

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 [evaluation criteria](#) 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 #: 0121	NQF Project: Surgery Endorsement Maintenance 2010
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Risk-Adjusted Operative Mortality for Mitral Valve (MV) Replacement	
De.2 Brief description of measure: Percent of patients aged 18 years and older undergoing MV Replacement who die, including both 1) all deaths occurring during the hospitalization in which the procedure was performed, even if after 30 days, and 2) those deaths occurring 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 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
<p>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>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.</i></p> <p>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</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Agreement will be signed and submitted prior to or at the time of measure submission</p> <p>A.4 Measure Steward Agreement attached: STS Measure Steward Agreement. Fully Executed-634267315118486062.pdf</p>	<p>A</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

<p>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</p>	<p>B Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p>C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► Purpose: Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)</p>	<p>C Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p>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.1 Testing: Yes, fully developed and tested D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes</p>	<p>D Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p>(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):</p>	<p>Met Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p>Staff Notes to Reviewers (issues or questions regarding any criteria):</p>	
<p>Staff Reviewer Name(s):</p>	

<p>TAP/Workgroup Reviewer Name:</p>	
<p>Steering Committee Reviewer Name:</p>	
<p>1. IMPORTANCE TO MEASURE AND REPORT</p>	
<p>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</p>	<p>Eval Rating</p>
<p>(for NQF staff use) Specific NPP goal:</p>	
<p>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: Review of morbidity and mortality results of mitral valve replacement has impact on every center that tracks and reports their performance; the process of publishing and comparing institutional results provides benchmark feedback and triggers institutional programs to further improve their mitral valve procedural outcomes. 1a.4 Citations for Evidence of High Impact: - Birkmeyer NJ, Marrin CA, et al. Decreasing mortality for aortic and mitral valve surgery in Northern New England. Northern New England Cardiovascular Disease Study Group. Ann Thorac Surg. 2000;70(2):432-437. - Edwards FH, Petyerson ED, et al. Prediction of operative mortality following valve replacement surgery. JACC. 37:3:885-892. - Goodney PP, O'Connor GT, et al. Do hospitals with low mortality rates in coronary artery bypass also perform well in valve replacement? Ann Thorac Surg. 2003;76:1131-1137. - Mehta RH, Eagle KA, et al. Influence of age on outcomes in patients undergoing mitral valve replacement. Ann Thorac Surg. 2002;74:1459-1467.</p>	<p>1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>1b. Opportunity for Improvement</p>	<p>1b</p>

1b.1 Benefits (improvements in quality) envisioned by use of this measure: The benefit of reporting mitral valve replacement data is to expand the scope of procedures monitored by the STS and local institutions. Whether it takes 3 years or 6 months to reach the statistically significant reporting threshold of 100 cases, the ongoing surveillance tests the hypothesis that valve replacement outcomes parallel CAB performance. If not, quality improvement projects targeting mitral valve disease should be elaborated.

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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, 2005-December 31, 2009

Analysis includes 106 STS Adult Cardiac Surgery Database Participants who had at least 50 eligible cases for the measure and reported data (not restricted to this measure) to STS for at least 36 months in 2005-2009.

1b.4 Summary of Data on disparities by population group:

Please see attachment

1b.5 Citations for data on Disparities:

Analysis includes STS Adult Cardiac Surgery Database Participants that had more than 50 eligible cases in 2005-2009 and reported data for at least 36 months

1150 Patients from 15 Participants were included in the Gender = Male sub-group.

2971 Patients from 41 Participants were included in the Gender = Female sub-group.

154 Patients from 2 Participants were included in the Race = Black sub-group.

5567 Patients from 68 Participants were included in the Race = White sub-group.

171 Patients from 3 Participants were included in the Race = Other sub-group.

8255 Patients from 95 Participants were included in the Ethnicity = Non-Hispanic sub-group.

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*): Reporting an individual center's results in quartile relationship to all participating centers gives a program a reference point relative to peers and a sense of how much improvement is necessary to reach a level of performance expected by the center's cardiovascular leadership.

1c.2-3. Type of Evidence: Observational study, Expert opinion, Systematic synthesis of research, Meta-analysis, 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*):

All levels and processes of surgical care from pre-op evaluation and preparation to discharge planning influences the procedural outcome. Identifying the processes of care which most influence the outcome requires phase of care analysis so that quality improvement efforts are well-targeted.

