	4.4	12.0	7.4	44.7
Resuscitation	,										
No	766,674	98.94	2.2	1.3	3.5	9.4	0.4	5.1	14.1	5.4	51.5
Yes	6,939	0.90	17.1	3.0	11.4	37.5	0.9	14.0	46.1	18.2	24.3
Missing	1,268	0.16	2.2	0.8	3.4	8.0	0.6	3.9	11.5	7.3	45.0
Arrhythmia	,										
No arrhythmia	706,709	91.20	2.0	1.3	3.3	8.9	0.4	4.9	13.4	5.0	53.1
AFib/flutter	39,125	5.05	5.4	2.3	7.1	16.4	0.7	8.5	23.8	11.9	29.4
Heart block	10,026	1.29	5.8	1.9	6.8	16.8	0.6	9.2	24.2	9.4	36.4
Sustained VT/VF	14,336	1.85	8.2	2.0	6.8	23.8	0.6	11.1	31.5	12.0	33.0
Arrhythmia–other	1,853	0.24	3.8	1.6	5.3	12.9	0.6	6.5	19.1	7.3	39.2
Arrhythmia–missing type	1,344	0.17	3.9	1.7	4.4	11.9	0.7	7.3	17.5	8.3	37.9
Missing	1,488	0.19	2.7	1.0	3.0	7.1	0.5	3.8	11.1	6.5	45.5
Preoperative IABP	1,100	0.13	,	110	0.0	,,,	0.0	0.0	1111	0.0	10.0
No	714,824	92.25	2.0	1.3	3.3	8.0	0.4	4.9	12.8	4.9	52.8
Yes	58,134	7.50	6.9	2.2	7.7	30.8	0.6	9.6	34.4	12.9	32.0
Missing	1,923	0.25	4.2	1.7	4.3	10.9	0.6	5.8	16.0	7.2	45.7
NYHA class	1,720	0.20	1.2	1.7	1.0	10.7	0.0	3.0	10.0	7.2	10.7
I	97,812	12.62	1.5	1.1	2.5	6.3	0.3	4.4	10.6	3.9	57.0
II	187,947	24.25	1.3	1.1	2.6	6.5	0.3	4.2	10.7	3.8	56.5
III	287,760	37.14	2.0	1.3	3.6	9.0	0.3	5.0	13.9	5.4	51.3
IV	165,325	21.34	4.5	1.9	5.5	16.6	0.4	7.1	21.9	8.8	42.5
Missing	36,037	4.65	4.5 2.4	1.9	3.6	8.9	0.6	5.3	13.6	5.8	42.5 47.7
9	30,037	4.03	4.4	1.4	3.0	0.7	0.3	5.5	13.0	5.0	4/./
Congestive heart failure	666 E00	86.02	10	1.2	2.0	7.0	0.2	47	12.2	4.2	E4 7
No Voc	666,592 106,700	86.03	1.8	1.2	2.9	7.9	0.3	4.7	12.2	4.3	54.7
Yes	106,700	13.77	5.9	2.4	8.5	21.0	0.9	8.7	28.0	13.2	29.5
Missing	1,589	0.21	3.3	1.4	3.1	9.2	0.4	4.5	13.0	7.4	49.6

Table 1. Continued

	Numb Patie				Percen	t of Pat	ients Exp	eriencin	g Endpoi	nt	
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Number of diseased coronary vessels											
None	2,012	0.26	2.3	0.4	2.8	8.9	0.4	4.6	12.6	5.5	53.1
One	32,311	4.17	1.5	0.6	1.9	6.1	0.2	4.4	9.8	3.1	66.3
Two	150,881	19.47	1.8	1.0	2.7	8.0	0.4	4.5	12.0	4.5	56.3
Three	586,658	75.71	2.5	1.5	4.0	10.4	0.4	5.5	15.3	6.0	49.1
Missing	3,019	0.39	2.6	0.6	1.8	5.5	0.2	4.5	10.8	5.9	54.2
Left main disease ≥ 50%											
No	554,355	71.54	2.1	1.3	3.4	8.8	0.4	5.0	13.5	5.1	52.7
Yes	217,548	28.08	3.0	1.5	4.3	11.9	0.5	5.9	16.8	6.6	47.6
Missing	2,978	0.38	2.3	1.4	2.7	6.3	0.3	5.5	11.9	5.9	45.4
Ejection fraction (%)	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,										
< 25	25,323	3.27	7.2	2.2	8.0	25.2	0.8	10.5	31.9	13.7	27.8
25–34	57,460	7.42	4.6	2.1	6.1	17.6	0.6	7.6	23.8	10.3	36.8
35–44	108,623	14.02	3.0	1.7	4.7	12.4	0.6	6.0	17.5	7.2	45.7
45–54	189,478	24.45	1.9	1.3	3.4	8.7	0.4	4.8	13.2	5.0	53.1
≥ 55	351,455	45.36	1.5	1.1	2.7	6.8	0.3	4.4	11.1	3.9	56.1
	42,542	5.49	3.4	1.4	4.1	10.8	0.3	5.6	16.0	6.1	50.0
Missing	42,342	3.49	3.4	1.4	4.1	10.6	0.4	3.0	10.0	0.1	30.0
Mitral stenosis	75.6.600	07.64	2.2	1.4	2.6	0.7	0.4	F 0	111		F1 0
No	756,609	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.5	51.2
Yes	2,703	0.35	5.5	2.4	6.4	17.0	0.7	7.5	22.9	10.5	35.7
Missing	15,569	2.01	2.1	1.3	3.4	8.3	0.4	4.6	13.1	5.0	53.1
Aortic stenosis											
No	750,185	96.81	2.3	1.4	3.6	9.6	0.4	5.2	14.3	5.5	51.4
Yes	11,386	1.47	4.7	2.1	6.5	14.8	0.7	7.9	21.5	9.7	36.6
Missing	13,310	1.72	2.3	1.3	3.3	8.5	0.4	4.7	13.1	5.0	52.5
Tricuspid stenosis											
No	756,574	97.64	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	597	0.08	3.4	2.3	6.6	14.9	0.7	6.0	20.9	10.1	43.6
Missing	17,710	2.29	2.1	1.3	3.6	8.5	0.4	4.7	13.4	5.0	53.2
Pulmonic stenosis											
No	753,975	97.30	2.3	1.4	3.6	9.7	0.4	5.2	14.4	5.6	51.2
Yes	445	0.06	3.4	2.2	3.9	12.6	0.0	6.3	20.2	6.3	49.4
Missing	20,461	2.64	2.2	1.4	3.8	8.7	0.4	5.0	13.9	5.3	52.5
Mitral insufficiency											
None	622,173	80.29	2.1	1.2	3.3	8.9	0.4	4.9	13.4	5.0	53.2
Trivial	49,152	6.34	2.4	1.6	4.2	10.5	0.4	5.7	15.7	6.2	47.9
Mild	60,811	7.85	3.7	2.0	5.7	14.3	0.5	6.9	20.3	8.6	40.3
Moderate	16,723	2.16	6.7	2.7	7.9	20.1	0.7	9.6	28.0	12.5	30.3
Severe	2,143	0.28	8.7	3.1	8.9	24.1	0.6	11.0	32.6	15.1	28.2
Missing	23,879	3.08	2.1	1.2	3.0	7.5	0.4	4.7	12.0	5.2	51.5
Aortic insufficiency	20,019	3.00	2.1	1.2	3.0	7.0	0.1	1.7	12.0	0.2	01.0
None	705,771	91.08	2.3	1.3	3.5	9.5	0.4	5.1	14.1	5.4	51.9
Trivial M:14	17,988	2.32	3.6	2.1	5.6	13.4	0.5	7.0	19.4	8.3	40.9
Mild	18,571	2.40	4.1	2.2	5.9	14.3	0.4	7.3	20.8	9.0	37.9
Moderate	3,576	0.46	5.3	2.6	7.0	16.2	0.5	7.9	23.2	10.2	32.8
Severe	411	0.05	7.1	1.9	6.7	15.6	0.7	9.5	25.8	10.9	37.2
Missing	28,564	3.69	2.1	1.2	3.2	7.9	0.4	4.6	12.5	5.3	51.4
Tricuspid insufficiency											
None	675,778	87.21	2.2	1.3	3.4	9.4	0.4	5.1	13.9	5.3	52.1
Trivial	32,856	4.24	2.5	1.6	4.5	11.1	0.4	6.1	16.6	6.7	47.4
Mild	29,611	3.82	3.9	2.2	5.9	14.7	0.5	7.4	21.0	9.1	39.3
Moderate	5,753	0.74	7.6	3.0	9.0	22.7	0.5	9.8	30.2	13.7	26.9
Severe	728	0.09	9.1	2.9	10.5	24.2	0.4	10.9	33.0	17.2	26.2
Missing	30,155	3.89	2.2	1.2	3.2	7.9	0.4	4.6	12.6	5.2	51.7

Table 1. Continued

	Number of Patients		Percent of Patients Experiencing Endpoint								
Variable	N	%	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Pulmonic insufficiency											
None	724,258	93.47	2.3	1.4	3.6	9.7	0.4	5.2	14.3	5.5	51.4
Trivial	10,726	1.38	2.8	1.5	4.3	12.3	0.5	6.5	17.3	7.3	44.8
Mild	4,867	0.63	3.8	2.1	5.6	14.1	0.4	7.4	21.0	9.1	39.7
Moderate	546	0.07	6.6	3.1	7.8	17.6	0.2	7.9	24.4	11.5	29.7
Severe	217	0.03	5.1	0.5	5.1	9.7	0.5	6.5	15.7	8.8	50.7
Missing	34,267	4.42	2.2	1.3	3.5	8.3	0.4	4.8	13.2	5.5	50.7

CABG = coronary artery bypass graft surgery; Comp = composite adverse outcome (any); DSWI = deep sternal wound infection; IABP = intra-aortic balloon pump; CVA = cerebrovascular accident (stroke); MI = mvocardial Mort = mortality; Na = not applicable; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; Reop = reoperation; RF = renal failure; PLOS = prolonged length of stay; SLOS = short length of stay; Vent = prolonged ventila-VT = ventricular tachycardia. VF = ventricular fibrillation;

cholesterolemia, a decision was made not to include this variable in the new models.

#### Predictor Frequency

For each variable, the QMTF explored the overall prevalence and missing data frequency per year. Predictor variables that are rarely present in the development sample are difficult to model. For this reason, mitral (0.35%), tricuspid (0.08%), and pulmonic stenosis (0.06%), pulmonic insufficiency (0.10%), and endocarditis (0.09%) were not considered as variables in the new isolated CABG models.

#### Inconsistently Coded Variables

A few variables have been collected inconsistently or with questionable reliability, often for clinically unavoidable reasons. For example, pulmonary artery mean pressure data were missing for 70% of patients during 2002 to 2006. Furthermore, the value of this continuous variable may vary substantially depending on the clinical state and volume-loading status of the patient when the measurement is obtained. Because of these concerns, pulmonary artery pressure was not included in the models.

#### Derived or Redundant Variables

Several derived variables were considered for inclusion in the models. For example, body mass index (BMI) is a useful measure of overall body habitus. However, because BMI is highly correlated with body surface area (BSA), the more commonly used anthropometric measure in most previous STS models, the latter was retained in the new models. Similarly, there is a theoretical superiority to inclusion of glomerular filtration rate (GFR) rather than serum creatinine as a measure of renal function. However, the Modification of Diet in Renal Disease formula for estimating GFR is a complex function of creatinine, race, sex, and age, and not all laboratories perform this calculation automatically. Furthermore, as age, sex, and race are already model covariates, using GFR would complicate the interpretation of their regression coefficients. Some of the prognostic value of GFR

comes from these variables that are already included in the model. Finally, previous studies suggest that various measures of renal function used in CABG mortality risk models have similar performance [19]. For all these reasons, serum creatinine was retained as the measure of renal function.

#### Controversial Variables

RACE. Several variables raised particular clinical, statistical, or health policy issues. For example, race was an obvious candidate variable because it was a significant predictor (p < 0.001) of each endpoint except mortality and because the proportion of nonwhite patients varied substantially across institutions. In exploratory analyses, the association between race and outcomes persisted after adjusting for hospital identity, suggesting that this association is not explained by differences in hospital quality.

However, general principles of risk model development complicated the decision as to whether or not to include race in the models. When the dominant purpose of a risk model is adjustment of provider results, it is advisable to include only biological and clinical patient variables that are present before a patient's first contact with the provider. In this context, race is clearly a fixed biological characteristic, but its impact on patient outcomes may be mediated through other mechanisms. It is possible that certain racial and ethnic groups have worse outcomes not because of inherent biological characteristics but because of differences in the quality of care delivered to them. In this case, including race and ethnicity in a risk model could essentially select out or obscure the very disparity issues that society wishes to identify and correct. Inclusion of race and ethnicity in a risk model would say, in effect, that we expect nonwhites to have inferior results and would make an allowance for providers who care for such patients, just as we would for providers who care for patients in cardiogenic shock.

After deliberation regarding the pros and cons, the QMTF ultimately elected to retain race and ethnicity in the new models because of their impact on outcomes,

#### Table 2. Initial List of Potential Candidate Variables

#### Demographics

- 1. Age
- 2. Sex
- 3. Race (black, Caucasian, Hispanic, Asian, Native American, other)

Note: Data collection changed in v2.61. New version allows for multiple races (check all that apply). Added Hawaiian/Pacific Islander category. Hispanic ethnicity is a separate variable.

#### Anthropometric

- 4. Height
- 5. Weight

#### Status

- 6. Status (elective, urgent, emergent, salvage)
- 7. Shock
- 8. Resuscitation

#### Cardiac variables

9. Angina, angina type (STS categories are unstable, stable, no angina)

Note: Angina was removed on v2.61 data collection form. The new form has a variable called "cardiac presentation on admission." Angina is one of possible response categories to that field.

10. New York Heart Association functional class

Note: In v2.61, NYHA class is only collected if patient has congestive heart failure.

- 11. Arrhythmia and arrhythmia type (sustained VT/VF; heart block; AFib/flutter, None)
- 12. Myocardial infarction timing: ( $\leq 6$ , > 6 and < 24 hours; 1–7, 8–21, > 21 days)

#### Hemodynamic/catheterization variables

- 13. Ejection fraction
- 14. Number of diseased vessels (0, 1, 2, 3)
- 15. Left main disease
- 16. Pulmonary artery mean pressure
- 17. Mitral stenosis
- 18. Aortic stenosis
- 19. Tricuspid stenosis
- 20. Pulmonic stenosis
- 21. Mitral insufficiency (none, trivial, mild, moderate, severe)
- 22. Aortic insufficiency (none, trivial, mild, moderate, severe)
- 23. Tricuspid insufficiency (none, trivial, mild, moderate, severe)
- 24. Pulmonic insufficiency (none, trivial, mild, moderate, severe)

#### Comorbidities

- 25. Serum creatinine
- 26. Dialysis
- 27. Renal failure

Note: This variable was removed in v2.61.

- 28. Endocarditis (active, treated, none)
- 29. Diabetes and treatment (insulin, oral, diet, untreated, no diabetes)
- 30. Chronic lung disease (none, mild, moderate, severe)
- 31. Congestive heart failure
- 32. Peripheral vascular disease
- 33. Cerebrovascular disease
- 34. CVA and CVA timing (recent, remote, none)

Note: CVA is a child field of cerebrovascular disease in v2.61.

35. Hypercholesterolemia (v2.35, v2.41) and Dyslipidemia (v2.52)

Note: Data from all 3 versions were merged and analyzed under the variable name "hypercholesterolemia."

- 36. Hypertension
- 37. Smoker

Note: Major definition change in v2.61.

#### Preoperative interventions

- 38. Preoperative intra-aortic balloon pump
- 39. Preoperative inotropes
- 40. Immunosuppressive treatment
- 41. Prior percutaneous coronary intervention and timing ( $\leq$  6 hours, > 6 hours, none)

#### **Previous Interventions**

- 42. Prior coronary artery bypass graft surgery
- 43. Prior valve surgery
- 44. Prior other cardiac surgery
- 45. Number of previous cardiovascular surgeries

while recognizing the potential limitations of this decision.

PREOPERATIVE INTRA-AORTIC BALLOON PUMP. Preoperative intra-aortic balloon pump (IABP) is a proxy for more serious preoperative status of the patient (eg, unstable angina, ventricular dysfunction). It captures information that may not be present in other data elements, and it is associated with higher risk of postoperative morbidity and mortality. For these reasons, most CABG risk models include preoperative IABP as a risk predictor. However, placement of an IABP is also a highly discretionary care process the frequency of which varies widely among participating institutions. Indications are subjective and are often dictated by the cardiologist before even referring the patient for cardiac surgery. Based on CABG risk models, an institution that liberally utilizes IABPs will have a higher expected risk of morbidity and mortality (according to the model) compared with another institution with a similar case-mix but a more restrictive IABP policy. That would impact their relative O/E ratios and risk-adjusted outcomes.

Despite its discretionary nature (and the potential for gaming), the QMTF decided to retain IABP use in the models because it is such an important predictor. Ultimately, it was elected to model preoperative IABP as a joint variable with preoperative inotrope use as an overall measure of preoperative acuity/severity.

#### Review of External Sources

The QMTF also reviewed multiple external resources to aid in the selection of potential candidate variables [15, 16, 20]. First, all previous versions of the STS CABG risk models were reviewed. The QMTF also examined other CABG risk models including the European System for Cardiac Operative Risk Evaluation (EuroSCORE) [21], the New York Cardiac Surgery Reporting System [22], the Veterans Affairs Administration cardiac surgery models [23, 24], and the Northern New England Cardiovascular Disease Study Group model [25, 26]. We particularly wanted to identify variables that were found in some form across all the risk models. Subject to the constraints of version 2.61 data specifications, we made a special effort to include such variables in the new STS risk models, in some instances requiring us to "force" them into the models, as described in the section on the final variable selection procedure.

#### Missing Data

Missing data in the STS NCD are rare, having a frequency of less than 1% for most variables. Candidate predictor variables missing most commonly were ejection fraction (5.5%), New York Heart Association (NYHA) class (4.7%), tricuspid insufficiency (3.9%), aortic insufficiency (3.7%), mitral insufficiency (3.1%), aortic stenosis (1.7%), and creatinine/dialysis (1.5%).

Missing predictor values in the STS NCD were managed using imputation. Multiple imputation is the generally preferred statistical method [27], but single imputation was also considered based on the following

practical considerations: (a) the fraction of missing data in the STS NCD was small and, hence, single and multiple imputation would likely give similar point estimates; (b) a slight adjustment to the standard errors would not impact the study conclusions or the published risk algorithms; (c) the large sample size would make multiple imputation less practical to implement because of long computational times.

Prior to selecting an imputation strategy, exploratory analyses were performed using CABG data from 2002 to 2003 to compare single versus multiple imputation results for predicting mortality. These analyses confirmed that the choice between single versus multiple imputation would have only a slight impact on regression coefficients. For example, the estimated odds ratio for a 5-unit increase in ejection fraction was 0.90 (with a 95% confidence interval extending from 0.83 to 0.97) under single imputation and was 0.92 (with a confidence interval extending from 0.85 to 0.99) under multiple imputation. Other variables were missing less frequently than ejection fraction and were even less sensitive to the choice between single versus multiple imputation. Additional analyses of missing data consisted of reestimating the final model coefficients using single versus multiple imputation and comparing results. A summary of these investigations, as well as model coefficients and covariance matrices, are available at www.sts.org/riskmodels. For most patients, if risk were calculated using the multiple imputation model instead of single imputation, the relative change in their risk estimate would only be 1% to 2% (eg, 5% to 5.1% is a 2% change).

Based on the considerations described above, single imputation was used with the following specific rules: (1) binary (yes/no) risk factors were modeled as yes versus no or missing. Missing data for such variables usually implies their absence, and for most binary variables the composite event rates were similar for "no" and "missing" categories; (2) missing data on categorical predictor variables were imputed to the lowest risk value, which, in most instances, was the mode. In most instances, composite event rates for patients with missing data were among the lowest. It is the policy of the STS Data Warehouse and Analysis Center to discourage missing data through this default coding practice; and (3) missing data on continuous predictor variables were imputed to the conditional median. For ejection fraction, we conditioned on congestive heart failure (CHF) and sex. For BSA, we conditioned on sex. For serum creatinine, we conditioned on renal failure (although this approach will be modified when the model is ultimately applied to version 2.61 data, as renal failure has been removed).

For model endpoints (eg, mortality), missing data were handled by modeling yes versus no or missing. Thus, cases with missing data for an endpoint were analyzed as if the endpoint did not occur. Complete case analysis was not used because "missing" was not considered to be consistently coded for these variables. For example, some STS data managers have reported that they set complications to "no" unless there is explicit documentation in the medical record that the complication occurred. Other

data managers may leave the field missing unless there is explicit documentation that the complication did not occur. Thus, missing data may reflect differences in coding practices rather than truly unknown or missing data.

# Preliminary Analyses for Ordinal Categorical Variables and Continuous Variables

The QMTF conducted preliminary analyses to determine how best to model ordinal categorical variables and continuous variables. Categorical variables were entered into a logistic regression model by including a separate parameter for each category. Continuous variables were entered as piecewise linear functions (splines) with several changes of slope (knots). Terms were then removed one at a time using backward selection based on the Wald statistic. At each iteration, either two adjacent categories were collapsed into a single category or else two adjacent line segments were collapsed into a single line with no change of slope. The backward selection terminated when all adjacent categories and slopes were statistically different from one another at p < 0.001. This variable selection routine was performed separately for each endpoint. An expert panel determined the final coding based on the results of the backwards selection algorithm, supplemented by their clinical judgment and practical considerations. Table 3 summarizes these coding decisions.

#### **Specific Coding Decisions**

RACE AND ETHNICITY. In versions 2.35, 2.41, and 2.52.1, race was collected by choosing one of the following mutually exclusive response categories: Caucasian, black, Hispanic, Asian, Native American, and other. In version 2.61, the data collection form was modified to conform to standards adopted by the US Census Bureau. It allows for selecting one or more races per patient (ie, select all that apply), and treats ethnicity (Hispanic versus non-Hispanic) as a separate variable. Because of these differences, the mapping of race among data versions is not straightforward.

Ultimately, the QMTF decided to model race as black, Asian, Hispanic, and Caucasian/other (collapsed). Initially, these categories will be mapped to version 2.61 as follows: (1) black will include all black patients, regardless of ethnicity or additional races; (2) Hispanic will include all nonblack Hispanic patients; (3) Asian will include all Asian patients who are not also identified as black or Hispanic; and (4) all remaining patients will be placed in the Caucasian/other category. The validity of this mapping will be assessed once 2.61 data become available and future versions could employ race "bridging" methodologies.

BODY SURFACE AREA. Height and weight were replaced by BSA, which was modeled as a quadratic trend to allow for a possible U-shaped relationship with outcomes (eg, extreme obesity and cachexia). This quadratic polynomial was modeled separately for males and females. Any BSA values below 1.4 or above 2.6 were mapped to these

values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

ANGINA. Version 2.61 of the data collection form eliminates angina and substitutes a new variable called "cardiac presentation on admission," within which unstable angina is one of the possible response categories. The QMTF believed that unstable angina would be coded more consistently than any other angina class, and also that this was the most important type of angina presentation to include in the models. Angina coding was therefore restricted in the new risk models to "unstable angina without MI < 7 days (yes/no)." It was necessary to exclude patients with myocardial infarction less than 7 days because the new version 2.61 does not permit simultaneous coding of angina and acute myocardial infarction.

REOPERATIVE STATUS. The most important consideration with regard to reoperative status is the number of prior sternotomies, irrespective of the specific type of procedure performed. The revised models replaced prior CABG, prior valve, and prior "other" cardiac surgery with simply the number of previous cardiovascular surgeries.

ACUITY STATUS. The new models combine resuscitation with salvage status. By definition, all salvage patients should have resuscitation coded "yes."

NUMBER OF DISEASED CORONARY VESSELS. Outcomes are modeled using the number of diseased vessels (grouped as 0 or 1 versus 2 versus 3), as a linear effect across the three categories. This approach is consistent with the previous STS CABG models and was supported by the data.

NYHA CLASS. Version 2.61 uses NYHA class as a subfield of CHF. The grouping of NYHA IV versus less than IV (I–III) classes is consistent with all existing STS models. The final categories were no CHF, CHF not NYHA IV, and CHF plus NYHA IV.

AGE. Age was modeled as a linear spline with knots at ages 50 and 60 years.

EJECTION FRACTION. Ejection fraction (EF) was modeled linearly, and EFs below 10% and above 50% were mapped to these values respectively. Only 0.03% of patients have EFs lower than 10%; such values are considered invalid and are treated like missing data. The coding decision regarding EF values above 50% was based on preliminary analyses in which the data were used to suggest the functional form of continuous variables.

CREATININE. Creatinine was modeled as a linear spline with knots at 1.0 and 1.5. Creatinine levels less than 0.5 or greater than 5.0 were mapped to these values respectively, which represent the approximate 1st and 99th percentiles of the empirical distribution.

MORTALITY AND LENGTH OF STAY. The QMTF changed the previous STS definition of the "short postoperative length of stay (SLOS)" endpoint. The original definition did not specifically exclude early postoperative deaths, and such patients could have been inappropriately included with the remaining SLOS patients who had a particularly short and uncomplicated postoperative course. In the new models, patients who die within 5 days of surgery are included in the analysis but are not counted as a short stay.