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*): - Birkmeyer NJ, Marrin CA, et al. Decreasing mortality for aortic and mitral valve surgery in Northern New England. Northern New England Cardiovascular Disease Study Group. Ann Thorac Surg. 2000;70(2):432-437.

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<p>- Edwards FH, Petyerson ED, et al. Prediction of operative mortality following valve replacement surgery. JACC. 37:3:885-892.</p> <p>- Goodney PP, O'Connor GT, et al. Do hospitals with low mortality rates in coronary artery bypass also perform well in valve replacement? Ann Thorac Surg. 2003;76:1131-1137.</p> <p>- Mehta RH, Eagle KA, et al. Influence of age on outcomes in patients undergoing mitral valve replacement. Ann Thorac Surg. 2002;74:1459-1467.</p> <p>1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number): N/A</p> <p>1c.10 Clinical Practice Guideline Citation:</p> <p>1c.11 National Guideline Clearinghouse or other URL:</p> <p>1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):</p> <p>1c.13 Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF):</p> <p>1c.14 Rationale for using this guideline over others:</p>	
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i>?</p>	<p>1</p>
<p>Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i>, met? Rationale:</p>	<p>1 Y <input type="checkbox"/> N <input type="checkbox"/></p>
<p style="text-align: center;">2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES</p>	
<p>Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)</p>	<p>Eval Rating</p>
<p style="text-align: center;">2a. MEASURE SPECIFICATIONS</p>	
<p>S.1 Do you have a web page where current detailed measure specifications can be obtained? S.2 If yes, provide web page URL:</p> <p>2a. Precisely Specified</p>	
<p>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 MV Replacement 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</p> <p>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</p> <p>2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions): Number of isolated MV Replacement procedures with an operative mortality;</p> <p>Number of isolated MV Replacement 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)</p>	<p>2a-specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): All patients aged 18 years and older undergoing isolated MV Replacement surgery</p> <p>2a.5 Target population gender: Female, Male</p> <p>2a.6 Target population age range: 18 and older</p> <p>2a.7 Denominator Time Window (<i>The time period in which cases are eligible for inclusion in the denominator</i>): 60 months</p> <p>2a.8 Denominator Details (<i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i>): Number of isolated MV Replacement procedures;</p> <p>Isolated MV Replacement is determined as a procedure for which all of the following apply:</p> <ul style="list-style-type: none"> - OpValve is marked “Yes” - VSMV is marked “Yes” - VSMVPr is marked “Replacement” - (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 - OpCAB, VSAV, VSAVPr, ResectSubA, OpTricus, OpPulm, OpONCard, OCarLVA, OCarVSD, OCarSVR, OCarCong, OCarTrma, OCarCrTx, OCAoProcType, EndoProc, OCTumor, OCPulThromDis, OCarOthr are all marked “no” or “missing”
<p>2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): N/A</p> <p>2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>):</p>
<p>2a.11 Stratification Details/Variables (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>): N/A</p>
<p>2a.12-13 Risk Adjustment Type: Case-mix adjustment</p> <p>2a.14 Risk Adjustment Methodology/Variables (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>): Please see attachment</p> <p>2a.15-17 Detailed risk model available Web page URL or attachment: Attachment 2a.15 Detailed Risk Model-634267316854669390.pdf</p>
<p>2a.18-19 Type of Score: Rate/proportion</p> <p>2a.20 Interpretation of Score: Better quality = Lower score</p> <p>2a.21 Calculation Algorithm (<i>Describe the calculation of the measure as a flowchart or series of steps</i>): N/A</p>
<p>2a.22 Describe the method for discriminating performance (<i>e.g., significance testing</i>): 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.</p>
<p>2a.23 Sampling (Survey) Methodology (<i>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)</i>): N/A</p>
<p>2a.24 Data Source (<i>Check the source(s) for which the measure is specified and tested</i>)</p>