Table 3. Final List of Candidate Variables and Coding For STS Risk Models

Candidate Variables	Coding
Continuous variables	
Age <sup>a</sup>	Linear spline with knots at 50 and 60.
Ejection fraction <sup>a</sup>	Linear; values $>$ 50 are mapped to 50. Only 0.03% of patients have ejection fraction $<$ 10, and that is presumed to be a data entry error these values are considered invalid and are treated like missing data. The decision to consolidate values $>$ 50 was based on initial exploratory analyses in which data were used to suggest the functional form of continuous variables.
Body surface area <sup>a</sup>	Quadratic polynomial modeled separately for males and females. Note: body surface areas $< 1.4$ and $> 2.6$ were mapped to these values, respectively. <sup>c</sup>
Creatinine <sup>a</sup>	Linear spline with knots at 1.0 and 1.5. (Only for patients not on dialysis.) Note: Creatinine values < 0.5 and > 5.0 were mapped to these values, respectively. <sup>d</sup>
Time trend <sup>a</sup>	Ordinal categorical variable with separate category for each 6-month harvest interval.
Binary variables	
Dialysis <sup>a</sup>	Yes/no
Preoperative atrial fibrillation <sup>b</sup>	Yes/no
Shock	Yes/no
Female <sup>a</sup>	Yes/no
Hypertension	Yes/no
Immunosuppressive treatment	Yes/no
Percutaneous coronary intervention $\leq$ 6 hours	Yes/no
Preoperative intra-aortic balloon pump or inotropes	Yes/no
Peripheral vascular disease	Yes/no
Unstable angina (no myocardial infarction < 7 days)	Yes/no
Left main disease	Yes/no
Aortic stenosis	Yes/no
Aortic insufficiency	Defined as at least moderate (yes/no)
Mitral insufficiency	Defined as at least moderate (yes/no)
Tricuspid insufficiency	Defined as at least moderate (yes/no)
Categorical variables	· ·
Chronic lung disease	4 groups: (1) none, (2) mild, (3) moderate, (4) severe
CVD/CVA	3 groups: (1) no CVD, (2) CVD no CVA, (3) CVD + CVA
Diabetes mellitus	3 groups: (1) insulin diabetes, (2) noninsulin diabetes, (3) other or no diabetes
Number diseased coronary vessels	3 groups: (1) fewer than 2 diseased vessels, (2) 2 disease vessels, (3) 3 diseased vessels; modeled as linear across the categories.
Myocardial infarction	4 groups: (1) $\leq$ 6 hours, (2) $>$ 6 and $<$ 24 hours, (3) 1 to 21 days, (4) $>$ 21 days or no myocardial infarction.
Race	4 groups: (1) black, (2) Asian, (3) Hispanic, (4) other, including Caucasian
Status	4 groups: (1) elective, (2) urgent, (3) emergent, no resuscitation, (4) salvage or emergent with resuscitation
Previous cardiovascular operations	3 groups: 0 previous, 1 previous, 2 or more previous
CHF and NYHA class	3 groups: no CHF, CHF not NYHA IV, CHF + NYHA IV
Interactions	
Age by reoperation <sup>a</sup>	
Age by emergent status <sup>a</sup>	

<sup>&</sup>lt;sup>a</sup> These variables were forced into each model. <sup>b</sup> Preoperative atrial fibrillation was forced into the model for stroke. <sup>c</sup> These are the approximate 1st and 99th percentiles of the empirical distribution. Values less than 1.4 were mapped to 1.4. Values greater than 2.6 were mapped to 2.6. Estimates in the extreme tails of the body surface area distribution are highly influenced by data from other regions of the body surface area distribution (owing to use of a parametric, quadratic model) and may not be reliable. <sup>d</sup> These are approximately the 1st and 99th percentiles of the empirical distribution. Although we used a flexible spline model, linear splines can have unreliable extreme results in the tails due to the assumption that the effect is linear above the largest knot and below the smallest knot.

Table 4. Discrimination of Models (C-Index)

New STS	models—devel	opment sample	(C-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.810	0.716	0.795	0.756	0.706	0.657	0.724	0.769	0.727
New STS	models—valida	ntion sample (C	-index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.812	0.720	0.793	0.754	0.689	0.653	0.725	0.767	0.726
Old STS r	nodels—validat	tion sample (C-	index)					
Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
0.807	0.713	0.750	0.742	0.672	0.645	0.711	0.754	0.713
		outcom a (amy).	CVAt1	DCMI — 1		stion. Most – se	t-lit DI OC	

 $\begin{array}{lll} Comp = composite \ adverse \ outcome \ (any); & CVA = stroke; \\ length \ of \ stay; & Reop = reoperation; & RF = renal \ failure; \\ prolonged \ ventilation. & \end{array}$ 

 $\begin{aligned} DSWI &= \text{deep sternal wound infection;} &\quad Mort &= \text{mortality;} &\quad PLOS &= \text{prolonged} \\ SLOS &= \text{short length of stay;} &\quad STS &= \text{The Society of Thoracic Surgeons;} &\quad Vent &= \end{aligned}$ 

#### Final Variable Selection Procedure

#### Backward Selection

Using the remaining candidate variables and the coding schemes described previously, a supervised backward selection approach was then performed. Initial variable selection used the Wald  $\chi^2$  statistic with a significance criterion of 0.001. This high level of significance was chosen because of the very large sample size that resulted in quite small p values. An expert panel of cardiothoracic surgeons and biostatisticians then reviewed the selected variables and made several modifications. Measures of model performance (discrimination and calibration) were similar when all variables were retained in the models regardless of statistical significance or expert panel review.

#### Forced Variables

Several variables were included in the models regardless of statistical significance. These included all of the continuous variables (age, BSA, date of surgery [in 6-month intervals], creatinine, ejection fraction), plus sex and dialysis. In addition, atrial fibrillation was included a priori in the model for permanent stroke.

The rationale for including surgery date, a nonmodifiable variable of no intrinsic interest, was to adjust for changes in the frequency of adverse outcomes over the 5-year study period. We adjusted for surgery date to reduce potential confounding by time trends when estimating regression coefficients for variables that are of primary interest, such as preoperative clinical characteristics. For example, temporal changes in the frequency of coding for dyslipidemia, if they occur coincidentally with a secular declining trend in mortality rates, may lead to the unwarranted causal inferences unless there is adjustment for surgery date.

Date of surgery was categorized by 6-month intervals (corresponding to STS data harvests) and modeled as a linear trend across the ordinal categories. Surgery date is not included in the final risk algorithm and a patient's predicted risk is not dependent upon it. The intercept

parameter published in the Appendix has been adjusted to incorporate the time trend, and it reflects the baseline risk for a reference period of July to December 2006.

#### Interaction Terms

These models focused on main effects, and the final models included only four sets of preselected variable interactions: (1) sex by BSA; (2) sex by BSA squared; (3) age by reoperation; (4) age by emergent status. More extensive investigation for interactions was considered, including nonlinear, machine-learning approaches. However, the incremental value of such approaches remains uncertain [28], and interpretability can also become more problematic with numerous interaction terms.

Although multiple terms were allotted for modeling the main effects of age and reoperation, only a single degree of freedom was allotted for their interaction. The models defined a single variable interaction term for age and reoperation. It was equal to the patient's age minus 50 if the patient was at least 50 years old and had a previous CV surgery; otherwise it was equal to zero. This term represents the difference in the change of the slope of age at age 50 for patients who have had at least one previous CV surgery compared with patients who have not had a previous CV surgery. Similarly, only one degree of freedom was allotted for the interaction between age and status. The interaction represents the difference in the change of the slope of age at age 50 for patients with emergent or salvage status compared with patients with elective or urgent status. Although these interaction terms complicate the interpretation of other model variables, this was considered to be acceptable because the main focus of the analysis was prediction, not effect estimation.

#### Results

#### Model Performance

Table 4 presents the discrimination of each of the isolated CABG models as well as a comparison with the previous

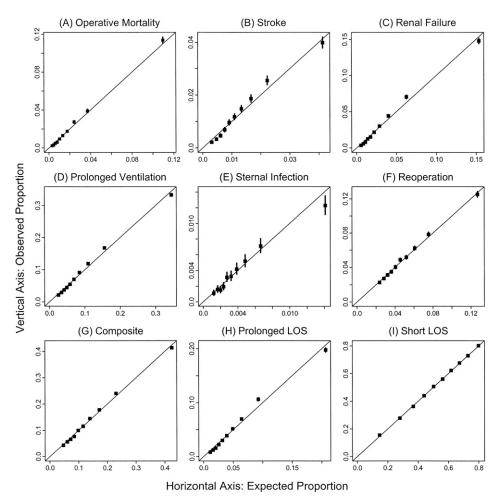


Fig 1. Plots of observed (O) versus expected (E) in validation sample

STS CABG risk models. For the new CABG models, discrimination ranged from 0.657 to 0.810 in the development sample and from 0.653 to 0.812 in the validation sample. The close agreement between c-indices from the development and validation samples reflects the large sample size and suggests that the models did not overfit the data. When the discrimination of the new and previous STS models were compared using the validation sample, the c-index of the new model was larger for each endpoint.

The Hosmer-Lemeshow test is not reported as an overall measure of calibration for these models because of its sensitivity to sample size. With samples as large as those used to develop these models, the null hypothesis will inevitably be proven false, given that all such models are only approximations [29]. As an alternative to such global measures of calibration, Figure 1 shows plots of observed versus expected event proportions within deciles of predicted risk for a variety of endpoints. For each endpoint, the absolute difference between the observed and expected proportions was less than 1.5% in each decile category. Additional analyses of model fit and discrimination are available online at www.sts.org/riskmodels.

#### Final Models

After calculating these measures of model performance, the final regression coefficients were estimated from the combined training and validation samples. Odds ratios for each predictor variable and model endpoint are summarized in Table 5. "Not applicable" indicates that the specific predictor was not included in a particular risk model. These final models were estimated using generalized estimating equations with empirical (sandwich) standard error estimates to account for clustering of patients within institutions [30]. An independence working correlation matrix was used to apply the generalized estimating equations method. With this approach, the estimated regression coefficients were identical to those obtained using ordinary logistic regression, but the standard errors were adjusted to account for correlated observations within hospitals.

#### Final Model Intercept and Coefficients

The Appendix contains the algorithm, intercept and coefficients for the final STS 2008 CABG risk models. The variance/covariance matrix is available on the web at www.sts.org/riskmodels. An on-line risk calculator is available at http://209.220.160.181/STSWebRiskCalc261/.

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Table 5. Estimated Odds Ratios for CABG Mortality, Morbidity, and Length of Stay Models

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50 (no reoperation, elective)	1.36 (1.24, 1.49)	1.78 (1.58, 1.99)	1.24 (1.16, 1.33)	1.06 (1.02, 1.10)	1.43 (1.23, 1.67)	1.14 (1.09, 1.19)	1.08 (1.05, 1.11)	1.35 (1.27, 1.43)	0.77 (0.75, 0.78)
Age 70 versus 50 (no reoperation, elective)	2.53 (2.31, 2.76)	2.43 (2.19, 2.71)	1.93 (1.81, 2.07)	1.42 (1.37, 1.47)	1.70 (1.47, 1.97)	1.45 (1.39, 1.51)	1.49 (1.44, 1.53)	2.17 (2.05, 2.29)	0.44 (0.43, 0.45)
Age 80 versus 50 (no reoperation, elective)	4.70 (4.29, 5.15)	3.34 (2.99, 3.72)	3.01 (2.80, 3.24)	1.90 (1.82, 1.99)	2.02 (1.73, 2.36)	1.85 (1.76, 1.94)	2.05 (1.98, 2.12)	3.48 (3.28, 3.69)	0.25 (0.24, 0.26)
BSA 1.6 versus 2.0 among females	1.26 (1.19, 1.32)	1.15 (1.08, 1.23)	0.84 (0.80, 0.89)	1.03 (1.00, 1.06)	0.49 (0.43, 0.57)	1.23 (1.18, 1.28)	1.03 (1.01, 1.06)	0.94 (0.90, 0.97)	1.17 (1.14, 1.20)
BSA 1.6 versus 2.0 among males	1.75 (1.64, 1.86)	1.19 (1.08, 1.31)	1.24 (1.17, 1.32)	1.40 (1.34, 1.46)	0.77 (0.63, 0.93)	1.40 (1.33, 1.46)	1.35 (1.30, 1.40)	1.43 (1.36, 1.50)	0.79 (0.77, 0.82)
BSA 1.8 versus 2.0 among females	1.02 (0.99, 1.05)	1.07 (1.03, 1.11)	0.86 (0.84, 0.88)	0.95 (0.94, 0.97)	0.67 (0.63, 0.71)	1.06 (1.04, 1.08)	0.96 (0.94, 0.97)	0.90 (0.88, 0.92)	1.14 (1.13, 1.16)
BSA 1.8 versus 2.0 among males	1.20 (1.17, 1.23)	1.09 (1.05, 1.13)	1.02 (1.00, 1.04)	1.09 (1.07, 1.10)	0.85 (0.79, 0.91)	1.13 (1.11, 1.15)	1.08 (1.07, 1.09)	1.10 (1.08, 1.12)	0.96 (0.95, 0.97)
BSA 2.2 versus 2.0 among females	1.20 (1.14, 1.27)	0.95 (0.88, 1.02)	1.32 (1.27, 1.37)	1.18 (1.15, 1.22)	1.62 (1.51, 1.74)	1.03 (1.00, 1.07)	1.19 (1.16, 1.21)	1.28 (1.24, 1.32)	0.78 (0.77, 0.80)
BSA 2.2 versus 2.0 among males	1.01 (0.99, 1.03)	0.92 (0.90, 0.95)	1.17 (1.15, 1.19)	1.10 (1.08, 1.11)	1.27 (1.22, 1.32)	0.97 (0.96, 0.99)	1.07 (1.06, 1.08)	1.08 (1.07, 1.10)	0.90 (0.89, 0.91)
Creatinine 1.5 versus 1.0	1.66 (1.57, 1.76)	1.39 (1.30, 1.49)	3.36 (3.16, 3.58)	1.56 (1.51, 1.62)	1.44 (1.28, 1.62)	1.33 (1.28, 1.38)	1.76 (1.70, 1.82)	1.65 (1.59, 1.72)	0.69 (0.67, 0.71)
Creatinine 2.0 versus 1.0	1.94 (1.84, 2.04)	1.49 (1.39, 1.58)	4.06 (3.83, 4.31)	1.73 (1.68, 1.79)	1.47 (1.30, 1.65)	1.44 (1.40, 1.49)	2.05 (1.98, 2.11)	1.92 (1.86, 2.00)	0.55 (0.53, 0.57)
Creatinine 2.5 versus 1.0	2.26 (2.14, 2.39)	1.59 (1.47, 1.71)	4.90 (4.61, 5.21)	1.92 (1.85, 1.99)	1.50 (1.30, 1.72)	1.57 (1.51, 1.64)	2.39 (2.30, 2.48)	2.24 (2.15, 2.34)	0.44 (0.42, 0.46)
Dialysis versus no dialysis and creatinine = 1.0	3.84 (3.54, 4.16)	1.67 (1.48, 1.88)	NA	2.85 (2.68, 3.03)	2.13 (1.78, 2.56)	1.86 (1.73, 2.00)	2.46 (2.33, 2.60)	2.80 (2.63, 2.98)	0.27 (0.25, 0.29)
EF per 10-unit decrease	1.19 (1.17, 1.22)	1.14 (1.11, 1.16)	1.08 (1.06, 1.10)	1.18 (1.16, 1.20)	1.11 (1.07, 1.16)	1.11 (1.09, 1.13)	1.16 (1.15, 1.18)	1.17 (1.15, 1.19)	0.84 (0.83, 0.85)
Preoperative atrial fibrillation	1.36 (1.28, 1.44)	1.21 (1.12, 1.30)	1.24 (1.18, 1.30)	1.20 (1.16, 1.24)	NA	1.26 (1.21, 1.31)	1.24 (1.21, 1.28)	1.42 (1.37, 1.48)	0.61 (0.59, 0.63)
CHF not NYHA IV	1.21 (1.15, 1.28)	NA	1.36 (1.30, 1.43)	1.31 (1.26, 1.35)	1.33 (1.19, 1.48)	1.16 (1.11, 1.21)	1.27 (1.23, 1.31)	1.43 (1.38, 1.48)	0.72 (0.70, 0.75)
CHF NYHA IV	1.39 (1.31, 1.47)	NA	1.35 (1.28, 1.42)	1.52 (1.45, 1.59)	1.45 (1.25, 1.67)	1.26 (1.20, 1.32)	1.48 (1.42, 1.54)	1.50 (1.44, 1.57)	0.65 (0.61, 0.68)
Chronic lung disease, mild	1.22 (1.16, 1.29)	NA	1.14 (1.08, 1.21)	1.36 (1.31, 1.41)	1.56 (1.40, 1.73)	1.11 (1.07, 1.15)	1.23 (1.19, 1.27)	1.34 (1.29, 1.39)	0.79 (0.76, 0.82)
Chronic lung disease, moderate	1.40 (1.32, 1.49)	NA	1.25 (1.18, 1.33)	1.65 (1.57, 1.73)	1.80 (1.58, 2.06)	1.20 (1.14, 1.26)	1.42 (1.36, 1.47)	1.65 (1.58, 1.73)	0.68 (0.65, 0.71)
Chronic lung disease, severe	2.35 (2.19, 2.52)	NA	1.66 (1.54, 1.79)	2.37 (2.24, 2.51)	2.40 (2.06, 2.79)	1.54 (1.44, 1.64)	1.98 (1.90, 2.07)	2.46 (2.34, 2.60)	0.48 (0.45, 0.51)
CVD with CVA	1.31 (1.24, 1.38)	2.09 (1.96, 2.22)	1.18 (1.12, 1.23)	1.35 (1.31, 1.39)	NA	1.21 (1.17, 1.26)	1.32 (1.29, 1.36)	1.45 (1.40, 1.51)	0.70 (0.68, 0.72)

Table 5. Continued

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
CVD without CVA	1.14 (1.08, 1.20)	1.65 (1.54, 1.75)	1.11 (1.06, 1.17)	1.15 (1.11, 1.18)	NA	1.12 (1.08, 1.17)	1.17 (1.14, 1.20)	1.14 (1.10, 1.18)	0.85 (0.81, 0.89)
Diabetes, insulin dependent	1.30 (1.24, 1.37)	1.19 (1.12, 1.27)	1.80 (1.72, 1.87)	1.22 (1.18, 1.26)	2.24 (2.02, 2.48)	1.14 (1.10, 1.18)	1.30 (1.27, 1.34)	1.59 (1.53, 1.64)	0.64 (0.62, 0.66)
Diabetes, noninsulin dependent	1.01 (0.97, 1.06)	1.16 (1.11, 1.22)	1.32 (1.28, 1.36)	1.04 (1.02, 1.07)	1.38 (1.27, 1.49)	0.98 (0.96, 1.01)	1.08 (1.06, 1.10)	1.15 (1.12, 1.17)	0.87 (0.86, 0.88)
Diseased vessels (2 versus 1, or 3 versus 2)	1.17 (1.12, 1.23)	1.35 (1.29, 1.42)	1.23 (1.19, 1.27)	1.19 (1.16, 1.22)	1.15 (1.07, 1.24)	1.07 (1.05, 1.10)	1.16 (1.14, 1.18)	1.15 (1.11, 1.18)	0.81 (0.80, 0.82)
Preoperative IABP/ inotropes	1.41 (1.33, 1.49)	NA	1.43 (1.36, 1.51)	2.56 (2.42, 2.72)	NA	1.37 (1.31, 1.43)	1.96 (1.86, 2.06)	1.60 (1.53, 1.67)	0.60 (0.57, 0.63)
Shock	2.29 (2.12, 2.47)	1.38 (1.23, 1.55)	1.65 (1.54, 1.77)	2.08 (1.96, 2.21)	NA	1.43 (1.34, 1.52)	2.10 (1.99, 2.23)	1.73 (1.62, 1.84)	0.58 (0.54, 0.62)
Female versus male (at BSA = 1.8)	1.31 (1.25, 1.36)	1.32 (1.24, 1.39)	1.25 (1.21, 1.31)	1.33 (1.29, 1.36)	1.19 (1.06, 1.35)	0.90 (0.87, 0.93)	1.18 (1.15, 1.21)	1.24 (1.20, 1.28)	0.65 (0.63, 0.66)
Hypertension	NA	1.29 (1.22, 1.37)	1.25 (1.20, 1.30)	1.10 (1.08, 1.13)	NA	NA	1.12 (1.10, 1.15)	1.07 (1.04, 1.11)	0.92 (0.90, 0.94)
Immunosuppressive treatment	1.48 (1.37, 1.60)	NA	1.21 (1.12, 1.31)	1.11 (1.05, 1.18)	NA	1.32 (1.24, 1.41)	1.20 (1.14, 1.26)	1.28 (1.20, 1.37)	0.80 (0.76, 0.84)
Aortic insufficiency, moderate/severe	NA	0.82 (0.75, 0.89)							
Mitral insufficiency, moderate/severe	1.31 (1.21, 1.41)	NA	NA	1.12 (1.06, 1.18)	NA	1.24 (1.16, 1.32)	1.20 (1.15, 1.26)	1.15 (1.09, 1.22)	0.85 (0.80, 0.91)
Tricuspid insufficiency, moderate/severe	NA	NA	1.31 (1.17, 1.45)	1.28 (1.18, 1.39)	NA	NA	1.24 (1.16, 1.33)	NA	0.78 (0.71, 0.87)
$PCI \le 6 \text{ hours}$	1.37 (1.24, 1.50)	NA	1.29 (1.16, 1.43)	1.21 (1.13, 1.29)	NA	1.30 (1.19, 1.42)	1.31 (1.23, 1.39)	1.17 (1.07, 1.27)	0.79 (0.74, 0.84)
Peripheral vascular disease	1.42 (1.36, 1.48)	1.32 (1.26, 1.39)	1.21 (1.17, 1.26)	1.22 (1.19, 1.26)	1.36 (1.24, 1.48)	1.24 (1.20, 1.28)	1.25 (1.22, 1.28)	1.31 (1.28, 1.35)	0.82 (0.81, 0.84)
Aortic stenosis	NA	NA	NA	1.18 (1.11, 1.26)	NA	NA	1.16 (1.10, 1.22)	1.15 (1.07, 1.23)	0.87 (0.82, 0.92)
Left main disease	NA	NA	NA	1.07 (1.04, 1.09)	NA	NA	1.04 (1.02, 1.06)	NA	NA
MI 1–21 days	1.37 (1.32, 1.44)	1.31 (1.25, 1.37)	1.27 (1.22, 1.32)	1.34 (1.29, 1.38)	NA	NA	1.23 (1.20, 1.25)	1.22 (1.18, 1.25)	0.88 (0.86, 0.90)
MI > 6 and < 24 hours	1.59 (1.46, 1.74)	1.59 (1.43, 1.76)	1.48 (1.36, 1.60)	1.59 (1.49, 1.68)	NA	NA	1.43 (1.37, 1.50)	1.31 (1.24, 1.39)	0.80 (0.76, 0.84)
$MI \leq 6 \text{ hours}$	1.70 (1.53, 1.89)	1.49 (1.31, 1.68)	1.43 (1.29, 1.57)	1.56 (1.45, 1.67)	NA	NA	1.44 (1.35, 1.53)	1.30 (1.21, 1.40)	0.82 (0.77, 0.87)
Time trend, per 6- month harvest interval	0.97 (0.97, 0.98)	0.97 (0.96, 0.98)	1.01 (1.00, 1.02)	1.01 (1.01, 1.02)	0.97 (0.95, 0.99)	0.99 (0.99, 1.00)	1.00 (1.00, 1.01)	1.00 (0.99, 1.01)	0.99 (0.98, 1.00)
Race Asian	NA	1.33 (1.14, 1.55)	1.08 (0.96, 1.22)	1.33 (1.21, 1.47)	1.00 (0.66, 1.51)	1.31 (1.17, 1.46)	1.23 (1.15, 1.31)	1.26 (1.13, 1.40)	0.70 (0.61, 0.81)
Race black	NA	1.41 (1.30, 1.54)	1.24 (1.16, 1.33)	1.37 (1.27, 1.48)	1.30 (1.13, 1.51)	1.21 (1.14, 1.30)	1.31 (1.24, 1.38)	1.43 (1.34, 1.51)	0.69 (0.65, 0.73)
Race Hispanic	NA	1.12 (0.98, 1.27)	1.24 (1.11, 1.39)	1.16 (1.07, 1.26)	1.30 (1.07, 1.58)	1.05 (0.97, 1.13)	1.12 (1.05, 1.19)	1.09 (0.99, 1.20)	0.85 (0.77, 0.94)

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SCTS
Reoperation, 1 previous operation <sup>a</sup>	3.13 (2.74, 3.57)	NA	1.52 (1.35, 1.71)	.52 (1.35, 1.71) 1.72 (1.58, 1.86)	NA	1.57 (1.43, 1.74)	1.57 (1.43, 1.74) 1.61 (1.50, 1.72) 1.62 (1.47, 1.80) 0.72 (0.67, 0.78)	1.62 (1.47, 1.80)	0.72 (0.67, 0.78)
Reoperation, $\geq 2$ previous operations <sup>a</sup>	4.19 (3.45, 5.09)	NA	1.58 (1.33, 1.87)	.58 (1.33, 1.87) 1.86 (1.62, 2.14)	NA	1.71 (1.44, 2.03)	1.71 (1.44, 2.03) 1.84 (1.65, 2.05)	1.79 (1.53, 2.08)	0.64 (0.56, 0.73)
Status urgent <sup>a</sup>	1.16 (1.10, 1.22)	1.11 (1.06, 1.17)	1.12 (1.05, 1.19)	1.24 (1.18, 1.31)	1.20 (1.10, 1.32)	1.18 (1.13, 1.23)	1.18 (1.14, 1.22)	1.20 (1.15, 1.25)	0.86 (0.83, 0.90)
Status emergent, no resuscitation <sup>a</sup>	2.83 (2.52, 3.18)	2.12 (1.82, 2.48)	1.68 (1.49, 1.89)	2.14 (1.96, 2.34)	1.87 (1.46, 2.40)	1.83 (1.68, 1.99)	1.77 (1.64, 1.91)	2.12 (1.93, 2.32)	0.62 (0.58, 0.67)
Status emergent with resuscitation or salvage <sup>a</sup>	8.00 (6.91, 9.26)	8.00 (6.91, 9.26) 2.51 (1.98, 3.18)	2.16 (1.82, 2.55)	3.01 (2.68, 3.38)	2.09 (1.45, 3.01)	2.34 (2.06, 2.65) 3.65 (3.26, 4.09)	3.65 (3.26, 4.09)	2.39 (2.10, 2.72) 0.34 (0.30, 0.38)	0.34 (0.30, 0.38)
Unstable angina	1.12 (1.07, 1.17)	NA	1.11 (1.05, 1.17)	.11 (1.05, 1.17) 1.05 (1.01, 1.10)	NA	NA	NA	NA	NA

<sup>a</sup> Variable interacts with age. Reported odds ratio represents effect of risk factor for patients aged 50 years old.