<p>Electronic Clinical Data : Registry</p> <p>2a.25 Data source/data collection instrument (<i>Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.</i>): STS Adult Cardiac Surgery Database - Version 2.73</p> <p>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/STSAultCVDDataCollectionForm2_7_Annotated_20101021.pdf</p> <p>2a.29-31 Data dictionary/code table web page URL or attachment: URL http://www.sts.org/documents/pdf/ndb2010/STSAultCVDDataSpecificationsV2_7_20101021.pdf -- an updated version will be made available on the STS Website in mid-December of 2010</p> <p>2a.32-35 Level of Measurement/Analysis (<i>Check the level(s) for which the measure is specified and tested</i>) Clinician : Group/Practice, Clinician : Team, Facility, Population : County or City, Population : National, Population : Regional, Population : State</p> <p>2a.36-37 Care Settings (<i>Check the setting(s) for which the measure is specified and tested</i>) Hospital/Acute Care Facility</p> <p>2a.38-41 Clinical Services (<i>Healthcare services being measured, check all that apply</i>) Clinicians: Physicians (MD/DO)</p>	
TESTING/ANALYSIS	
<p>2b. Reliability testing</p> <p>2b.1 Data/sample (<i>description of data/sample and size</i>): STS Adult Cardiac Surgery Database - Compared results between two proximate time periods with one-year overlap: January 2005-December 2007 and January 2007-December 2009.</p> <p>2b.2 Analytic Method (<i>type of reliability & rationale, method for testing</i>): Compared results between two proximate time periods with one-year overlap: January 2005-December 2007 and January 2007-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.</p> <p>2b.3 Testing Results (<i>reliability statistics, assessment of adequacy in the context of norms for the test conducted</i>): Please see attachment</p>	<p>2b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>2c. Validity testing</p> <p>2c.1 Data/sample (<i>description of data/sample and size</i>): STS Adult Cardiac Surgery Database</p> <p>Audits conducted in 2010, all cases performed in 2009; N = 40 randomly selected sites participating in the STS Adult Cardiac Surgery Database</p> <p>2c.2 Analytic Method (<i>type of validity & rationale, method for testing</i>): 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 Iowa Foundation for Medical Care (IFMC), the quality improvement organization for Iowa and Illinois, has conducted audits on behalf of STS since 2006.</p> <p>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</p>	<p>2c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

<p>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.</p> <p>2c.3 Testing Results (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>): Mortality Operative Death: 100.0% agreement rate</p>	
<p>2d. Exclusions Justified</p> <p>2d.1 Summary of Evidence supporting exclusion(s): N/A</p> <p>2d.2 Citations for Evidence:</p> <p>2d.3 Data/sample (<i>description of data/sample and size</i>):</p> <p>2d.4 Analytic Method (<i>type analysis & rationale</i>):</p> <p>2d.5 Testing Results (<i>e.g., frequency, variability, sensitivity analyses</i>):</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (<i>description of data/sample and size</i>): Please see Risk Adjustment Type section above</p> <p>2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>): Detailed information regarding the risk adjustment model can be found in the attachment: O'Brien SM, Shahian DM, 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 2--isolated valve surgery. <i>Ann Thorac Surg</i> 2009 Jul;88(1 Suppl):S23-42.</p> <p>2e.3 Testing Results (<i>risk model performance metrics</i>):</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): 106 STS Adult Cardiac Surgery Database Participants who had at least 50 eligible cases for the measure and reported data to STS for at least 36 months in 2005-2009; January 1, 2005-December 31, 2009</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (<i>type of analysis & rationale</i>): 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.</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>2f.3 Provide Measure Scores from Testing or Current Use (<i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningful differences in performance</i>): Please see attachment</p>	
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (<i>description of data/sample and size</i>): N/A</p> <p>2g.2 Analytic Method (<i>type of analysis & rationale</i>):</p> <p>2g.3 Testing Results (<i>e.g., correlation statistics, comparison of rankings</i>):</p>	<p>2g</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>): N/A</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:</p>	<p>2h</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met? Rationale:</p>	<p>2</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>3. USABILITY</p>	
<p>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)</p>	<p>Eval Rating</p>
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: In use</p> <p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). <u>If not publicly reported</u>, state the plans to achieve public reporting within 3 years</i>): 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 Care--use 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 infection--an "any-or-none" measure). Composite star ratings are presented in the health section of the Consumers Union website, www.ConsumerReportsHealth.org</p> <p>STS will begin developing composite measures to be used for public reporting for AVR, AVR+CABG, MV Repair, MV Repair + CABG, MV Replacement, and MV Replacement + CABG surgeries. STS's plan is to develop one composite per year beginning with AVR (and continuing in the order listed).</p> <p>3a.3 If used in other programs/initiatives (<i>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</i>):</p> <p>Testing of Interpretability (<i>Testing that demonstrates the results are understood by the potential users</i>)</p>	<p>3a</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