CVD = cerebrovascular disease; = renal failure; NA = not applicable; = cerebrovascular accident, or stroke; Mort = mortality; = peripheral vascular disease; Comp = composite adverse outcome (any); .BP = intra-aortic balloon pump; MI = r = intra-aortic balloon pump; N PLOS = prolonged length of stay; BSA = body surface area; CH = deep sternal wound infection; Heart Association; short length of stay; Previously, the STS risk models were completely upgraded every 3 years, with annual recalibration in the interim to assure that the benchmark O/E ratio is always 1. In the near future, annual upgrades of the models are planned.

#### Limitations

Regardless of sample size or degree of statistical sophistication, all risk models are imperfect representations of reality. Although the STS risk models are based upon excellent clinical data and large sample sizes, there are some risk factors that are rare in the overall population but, when present, may be important predictors of outcome for specific patients. Some such variables, such as liver disease, are not included in the risk models, and the mortality risk for patients with these risk factors may be underestimated. Addition of a number of such variables will be considered at the next major specification upgrade.

There are other variables whose specifications undergo small but important changes over time, often in response to comments from STS database participants. These refinements are discussed on regular biweekly conference calls open to database participants, and suggested changes are regularly communicated to participants through a variety of means including FAQ's. With each major specification upgrade, they are incorporated into the new software specifications.

Audit is extremely important to assure the accuracy of any data registry. For the STS database and the risk models derived from it, robust audit is particularly critical as this registry is increasingly used for public reporting of outcomes and pay for performance. Studies suggest that the accuracy of the STS database is high for most important variables [31-35], although these audits are currently restricted to a limited number of sites annually because of budgetary constraints. In these audits, one of the most problematic variables has been 30-day mortality status (as opposed to in-hospital mortality). This is often a difficult endpoint to ascertain and may require more substantial investment of time and effort by participants, particularly for patients referred from outside their own institutions. Analysis of STS data suggests that approximately 90% of 30-day deaths occur in-hospital. Thus, if some patients recorded as being alive at 30 days have actually had their status ascertained only during the index hospitalization, the impact of this misclassification on the risk models should be negligible. This hypothesis was confirmed by comparing the odds ratios of all model variables for in-hospital versus 30-day mortality. Differences between the two were quite small, and these data are available on the web at www. sts.org/riskmodels. A new risk model for in-hospital mortality has been developed and placed on the same STS website. Furthermore, an aggressive program is in place to further enhance the accuracy of 30-day follow-up. In 2009, STS instituted a requirement that participants maintain documentation of the method by which they ascertained 30-day status, and that has become part of our routine audit. Linkage of the STS database with external death registries, such as the Social Security Death Master File, will

further support this capability. Finally, plans are being developed to expand the audit of certain key variables such as 30-day mortality to a significantly greater number of sites annually.

#### **Conclusions**

Risk-adjustment models account for the effect of patient comorbidities on outcomes. STS risk models are based upon clinical data from the STS NCD, one of the oldest and largest of all specialty registries. The value of such clinical registries is particularly evident in today's health care environment, where accreditation, regulatory compliance, reimbursement, and referrals are increasingly based upon objective data. Organizations such as the AQA and the National Quality Forum that evaluate and endorse performance measures strongly advocate the use of risk-adjusted outcomes measures.

STS believes that clinical data are superior to those derived from administrative sources. Furthermore, given the substantial implications of risk-adjusted outcomes, we believe that all risk models used for profiling quality of care should be transparent to permit comprehensive peer review and to foster credibility among stakeholders.

We present a detailed exposition of the development and validation of the 2008 STS CABG risk model. This describes not only the statistical considerations but, just as importantly, the many clinical and pragmatic judgments that are always necessary in risk model development.

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#### **Appendix**

Regression Coefficients and Variable Definitions for STS 2008 CABG Models

For each endpoint, the formula for calculating a patient's predicted risk of the endpoint has the form:

Predicted Risk = 
$$\frac{e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}{1+e^{(\beta_0+\beta_1x_1+\beta_2x_2+\cdots+\beta_nx_n)}}$$

where  $x_1, x_2, \ldots, x_n$  denote patient preoperative risk factors (eg, quantitative variables such as age, and comorbidities coded as 1 = present, 0 = absent), and  $\beta_0, \beta_1, \ldots, \beta_n$  denote regression coefficients (numerical constants). Regression coefficients for each endpoint are presented in Appendix Table 1. The variables  $x_1, x_2, \ldots, x_n$  are the same for each endpoint and are defined in Appendix Table 2. The regression coefficient for the time trend is not presented. Instead, the intercept has been adjusted to incorporate the time trend. This adjusted intercept reflects the baseline risk for a reference period of July to December 2006.

Appendix Table 1. Regression Coefficients

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Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Intercept	-6.34090	-7.18174	-7.94605	-4.15175	-6.75378	-3.84861	-3.71671	-5.35975	2.84959
Atrial fibrillation	0.30830	0.18935	0.21351	0.17871	0.00000	0.23031	0.21565	0.35322	-0.49309
Age	-0.00259	0.00996	0.00678	0.00170	-0.00665	-0.00013	0.00247	0.00914	-0.01781
Age function 1	0.03325	0.04742	0.01496	0.00393	0.04270	0.01305	0.00515	0.02085	-0.00895
Age function 2	0.03140	-0.02582	0.02249	0.02366	-0.01895	0.01133	0.02441	0.01734	-0.02904
Age by reoperation function	-0.01714	-0.00098	-0.00291	-0.00459	0.00304	-0.00720	-0.00444	-0.00809	0.00449
Age by status function	-0.01366	-0.01363	-0.00022	-0.00106	-0.00352	-0.00435	0.00270	-0.00833	-0.00266
BSA function 1	-1.39342	-0.44041	-0.53672	-0.83950	0.65513	-0.83758	-0.75006	-0.89037	0.57952
BSA function 2	2.41303	0.06122	2.19879	2.15647	0.90025	1.16543	1.81770	2.15270	-1.83776
CHF but not NYHA IV	0.19229	0.00000	0.30971	0.26853	0.28272	0.14692	0.23695	0.35623	-0.32350
CHF and NYHA IV	0.32663	0.00000	0.30013	0.41599	0.36909	0.22846	0.39005	0.40757	-0.43827
Chronic lung disease mild	0.20273	0.00000	0.13488	0.30473	0.44371	0.10432	0.20878	0.29051	-0.23600
Chronic lung disease moderate	0.33843	0.00000	0.22530	0.50235	0.59021	0.18071	0.34720	0.50246	-0.39085
Chronic lung disease severe	0.85513	0.00000	0.50645	0.86175	0.87366	0.43034	0.68538	0.90211	-0.73862
Creatinine function 1	0.19353	0.02822	1.91934	-0.02712	-0.37465	0.01583	0.13361	-0.09060	0.00773
Creatinine function 2	0.82140	0.63174	0.50685	0.92120	1.09976	0.55107	0.99190	1.09571	-0.75781
Creatinine function 3	-0.70646	-0.52856	-2.04970	-0.68907	-0.68466	-0.39956	-0.81791	-0.70069	0.30449
CVD without prior CVA	0.13177	0.49807	0.10637	0.13792	0.00000	0.11403	0.15561	0.13271	-0.16385
CVD and prior CVA	0.26877	0.73600	0.16135	0.29946	0.00000	0.19208	0.28099	0.37248	-0.35706
Diabetes noninsulin dependent	0.01375	0.14992	0.27443	0.04283	0.31888	-0.01929	0.07453	0.13541	-0.13813
Diabetes insulin dependent	0.26312	0.14332	0.58581	0.19735	0.80627	0.12930	0.26525	0.46226	-0.44725
Dialysis	1.53777	0.54158	0.00000	1.01943	0.38312	0.63691	1.03466	0.93792	-1.30294
Ejection fraction function	0.01765	0.01274	0.00754	0.01669	0.01081	0.03091	0.01496	0.93792	-0.01756
Female	0.26801	0.01274	0.00754	0.28338	0.01081	-0.10270	0.01436	0.01342	-0.01750 $-0.43658$
Female by BSA function 1	0.82285	0.08974	0.96428	0.76954	1.11546	0.31901	0.66663	1.05623	-0.96846
Female by BSA function 2	0.05606	0.06490	-0.61086	-0.62558	0.17399	-0.02390	-0.25077	-0.35160	0.46088
Hypertension	0.00000	0.25718	0.22126	0.09930	0.00000	0.00000	0.11674	0.07200	-0.08155
IABP or inotropes	0.34193	0.00000	0.36023	0.94050	0.00000	0.31326	0.67253	0.47092	-0.51444
Immunosuppressive treatment	0.39159	0.00000	0.18881	0.10686	0.00000	0.27802	0.18030	0.24833	-0.22718
Insufficiency, aortic	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.19889
Insufficiency, mitral	0.26631	0.00000	0.00000	0.11169	0.00000	0.21170	0.18225	0.14174	-0.15962
Insufficiency, tricuspid	0.00000	0.00000	0.26729	0.24834	0.00000	0.00000	0.21893	0.00000	-0.24548
Left main disease	0.00000	0.00000	0.00000	0.06629	0.00000	0.00000	0.03570	0.00000	0.00000
MI 1 to 21 days	0.31810	0.27134	0.23962	0.28925	0.00000	0.00000	0.20524	0.19517	-0.12752
MI > 6 and < 24 hours	0.46614	0.46063	0.38917	0.46158	0.00000	0.00000	0.35859	0.27109	-0.22557
$MI \le 6 \text{ hours}$	0.53242	0.39601	0.35421	0.44230	0.00000	0.00000	0.36337	0.26311	-0.19946
No. diseased vessel function	0.16120	0.30339	0.20729	0.17622	0.13869	0.06895	0.15075	0.13589	-0.21043
PCI ≤ 6 hours	0.31149	0.00000	0.25189	0.18695	0.00000	0.26256	0.26774	0.15633	-0.23860
Peripheral vascular disease	0.34951	0.27985	0.19308	0.20240	0.30529	0.21306	0.22277	0.27380	-0.19321
Race black	0.00000	0.34423	0.21696	0.31563	0.26572	0.19456	0.26634	0.35426	-0.37515
Race Hispanic	0.00000	0.11002	0.21645	0.14802	0.26330	0.04798	0.11289	0.08968	-0.16091
Race Asian	0.00000	0.28567	0.07579	0.28561	-0.00145	0.26855	0.20484	0.23064	-0.35049
Reop, 1 previous operation	1.13997	0.00000	0.41962	0.53987	0.00000	0.45372	0.47614	0.48534	-0.32375
Reop, $\geq$ 2 previous operations	1.43250	0.00000	0.45592	0.62211	0.00000	0.53695	0.61014	0.57945	-0.44745
Shock	0.82667	0.32434	0.50003	0.73290	0.00000	0.35800	0.74320	0.54575	-0.54475
Status urgent	0.14608	0.10671	0.11226	0.21738	0.18496	0.16500	0.16492	0.18202	-0.14608
Status emergent	1.04010	0.75216	0.51857	0.76090	0.62665	0.60549	0.56983	0.75083	-0.47745
Status salvage	2.07934	0.91950	0.76808	1.10085	0.73651	0.84873	1.29422	0.87072	-1.08265
Stenosis aortic	0.00000	0.00000	0.00000	0.16529	0.00000	0.00000	0.14706	0.13988	-0.14173
Unstable angina	0.11217	0.00000	0.10287	0.05060	0.00000	0.00000	0.00000	0.00000	0.00000

 $BSA = body \ surface \ area; \ CHF = congestive \ heart \ failure; \ Comp = composite \ adverse \ event \ (any); \ CVA = cerebrovascular \ accident \ (stroke); \ CVD = cerebrovascular \ disease; \ DSWI = deep \ sternal \ wound \ infection; \ IABP = intra-aortic \ balloon \ pump; \ MI = myocardial \ infarction; \ Mort = mortality; \ NYHA = New \ York \ Heart \ Association; \ PCI = percutaneous \ coronary \ intervention; \ PLOS = prolonged \ length \ of \ stay; \ Reop = reoperation; \ RF = renal \ failure; \ SLOS = short \ length \ of \ stay; \ Vent = prolonged \ ventilation.$ 