<p>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</p>	
<p>3b/3c. Relation to other NQF-endorsed measures 3b.1 NQF # and Title of similar or related measures:</p>	
<p>(for NQF staff use) Notes on similar/related endorsed or submitted measures:</p>	
<p>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 <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</p>	<p>3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>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:</p>	<p>3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/></p>

	N <input type="checkbox"/>
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	
<p>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)</p>	4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4b. Electronic Sources	
<p>4b.1 Are all the data elements available electronically? (<i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i>) Yes</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p>	4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4c. Exclusions	
<p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</p>	4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences	
<p>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).</p> <p>When data collection on this measure is done through participation in the STS Adult Cardiac Surgery Database, an auditing strategy is in place.</p> <p>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.</p> <p>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.</p> <p>STS audited for these potential problems during testing. Please see IFMC audit results.</p>	4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4e. Data Collection Strategy/Implementation	4e

<p>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:</p> <p>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.</p> <p>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.</p> <p>4e.3 Evidence for costs:</p> <p>4e.4 Business case documentation:</p>	<p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>RECOMMENDATION</p>	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>A <input type="checkbox"/></p>
<p>CONTACT INFORMATION</p>	
<p>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</p> <p>Co.2 <u>Point of Contact</u> Jane, Han, MSW, jhan@sts.org, 312-202-5856-</p>	
<p>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</p> <p>Co.4 <u>Point of Contact</u> Jane, Han, MSW, jhan@sts.org, 312-202-5856-</p>	
<p>Co.5 Submitter If different from Measure Steward POC Jane, Han, MSW, jhan@sts.org, 312-202-5856-, Society of Thoracic Surgeons</p>	
<p>Co.6 Additional organizations that sponsored/participated in measure development</p>	

ADDITIONAL INFORMATION
<p>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.</p>
<p>Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>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</p>
<p>Ad.10 Copyright statement/disclaimers:</p>
<p>Ad.11 -13 Additional Information web page URL or attachment: Attachment 0121 Sections 2a.14, 1b.2, 1b.4, 2b.3, 2f.3, 3a.6.pdf</p>
<p>Date of Submission (MM/DD/YY): 10/28/2010</p>

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.

$$\text{logit}(\text{outcome}) \sim X\beta + (\gamma | \text{participant})$$

where X is the patient's risk factors, β is the regression coefficients of patient-level risk factors and γ is the participant level regression coefficient.

Inclusion Criteria

The patient level risk adjusted model was developed using a population of patients undergoing isolated valve procedure in the time period January 2002 – December 2006. For this measurement we re-fit the patient-level model using the latest four and a half years of data (January 2006 – 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 Isolated Valve Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preop atrial fibrillation, = 0 otherwise
Age function 1	= max (age – 50, 0)
Age function 3	= max (age – 75, 0)
Age by reoperation 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
Age by MVR function	= Age function 1 if operation is MVR, = 0 otherwise
Age by MVRepair function	= Age function 1 if operation is MVRepair, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	= (BSA 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
CHF by MVR function	= 1 if patient has CHF and operation is MVR, = 0 otherwise
CHF by MVRepair function	= 1 if patient has CHF and operation is MVRepair, = 0 otherwise
CLD function	= 0 if no CLD, = 1 if mild CLD, = 2 if moderate CLD, = 3 if severe CLD
CLD by MVR function	= CLD function if operation is MVR, = 0 otherwise
CLD by MVRepair function	= CLD function if operation is MVRepair, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
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
Diabetes by MVR function	= 1 if patient has diabetes and operation is MVR, = 0 otherwise
Diabetes by MVRepair function	= 1 if patient has diabetes and operation is MVRepair, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Dialysis by MVR function	= 1 if patient has history of dialysis and operation is MVR, = 0 otherwise
Dialysis by MVRepair function	= 1 if patient has history of dialysis and operation is MVRepair, = 0 otherwise
Ejection fraction function	= max (50–ejection fraction, 0)
Endocarditis, active	= 1 if patient has active endocarditis, = 0 otherwise
Female	= 1 if patient is female, = 0 otherwise