#### Appendix Table 2. Definition of Variables Appearing in STS 2008 CABG Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preoperative atrial fibrillation, = 0 otherwise
Age	= Patient age in years
Age function 1	$= \max(age-50, 0)$
Age function 2	$= \max(age-60, 0)$
Age by reop function	= Age function 1 if surgery is a reoperation, = 0 otherwise
Age by status function	= Age function 1 if status is emergent or salvage, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	$= (BSA \text{ function } 1)^2$
CHF but not NYHA IV	= 1 if patient has CHF and is not NYHA class IV, = 0 otherwise
CHF and NYHA IV	= 1 if patient has CHF and is NYHA class IV, = 0 otherwise
CLD mild	= 1 if patient has mild chronic lung disease, = 0 otherwise
CLD moderate	= 1 if patient has moderate chronic lung disease, = 0 otherwise
CLD severe	= 1 if patient has severe chronic lung disease, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
Creatinine function 2	= max ([creatinine function 1] – 1.0, 0)
Creatinine function 3	= max ([creatinine function 1] – 1.5, 0)
CVD without prior CVA	= 1 if patient has history of CVD and no prior CVA, = 0 otherwise
CVD and prior CVA	= 1 if patient has history of CVD and a prior CVA, = 0 otherwise
Diabetes, noninsulin	= 1 if patient has diabetes not treated with insulin, = 0 otherwise
Diabetes, insulin	= 1 if patient has diabetes treated with insulin, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Ejection fraction function	= max (50 – ejection fraction, 0)
Female	= 1 if patient is female, = 0 otherwise
Female by BSA function 1	= BSA function 1 if female, = 0 otherwise
Female by BSA function 2	= BSA function 2 if female, = 0 otherwise
Hypertension	= 1 if patient has hypertension, = 0 otherwise
IABP or inotropes	= 1 if patient requires IABP or inotropes preoperatively, = 0 otherwise
<del>-</del>	
Immunosuppressive treatment	= 1 if patient given immunosuppressive therapy within 30 days, = 0 otherwise
Insufficiency, aortic	= 1 if patient has at least moderate aortic insufficiency, = 0 otherwise
Insufficiency, mitral Insufficiency, tricuspid	= 1 if patient has at least moderate mitral insufficiency, = 0 otherwise
, I	= 1 if patient has at least moderate tricuspid insufficiency, = 0 otherwise
Left main disease	= 1 if patient has left main disease, = 0 otherwise
MI 1 to 21 days	= 1 if history of MI 1 to 21 days prior to surgery, = 0 otherwise
MI > 6 and < 24 hours	= 1 if history of MI > 6 and <24 hours prior to surgery, = 0 otherwise
$MI \le 6 \text{ hours}$	= 1 if history of MI $\leq$ 6 hours prior to surgery, = 0 otherwise
No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 0 otherwise
$PCI \leq 6 \text{ hours}$	= 1 if patient had $PCI \le 6$ hours prior to surgery, = 0 otherwise
Peripheral vascular disease	= 1 if patient has peripheral vascular disease, = 0 otherwise
Race black	= 1 if patient is black, = 0 otherwise
Race Hispanic	= 1 if patient is nonblack Hispanic, = 0 otherwise
Race Asian	= 1 if patient is nonblack, non-Hispanic, and is Asian, = 0 otherwise
Reop, 1 previous operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, ≥ 2 previous operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Status urgent	= 1 if status is urgent, = 0 otherwise
Status emergent	= 1 if status is emergent (but not resuscitation), = 0 otherwise
Status salvage	= 1 if status is salvage (or emergent plus resuscitation), = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwis

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident, or stroke; CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.

# NATIONAL QUALITY FORUM

# Measure Evaluation 4.1 December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the <u>evaluation criteria</u> are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

**TAP/Workgroup** (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

**Steering Committee:** Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

#### Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)

P = Partially (demonstrated to partially meet the criterion)

M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)

N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)

NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 0134	NQF Project: Surgery Endorsement Maintenance 2010
MEA	SURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Use of Internal Mamm	ary Artery (IMA) in Coronary Artery Bypass Graft (CABG)
De.2 Brief description of measure: Perce artery bypass graft (CABG) who received ar	ntage of patients aged 18 years and older undergoing isolated coronary in internal mammary artery (IMA) graft
1.1-2 Type of Measure: Process De.3 If included in a composite or paired OT1-013-09 - The STS CABG Composite Score	with another measure, please identify composite or paired measure re
De.4 National Priority Partners Priority And De.5 IOM Quality Domain: Safety De.6 Consumer Care Need: Getting bette	•

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	NQF Staff
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.  A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes  A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):  A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission  A.4 Measure Steward Agreement attached: STS Measure Steward Agreement. Fully Executed-634267369788886638.pdf	A Y N

<b>B.</b> The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section	B Y N
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement.  ▶ Purpose: Public reporting, Internal quality improvement	C Y□ N□
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.  D.1Testing: Yes, fully developed and tested  D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?  Yes	D Y N
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y□ N□
Staff Notes to Reviewers (issues or questions regarding any criteria):	
Staff Reviewer Name(s):	
TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
3	
1. IMPORTANCE TO MEASURE AND REPORT	
	Eval Rating
1. IMPORTANCE TO MEASURE AND REPORT  Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)	
1. IMPORTANCE TO MEASURE AND REPORT  Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact	
1. IMPORTANCE TO MEASURE AND REPORT  Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance.  Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)  1a. High Impact  (for NQF staff use) Specific NPP goal:  1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, Leading cause of morbidity/mortality, High resource use, Severity of illness, Patient/societal consequences of poor quality  1a.2  1a.3 Summary of Evidence of High Impact: The internal mammary artery has definitively and repeatedly been shown to be the best conduit for coronary bypass grafting. It has been shown to have the highest patency rates compared to other conduits and its use substantially increases patient survival in the long	

and other adverse outcomes associated with coronary artery bypass surgery. Circulation. 2001;103(4):507-	
512 Morris RJ, Strong MD, et al. Internal thoracic artery for coronary artery grafting in octogenarians.	
Ann Thorac Surg. 1996;62:16-22.  Loop FD, Lytle BW, Cosgrove DM, et al. Influence of the internal-mammary-artery graft on 10-year	
survival and other cardiac events. N Engl J Med. 1986 Jan 2;314(1):1-6.	
- Lytle BW, Blackstone EH, Loop FD, et a. Two internal thoracic artery grafts are better than one. J Thorac Cardiovasc Surg. 1999 May;117(5):855-72.	
1b. Opportunity for Improvement	
1b.1 Benefits (improvements in quality) envisioned by use of this measure: Use of the internal mammary artery as coronary bypass conduit has definitively and repeatedly been shown to substantially increase patient survival in the long term. Using this measure should encourage, and potentially increase, the use of the internal mammary arteries as coronary bypass conduits.	
1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: Please see attachment	
1b.3 Citations for data on performance gap: Dates: January 1, 2009-December 31, 2009	
Analysis includes 615 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months.	
1b.4 Summary of Data on disparities by population group:	1b
1b.5 Citations for data on Disparities:	C   P   M   N
1c. Outcome or Evidence to Support Measure Focus	
1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): The internal mammary artery has the highest patency rates of the coronary bypass conduit conduits and its use is associated with the greatest freedom from mortality benefit when compared to other conduit choices. Patients with internal mammary arteries as bypass conduit tend to live longer and have fewer cardiac events than patients with alternate conduits.	
<b>1c.2-3. Type of Evidence:</b> Observational study, Randomized controlled trial, Expert opinion, Systematic synthesis of research, Other Clinical results from approximately 90% of cardiac surgery centers in the US	
1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):  The superiority of internal mammary arteries over saphenous vein grafts as coronary artery bypass conduits has been known for at least 25 years. The overwhelming evidence came initially both from retrospective reviews and randomized controlled trials. The Cleveland Clinic showed in a 10 year review in 1986 that survival after coronary bypass grafting was improved if an internal mammary artery was placed to the left	
anterior descending coronary artery versus a saphenous vein graft. A randomized controlled trial, begun in 1975, with 10 year follow-up on 80 patients gave similar results. Since then, a plethora of studies, including The Society of Thoracic Surgeons Adult Cardiac database evaluation, have continued to prove that patients with internal mammary artery grafts, especially to the left anterior descending coronary artery, live longer than any other conduit combination. Most, if not all, of this benefit is derived from the improved long-term patency rates associated with internal mammary arteries over other conduits. This observation is also well documented in the literature.	1c C   P
1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by	M_ N□

	٠,٠٠	#0134
whom):		
1c.6 Method for rating evidence:		
1c.7 Summary of Controversy/Contradictory Evidence:		
<b>1c.8 Citations for Evidence (</b> <i>other than guidelines</i> <b>):</b> - Abramov D, Tamariz MG, Sever JY, Christakis GT, Bhatnagar G, Heenan AL, Goldman BS, Fremes SE. The influence of gender on the outcome of coronary artery bypass surgery. Ann Thorac Surg. 2000;70:800-806.		
- Arkansas Foundation for Medical Care. Coronary Artery Bypass Graft Surgery: Performance Measure and Risk Adjustment Methodology. Final Report to the Centers for Medicare and Medicaid Services; September 2002.	es	
- Ferguson TB Jr, Coombs LP, Peterson ED. Internal thoracic artery grafting in the elderly patient undergoing coronary artery bypass grafting: room for process improvement? J Thorac Cardiovasc Surg. 2002;123(5):869-880.		
- Leavitt B, O'Connor GT, et al. Use of the internal mammary artery graft and in-hospital mortality and other adverse outcomes associated with coronary artery bypass surgery. Circulation. 2001;103(4):507-512.		
- Morris RJ, Strong MD, et al. Internal thoracic artery for coronary artery grafting in octogenarians. Ann Thorac Surg. 1996;62:16-22.		
- Loop FD, Lytle BW, Cosgrove DM, et al. Influence of the internal-mammary-artery graft on 10-year survival and other cardiac events. N Engl J Med. 1986 Jan 2;314(1):1-6.		
- Lytle BW, Blackstone EH, Loop FD, et a. Two internal thoracic artery grafts are better than one. Thorac Cardiovasc Surg. 1999 May;117(5):855-72.	J	
1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):		
1c.10 Clinical Practice Guideline Citation: 1c.11 National Guideline Clearinghouse or other URL:		
1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):		
1c.13 <b>Method for rating strength of recommendation</b> ( <i>If different from USPSTF system</i> , also describe rating and how it relates to USPSTF):		
1c.14 Rationale for using this guideline over others:		
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance Measure and Report?</i>	to	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:		1 Y□ N□
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES		
Extent to which the measure, <u>as specified</u> , produces consistent (reliable) and credible (valid) results about the quality of care when implemented. ( <u>evaluation criteria</u> )	t	Eval Rating
2a. MEASURE SPECIFICATIONS		

	NQF	- #UI3 <sup>2</sup>
S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:		
2a. Precisely Specified		
2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):  Number of patients undergoing isolated coronary artery bypass graft (CABG) who received an internal mammary artery (IMA) graft		
2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator	r <b>):</b>	
2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes logic, and definitions):  Number of isolated CABG procedures in which IMA Artery Used [IMAArtUs (STS Adult Cardiac Surgery Database Version 2.73)] is marked "Left IMA," "Right IMA," or "Both IMAs"	,	
2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured): All patients undergoing isolated CABG		
2a.5 Target population gender: Female, Male 2a.6 Target population age range: 18 and older		
2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator): 12 months		
2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):  Number of isolated CABG procedures		
Isolated CABG is determined as a procedure for which all of the following apply:  OpcAB is marked "Yes"  (VADProc is marked "No" or "Missing") or (VADProc is marked "Yes, Implanted" and UnplVAD is marked "yes")  OcarASDTy is marked "PFO" or "missing"  OcarAFibAProc is marked "primarily epicardial" or "missing" and  OpValve, VSAV, VSAVPr, ResectSubA, VSMV, VSMVPr, OpTricus, OpPulm, OpONCard, OcarLVA, OcarVSD, OcarSVR, OcarCong, OcarTrma, OcarCrTx, OcAoProcType, EndoProc, OcTumor, OcPulThromDisOCarOthr are all marked "no" or "missing"	,	
2a.9 Denominator Exclusions (Brief text description of exclusions from the target population): Cases are removed from the denominator if the patient had a previous CABG prior to the current admission or if IMA was not used and one of the following reasons was provided:  - The IMA is not a suitable conduit due to size or flow - Subclavian stenosis - Previous cardiac or thoracic surgery - Previous mediastinal radiation - Emergent or salvage procedure - No LAD disease		
2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions): Patients with previous CABG, identified where PrCAB is marked "yes"		2a- specs
or		ון א

IMA Artery Used (IMAArtUs) is marked "no IMA" and primary reason for no IMA (NoIMARsn) is marked as any

N

of the following:

- The IMA is not a suitable conduit due to size or flow
- Subclavian stenosis
- Previous cardiac or thoracic surgery
- Previous mediastinal radiation
- Emergent or salvage procedure
- No LAD disease

**2a.11 Stratification Details/Variables** (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):

N/A

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

**2a.14 Risk Adjustment Methodology/Variables** (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Rate/proportion

2a.20 Interpretation of Score: Better quality = Higher score

**2a.21 Calculation Algorithm** (Describe the calculation of the measure as a flowchart or series of steps): N/A

**2a.22** Describe the method for discriminating performance (e.g., significance testing):
Two-sided 95% binomial confidence intervals; a confidence interval is calculated for each database participant. If the overall STS database result falls within the participant's 95% binomial confidence interval, the participant's performance is considered not significantly different from the overall database result. If the overall STS database result falls to the right of the participant's 95% binomial confidence

result. If the overall STS database result falls to the right of the participant's 95% binomial confidence interval, then the participant's performance is considered significantly lower than the overall database results. If the overall STS database result falls to the left of the participant's 95% binomial confidence interval, then the participant's performance is considered significantly higher than the overall database results.

**2a.23 Sampling (Survey) Methodology** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A

**2a.24 Data Source (**Check the source(s) for which the measure is specified and tested) Registry data

**2a.25** Data source/data collection instrument (Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):

STS Adult Cardiac Surgery Database - Version 2.73

**2a.26-28** Data source/data collection instrument reference web page URL or attachment: URL Data Collection Form (an updated version will be made available on the STS Website in mid-December of 2010)---http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataCollectionForm2\_7\_Annotated\_20101021.pdf

2a.29-31 Data dictionary/code table web page URL or attachment: URL

http://www.sts.org/documents/pdf/ndb2010/STSAdultCVDataSpecificationsV2\_7\_20101021.pdf -- an updated version will be made available on the STS Website in mid-December of 2010

**2a.32-35 Level of Measurement/Analysis** (Check the level(s) for which the measure is specified and tested)

Clinicians: Group, Facility/Agency, Population: national, Population: regional/network, Population: states, Population: counties or cities

**2a.36-37 Care Settings (**Check the setting(s) for which the measure is specified and tested) Hospital

2a.38-41 Clinical Services (Healthcare services being measured, check all that apply) Clinicians: Physicians (MD/DO)				
TESTING/ANALYSIS				
2b. Reliability testing				
<b>2b.1 Data/sample</b> (description of data/sample and size): STS Adult Cardiac Surgery Database - Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009.				
<b>2b.2 Analytic Method</b> (type of reliability & rationale, method for testing): Compared results between two proximate time periods: January 2008-December 2008 and January 2009-December 2009. Excluded from analysis are participants that did not submit results for both time periods. As database participants can change their underlying care processes at any time, we would not expect perfect correlation between two sets of results from even proximate time periods.	2b C□			
<b>2b.3 Testing Results</b> (reliability statistics, assessment of adequacy in the context of norms for the test conducted):  Please see attachment	P N			
2c. Validity testing				
2c.1 Data/sample (description of data/sample and size): STS Adult Cardiac Surgery Database				
Audits conducted in 2010, all cases performed in 2009; N = 40 randomly selected sites participating in the STS Adult Cardiac Surgery Database				
<b>2c.2 Analytic Method</b> (type of validity & rationale, method for testing): Participating sites are randomly selected for participation in STS Adult Cardiac Surgery Database Audit, which is designed to evaluate the accuracy, consistency, and comprehensiveness of data collection and ultimately validate the integrity of the data contained in the database. The lowa Foundation for Medical Care (IFMC), the quality improvement organization for lowa and Illinois, has conducted audits on behalf of STS since 2006.				
Each year, the IFMC conducts audits at randomly selected sites throughout the country and tracks the individual agreement rates by variable and by year. More specifically, for each site, agreement rates are calculated for 73 individual elements. In addition, aggregate agreement rates for each element, variable category (e.g., pre-operative risk factors, previous interventions, etc), and overall for all categories are calculated for all sites. While this is not region specific, it is data point specific and comparison agreement rates confirm the improvement over time as well as the consistency.	2c C□			
2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):  IMA Used as Grafts: 99.6% agreement rate	P   M   N			
2d. Exclusions Justified				
2d.1 Summary of Evidence supporting exclusion(s):				
2d.2 Citations for Evidence:				
<b>2d.3 Data/sample</b> (description of data/sample and size): Dates: January 1, 2009-December 31, 2009; 640 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months. Patients with prior CABG operations are excluded from this NQF measure.	2d C P M N			

2d.4 Analytic Method (type analysis & rationale):	
2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses): Please see attachment	
2e. Risk Adjustment for Outcomes/ Resource Use Measures	
2e.1 Data/sample (description of data/sample and size):	
2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):	
2e.3 Testing Results (risk model performance metrics):	2e C   P   M   N
2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:	NA 🗌
2f. Identification of Meaningful Differences in Performance	
<b>2f.1 Data/sample from Testing or Current Use</b> (description of data/sample and size): 615 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months; January 1, 2009-December 31, 2009	
2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):  Two-sided 95% binomial confidence intervals; a confidence interval is calculated for each database participant. If the overall STS database result falls within the participant's 95% binomial confidence interval, the participant's performance is considered not significantly different from the overall database result. If the overall STS database result falls to the right of the participant's 95% binomial confidence interval, then the participant's performance is considered significantly lower than the overall database results. If the overall STS database result falls to the left of the participant's 95% binomial confidence interval, then the participant's performance is considered significantly higher than the overall database results.	
<b>2f.3 Provide Measure Scores from Testing or Current Use</b> (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):  Please see attachment	2f C P M N
2g. Comparability of Multiple Data Sources/Methods	
2g.1 Data/sample (description of data/sample and size):	
2g.2 Analytic Method (type of analysis & rationale):	2g C∐
2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):	P   M   N   NA
2h. Disparities in Care	2h
2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts):	C
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:	M   N   NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Scientific	2
Acceptability of Measure Properties?  Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure	2

Properties, met? Rationale:	C □ P □
	M   N
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	Eval Rating
3a. Meaningful, Understandable, and Useful Information	
3a.1 Current Use: In use	
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):  This measure is one of eleven component measures of the STS CABG Composite Score. Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org	
Currently, there are 221 STS Adult Cardiac Surgery Database participating hospitals who voluntarily participate in this initiative.	
<b>3a.3 If used in other programs/initiatives</b> ( <i>If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years</i> ):  CMS Physician Quality Reporting Initiative (PQRI), www.cms.hhs.gov/pqri	
Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)  3a.4 Data/sample (description of data/sample and size): See 3a.6 below	
3a.5 Methods (e.g., focus group, survey, QI project):	3a C□
3a.6 Results (qualitative and/or quantitative results and conclusions): Please see attachment	P   M   N
3b/3c. Relation to other NQF-endorsed measures	
<b>3b.1 NQF # and Title of similar or related measures:</b> OT1-013-09 - The STS CABG Composite Score; Component measures: 0114 Risk-Adjusted Post-Operative Renal Failure, 0115 Risk-Adjusted Surgical Re-exploration, 0116 Anti-Platelet Medication at Discharge, 0117 Beta Blockade at Discharge, 0118 Anti-Lipid Treatment at Discharge, 0119 Risk-Adjusted Operative Mortality for CABG, 0127 Pre-Operative Beta Blockade, 0129 Risk-Adjusted Prolonged Intubation (ventilation), 0130 Risk-Adjusted Deep Sternal Wound Infection Rate, 0131 Risk-Adjusted Stroke/Cerebrovascular Accident, 0134 Use of Internal Mammary Artery (IMA) in Coronary Artery Bypass Graft (CABG)	
(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): 3b.2 Are the measure specifications harmonized? If not, why? N/A; however, data definitions and key elements have been established by a multi-societal writing committee called the "ACCF/AHA Writing Committee to Develop Acute Coronary Syndromes and Coronary Artery Disease Clinical Data Standards" with representatives from each of the following organizations:	3b C P
Agency for Healthcare Research and Quality American College of Cardiology American College of Chest Physicians	M NA

American College of Emergency Physicians American College of Physicians American College of Preventative Medicine American Heart Association American Medical Association Centers for Disease Control and Prevention	
Emergency Nurses Association Food and Drug Administration Joint Commission on Accreditation of Healthcare Organizations National Association of Emergency Medical Technicians National Association of EMS Physicians	
National Heart, Lung, and Blood Institute Preventive Cardiovascular Nurses Association Society for Academic Emergency Medicine Society of Chest Pain Centers and Providers Society of General Internal Medicine Society of Thoracic Surgeons	
3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF- endorsed measures:	3c C□ P□
5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:	M NO NA
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability?</i>	3
Steering Committee: Overall, to what extent was the criterion, <i>Usability</i> , met? Rationale:	3 C   P   M   N
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. ( <a href="evaluation criteria">evaluation criteria</a> )	Eval Rating
4a. Data Generated as a Byproduct of Care Processes	
<b>4a.1-2</b> How are the data elements that are needed to compute measure scores generated?  Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition), Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)	4a C P M N
4b. Electronic Sources	
<b>4b.1 Are all the data elements available electronically?</b> (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims) Yes	4b C□ P□
4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	M N
4c. Exclusions	4c C□
4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?	P   M

No	N NA
4c.2 If yes, provide justification.	
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.  This measure may be susceptible to human error (i.e., recording the measure inaccurately or not at all).	
When data collection on this measure is done through participation in the STS Adult Cardiac Surgery Database, an auditing strategy is in place.	
Both STS and the Duke Clinical Research Institute have a list of database participants making participation in the STS Adult Cardiac Surgery Database easy to track.	
Each participant is responsible for the quality and accuracy of the data they submit to the database. The participant agrees to the following quality control measures in the participation agreement: i) Participant hereby warrants that all data submitted for inclusion in the STS National Database will be accurate and complete, and acknowledges that such data may be subject to independent audit. Participant will use its best efforts to address any data or related deficiencies identified by the independent data warehouse service provider and agrees to cooperate with and assist STS and its designees in connection with the performance of any independent audit.	
ii) Participant warrants that it will take all reasonable steps to avoid the submission of duplicative data for inclusion in the STS National Database, including but not limited to apprising the Director of the STS National Database and the independent data warehouse service provider about any other Participation Agreements in which an individual cardiothoracic surgeon named above or on Schedule A attached hereto (as amended from time to time) is also named.	4d C□ P□
STS audited for these potential problems during testing. Please see IFMC audit results.	N
4e. Data Collection Strategy/Implementation	
4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:	
<b>4e.2 Costs to implement the measure</b> (costs of data collection, fees associated with proprietary measures):  Data Collection:	
There are no direct costs to collect the data for this measure. Costs to develop the measure included volunteer cardiothoracic surgeon time, STS staff time, and DCRI statistician and project management time.	
Other fees: STS Adult Cardiac Surgery Database participants (single cardiothoracic surgeons or a group of surgeons) pay annual participant fees of \$2,950 or \$3,700, depending on whether participants are STS members (or whether the majority of surgeons in a group are STS members). As a benefit of STS membership, STS members are charged the lesser of the two fees.	
4e.3 Evidence for costs:	4e C□ P□
4e.4 Business case documentation:	M□ N□
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for Feasibility?	4

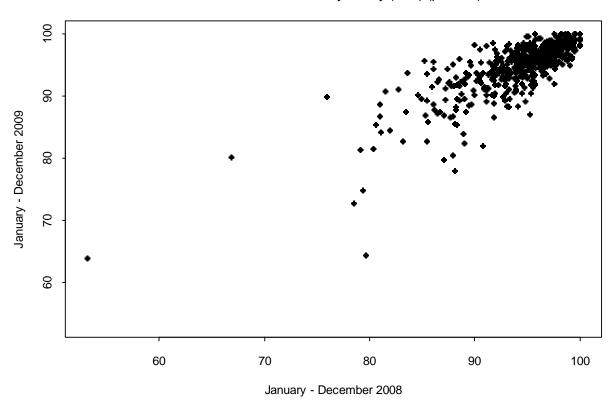
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Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i> , met? Rationale:	4 C   P   M   N
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time- limited
Steering Committee: Do you recommend for endorsement? Comments:	Y □ N □ A □
CONTACT INFORMATION	
Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization The Society of Thoracic Surgeons, 633 N. Saint Clair Street, Suite 2320, Chicago, Illinois, 60611  Co.2 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Measure Developer If different from Measure Steward Co.3 Organization The Society of Thoracic Surgeons, 633 N. Saint Clair Street, Suite 2320, Chicago, Illinois, 60611 Co.4 Point of Contact Jane, Han, MSW, jhan@sts.org, 312-202-5856-	
Co.5 Submitter If different from Measure Steward POC Jane, Han, MSW, jhan@sts.org, 312-202-5856-, The Society of Thoracic Surgeons	
Co.6 Additional organizations that sponsored/participated in measure development	
ADDITIONAL INFORMATION	
Workgroup/Expert Panel involved in measure development Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organization Describe the members' role in measure development. Members of the STS Task Force on Quality Initiatives provide clinical expertise as needed. The STS Workfor National Databases meets at the STS Annual Meeting and reviews the measures on a yearly basis. Changes of updates to the measure will be at the recommendation of the Workforce.	ce on
Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment	
Measure Developer/Steward Updates and Ongoing Maintenance Ad.6 Year the measure was first released: 2004 Ad.7 Month and Year of most recent revision: 12, 2010 Ad.8 What is your frequency for review/update of this measure? annually Ad.9 When is the next scheduled review/update for this measure? 2011	
Ad.10 Copyright statement/disclaimers:	
Ad.11 -13 Additional Information web page URL or attachment: Attachment 0134 Sections 1b.2, 2b.3, 2 2f.3, 3a.6.pdf	d.5,
Date of Submission (MM/DD/YY): 01/12/2011	

**1b.2. Summary of Measure Results Demonstrating Performance Gap** (Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.)

Measurement	Use of Internal Mammary Artery (IMA)
N	615
Mean	94.7%
1 <sup>st</sup>	78.9%
5 <sup>th</sup>	87.0%
10 <sup>th</sup>	89.6%
25 <sup>th</sup>	92.9%
Median	95.8%
75 <sup>th</sup>	97.7%
90 <sup>th</sup>	98.8%
95 <sup>th</sup>	99.2%
99 <sup>th</sup>	100.0%
Outlier	220 (35.8%)
High	129
Low	91

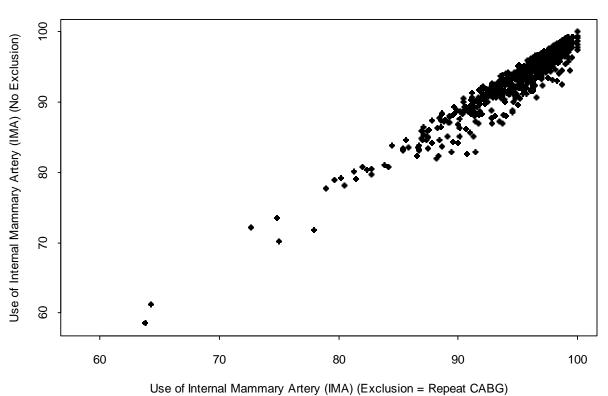
Testing results:  $\rho = 0.77$ 

Use of Internal Mammary Artery (IMA) ( $\rho$ =0.77)



Use of Internal Mammary				
Artery (IMA)				
# of Patients	144,060			
# excluded	5,086			
% excluded 0.04				

## Use of Internal Mammary Artery (IMA) (ρ=0.93)



# **2f.3. Measure Scores from Testing or Current Use** (Description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)

Results below are from January 1, 2009-December 31, 2009. Sample contains 615 STS Adult Cardiac Surgery Database Participants who had at least 100 eligible cases for the measure and reported data to STS for all 12 months.

Measurement	Use of Internal Mammary Artery (IMA)
N	615
Mean	94.7%
1 <sup>st</sup>	78.9%
5 <sup>th</sup>	87.0%
10 <sup>th</sup>	89.6%
25 <sup>th</sup>	92.9%
Median	95.8%
75 <sup>th</sup>	97.7%
90 <sup>th</sup>	98.8%
95 <sup>th</sup>	99.2%
99 <sup>th</sup>	100.0%
Outlier†	220 (35.8%)
High	129
Low	91

<sup>†</sup>Represents the number of participants that are outliers according to two-sided 95% binomial confidence interval.

#### **3a.6. Results** (Qualitative or quantitative results and conclusions)

Although formal testing of interpretability has not been performed, this measure has been used and reported for STS Adult Cardiac Surgery database participants since 2007. Current report presentation and interpretation manuals are presented below. These materials are updated as needed based upon feedback from database participants.

#### 1) Report Overview and Interpretation Manual:

#### **The NQF Measures Report**

#### a. Organization

This report section is separated into three areas corresponding to: 1) NQF volume measures, 2) NQF process measures, and 3) NQF outcomes measures, in that order. The header at the top of each page references the report section for that page. Each NQF measure is presented on a single row in the section. Tabular data are on the left-hand side of each page and a standard graphic representation is shown on the right-hand side.

#### b. Statistical Calculation and Details – NQF Measures

**Time period:** This report section contains information on the individual STS participant and overall STS performance for the <u>most recent 12 months for volume, process and CABG outcomes measures and the most recent 60 months for Valve and Valve + CABG outcomes. The 5 years (60 months) of performance for outcomes involving Valve procedures is necessary due to smaller sample sizes.</u>

**Volume Measures:** The NQF report provides average annual case volumes data for three surgery categories: i) Isolated CABG, ii) Valve without CABG, and iii) combined CABG + Valve. Definitions of the three surgery categories are provided in Table 2 of this NQF Report Overview. For each type of surgery, the <u>participant's annualized volume</u> is calculated as:

Participant Annualized Volume = 12 x (# of surgeries) / (# of months)

where (# of surgeries) denotes the number of surgeries of the specified type performed by the participant during the specified time period, and (# of months) is the number of months during the specified time period for which the participant submitted at least one cardiac surgery of any type. The intent of calculating "annualized" volumes is to adjust for participants who participated in the database for fewer months than the time period specified. For participants who participated in the database and submitted cases every month during 2006, the annualized volume for 2006 is simply the total number of cases.

The <u>STS</u> Average Annualized Volume is the average value of all of the participant annualized volumes across the entire population of STS participants. The <u>Participant Percentile</u> indicates the percent of STS participants whose annualized volumes are less than, or equal to, your own. Higher percentiles indicate higher volumes in relation to other STS participant sites. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant annualized volumes across all database participants. For example, 90% of participants have annualized volumes less than or equal to the value marked "90<sup>th</sup> percentile." Confidence intervals are not provided for volume measures, as volume is known with certainty and is not estimated.

**Process Measures:** The NQF process measures provide data on the frequency of usage of five therapies among subsets of Isolated CABG patients. The therapies are: i) preoperative beta blockade therapy, ii) use of IMA, iii) discharge anti-platelet medication, iv) discharge beta blockade therapy, and v) discharge anti-lipid medication. The patient population for each measure differs, in accordance with the NQF specifications (see Table 2 of this NQF Report Overview for details). The number of <u>Eligible</u>

Procedures is the number of cases performed by the participant during the specified time period who meet the eligibility requirements to be included in the calculations when summarizing the participant's data. Beginning with the 2008 Harvest 3 report (covering the procedure time period through 6/30/2008), STS implementation of NQF medication process measures using data version 2.61 excludes records for which the medication was contraindicated/not indicated from the eligible population. The main summary statistic, Participant Usage, is the percent of eligible Isolated CABG cases during the specified time period for which the patient received the specified therapy. The Overall STS Usage is the percent of all eligible patients in the entire STS population during the specified time period who received the specified therapy. In calculating these percentages, missing data are treated as a "No", emphasizing the importance of having complete data in these fields.

The <u>Participant Percentile</u> indicates the percent of STS participants who applied the therapy in their respective populations less frequently than or as frequently as did your institution. The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of participant usage across all participants in the database. For example, 90% of participants use the therapy less frequently than the amount indicated by the "90<sup>th</sup> percentile". A bar identified as "Participant" indicates the point estimate and limits of a 95% Confidence Interval (CI) for the participant's usage of therapy. The underlying parameter being estimated is the long-run usage rate that would be observed in a large sample of patients. The 95% CI indicates the range of usage rates that are consistent with the data in light of sampling variability.

Outcomes Measures: The NQF outcomes data provide risk-adjusted analyses of mortality and morbidity for Isolated CABG surgery as well as risk-adjusted operative mortality for Isolated AVR, Isolated MVR, AVR+CABG, and MVR+CABG. The main summary statistic provided is the Participant's Estimated Odds Ratio (OR) based on a hierarchical logistic regression analysis. The OR measures the impact that a participant's performance level has on a patient's probability of experiencing an adverse outcome. The interpretation is similar to that of an O/E ratio (see the Risk-Adjusted Results: Overview portion of the General Report Overview for details on STS risk adjustment). An OR greater than 1.0 implies that the participant increases a patient's risk of experiencing the outcome, relative to an "average" STS participant. An OR less than 1.0 implies that the participant decreases a patient's risk of experiencing the outcome, relative to an "average" STS participant. Each measure is calculated among patients undergoing surgery of the type specified during the time period specified who additionally meet certain eligibility requirements. The column labeled Eligible Procedures indicates the number of patients who met the inclusion criteria to be included in the analysis for the indicated measure. The Participant Percentile is the percent of STS participants who have an estimated OR that is greater than or equal to your estimated OR. Note that this is different than performance percentiles for process measures, where the percentile indicates the percentage of STS participants with performance that is less than the specified number. This simply reflects the fact that high process compliance is desirable, whereas a high OR is undesirable.

The <u>Observed Participant Rate</u> is the percent of eligible patients who experienced the specified outcome. Unlike the participant estimated OR, the observed participant rate is not risk-adjusted. The estimated OR is the main summary statistic for summarizing the NQF measure in this report.

The <u>Distribution of Participant Values</u> shows the range and percentiles of the distribution of estimated Odds Ratios across all STS participants. For example, 90% of STS participants have an OR greater than the value indicated by the "90<sup>th</sup> percentile." The line that extends to the left and right of the Participant Value indicates the lower and upper limits of a 95% Confidence Interval (CI) surrounding the participant's estimated OR.

#### c. Technical Notes

**Calculation of Percentiles for the Distribution of Participant Values:** The graph provided for each measure contains information about the distribution of the value of the measure across all STS

participants, namely the minimum, maximum,  $10^{th}$  percentile,  $50^{th}$  percentile, and 90th percentile. The " $X^{th}$ " percentile, denoted  $P_x$ , is loosely defined as the number having the property that X% of the participant values are less than  $P_x$ , and (100 - X)% of the participant values are greater than  $P_x$ . For process measures, participants with greater than 5% missing data were excluded when calculating percentiles of the STS distribution and do not have a calculated participant percentile. For participants having less than 5% missing data on a process measure, the missing values on the process measure were converted to "No" before calculating percentiles. For outcomes measures, all participants submitting at least one eligible case were included when calculating percentiles of the STS distribution. Missing data on outcomes variables were treated as "No."

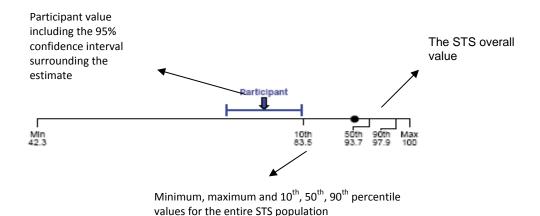
NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion criteria, and rules for handling missing data in the NQF section versus the rest of the report. Definitions used in the NQF report were designed to match current NQF specifications as closely as possible. It is expected that these differences will eventually disappear as the NQF measures are refined. Some important differences are:

Case Volumes – The NQF report section presents "annualized" volumes. These are case volumes that have been adjusted for the number of months that a participant was an active contributor to the database. Elsewhere in the STS report, total case volumes are presented without adjustment for the length of participation.

Eligible Cases - The NQF report also presents the number of "eligible cases" for each measure. Separate inclusion criteria are applied to each measure, and these inclusion criteria do not always match the definitions used elsewhere in the STS report. Please refer to the footnotes in each section for specific details.

#### **Interpretation Manual**

In addition to the statistics provided for each of the STS Composite Quality Domains and NQF measures, a figure representing the distribution of values for the entire STS population is provided.



The figure allows participants to quickly judge their performance relative to the overall STS. The scale of the figure is set up such that the right side of the distribution represents the <u>most</u> favorable performance and the left side represents the <u>least</u> favorable performance (Note that in some cases smaller numbers will be on the left; in other instances, smaller numbers will be on the right. For example, for the Pre-operative Beta Blockade Therapy measure, the far left side of the distribution will contain the *lowest* percentage Beta Blockade Therapy for an STS participant – this corresponds to least

favorable performance. Alternatively, for the Operative Mortality Measure, the far left side of the distribution will contain the *highest* Estimated Odds Ratio – this also corresponds to least favorable performance). If a participant's value for a given measure is to the left of the STS overall value, the participant is performing worse on that measure than the overall STS. Conversely, if the participant's value for a given measure is located to the right of the overall STS value, the participant is performing better than the overall STS.

**NOTE!** Care should be given to reading these figures. In some instances, the various percentiles presented cluster very close together in the data. In such cases, the label for the percentile is not necessarily located immediately at the point on the distribution where the percentile occurs. An example of this is apparent in the figure above: The 50<sup>th</sup> percentile corresponds to a value of 93.7 and looks to align fairly closely with the STS overall value as represented by the large black dot. However, the expandable figure marking actually points to a place somewhere to the right of the STS overall value for the 50<sup>th</sup> percentile marking. So the STS overall value would be some amount less than 93.7.

Also, please note that in some cases, small sample sizes preclude valid comparisons between the participant and the STS overall. Such instances are clearly noted in the report output.

#### a. NQF Measures Interpretation Example

Sample CABG Operative Mortality results – tabular and figure representation.

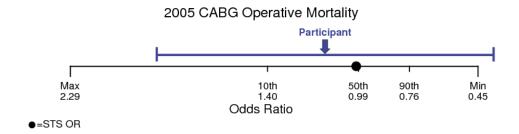
NQF	Eligible	Participant	Participant	Participant
Measure	Procedures	Estimated OR	Percentile	Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

Eligible Procedures: 74 patients met the inclusion criteria for the indicated measure.

Participant Estimated OR (Odds Ratio): The main summary statistic measuring the impact that a participant's performance has on a patient's probability of experiencing an adverse outcome has a value of 1.14 indicating worse than expected performance.

Participant Percentile: 26.3% of STS participants had an estimated OR greater than or equal to your estimated OR. In other words, 26.3% had the same or worse performance.

Participant Observed Rate: 5.4% of the 74 eligible patients experienced the specified outcome.



The highest OR among all STS participants = 2.29 The lowest OR among all STS participants = 0.45 The STS average OR is 1.00

### 2) Sample page from section of the report that contains NQF measure results:



# NQF Measures Process Measures Participant 99999 STS Period Ending 12/31/2008



NQF Measure	Eligible Procedures	Participant Usage (95% CI)	Participant Percentile	Overall STS Usage	Distribution of Participant Values
Jan 2008 - Dec 2008 Preoperative Beta Blockade Therapy <sup>1</sup>	541	89.3% (86.4 , 91.8)	69.9	82.1%	Participant
Jan 2008 - Dec 2008 Use of IMA <sup>2</sup>	536	96.5% (94.5 , 97.9)	63.3	94.2%	Participant  Min 10th 50th 90th Max 53.2 87.8 95.2 98.9 100
Jan 2008 - Dec 2008 Discharge Anti-Platelet Medication <sup>3</sup>	536	98.7% (97.3 , 99.5)	68.7	96.1%	Participant  Min 10th 50th 90th Max 16.7 92.1 97.5 100 100
Jan 2008 - Dec 2008 Discharge Beta Blockade Therapy <sup>4</sup>	538	96.1% (94.1 , 97.6)	53.4	93.7%	Participant  Min 10th 50th 80th Max 15.1 85.3 85.7 100 100
Jan 2008 - Dec 2008 Discharge Anti-Lipid Treatment⁴	535	91.8% (89.1 , 94.0)	40.7	91.4%	Participant

Excludes v2.61 contranindicated / not indicated records.

Excludes patients with prior CABG surgery

Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.

Excludes in-hospital mortalities. Excludes v2.61 contranindicated / not indicated records.