Female by MVR function	= 1 if female and operation is MVR, = 0 otherwise
Female by MVRepair function	= 1 if female and operation is MVRepair, = 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
IABP by MVR function	= 1 if patient requires preop IABP/inotropes and operation is MVR, = 0 otherwise
IABP by MVRepair function	= 1 if patient requires preop IABP/inotropes and operation is MVRepair, = 0 otherwise
Immunosuppressive treatment	= 1 if patient received immunosuppressive therapy within 30 days, = 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 \leq 21 days	= 1 if patient has history of MI within 21 days of surgery, = 0 otherwise
MVR	= 1 if valve operation is mitral valve replacement, = 0 otherwise
MVRepair	= 1 if valve operation is mitral valve repair, = 0 otherwise
No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 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
Reop, 1 prior operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, \geq 2 prior operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Reop by MVR function	= 1 if surgery is a reoperation and operation is MVR, = 0 otherwise
Reop by MVRepair function	= 1 if surgery is a reoperation and operation is MVRepair, = 0 otherwise
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Shock by MVR function	= 1 if shock and operation is MVR, = 0 otherwise
Shock by MVRepair function	= 1 if shock and operation is MVRepair, = 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
Status by MVR function	= 1 if status is emergent or salvage and operation is MVR, = 0 otherwise
Status by MVRepair function	= 1 if status is emergent or salvage and operation is MVRepair, = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Stenosis mitral	= 1 if patient has mitral 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; MVR = mitral valve replacement; MVRepair = mitral valve repair; NYHA = New York Heart Association; PCI = percutaneous coronary intervention;

The final patient-level model was built by step-wise selection method with several variables decided by surgeon panel 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 “90th percentile” below.

<i>Measurement</i>	<i>Risk-Adjusted Operative Mortality for Mitral Valve Replacement Surgery</i>
N	106
Mean	1.0
1 st	2.1
5 th	1.7
10 th	1.4
25 th	1.1
Median	0.9
75 th	0.7
90 th	0.6
95 th	0.5
99 th	0.4
Outlier	9 (8.5)
High	6
Low	3

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:

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

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).

<i>Measurement</i>	<i>Risk-Adjusted Operative Mortality for Mitral Valve Replacement Surgery</i>
N	106
Mean	5.4
1 st	2.3

*Risk-Adjusted Operative Mortality for Mitral Valve
Replacement Surgery*

5 th	3.1
10 th	3.5
25 th	4.2
Median	5.1
75 th	6.3
90 th	7.8
95 th	8.5
99 th	11.1
Outlier	9 (8.5)
High	6
Low	3

1b.4. Summary of Measure Results on Disparities by Population Group *(Descriptive statistics for performance results for this measure by population group)*

<i>Risk-Adjusted Operative Mortality for MV Replacement - Risk Adjusted Rate</i>		
<i>Population Group</i>		
<i>Measurement</i>	<i>Men</i>	<i>Women</i>
N	15*	41
Mean	4.7	5.3
1 st	3.6	2.5
5 th	3.6	3.3
10 th	3.7	3.7
25 th	4.3	4.4
Median	4.5	5.1
75 th	5.6	6.5
90 th	6.0	6.9
95 th	6.4	7.7
99 th	6.4	8.7
Outlier	0 (0.0%)	1 (2.4%)
High	0	1
Low	0	0

**All Participants Measurements when Participants included in the subgroup analysis are 15 or fewer*

<i>Risk-Adjusted Operative Mortality for MV Replacement - Risk Adjusted Rate</i>	
<i>Population Group</i>	
<i>Men</i>	
<i>Participant</i>	
1	3.6
2	3.7
3	4.1
4	4.3
5	4.4
6	4.4
7	4.4
8	4.5
9	4.5

*Risk-Adjusted Operative
Mortality for MV
Replacement - Risk
Adjusted Rate*

*Population
Group*

Men

Participant

10	4.6
11	4.9
12	5.6
13	5.6
14	6.0
15	6.4

*Risk-Adjusted Operative Mortality for MV Replacement–
Risk Adjusted Rate*

Population Group

	<i>Black</i>	<i>White</i>	<i>Other</i>
<i>Measurement</i>			
N	2*	68	3*
Mean	5.9	5.2	5.9
1 st	5.8	3.0	5.6
5 th	5.8	3.4	5.6
10 th	5.8	3.7	5.6
25 th	5.8	4.3	5.6
Median	5.9	5.1	6.0
75 th	5.9	5.7	6.2
90 th	5.9	6.5	6.2
95 th	5.9	7.1	6.2
99 th	5.9	9.6	6.2
Outlier	0 (0.0%)	1 (1.5%)	0 (0.0%)
High	0	1	0
Low	0	0	0

**All Participant Measurements when Participants included in the subgroup analysis are 15 or fewer*

*Risk-Adjusted Operative Mortality for MV
Replacement - Risk Adjusted Rate*

<i>Participant</i>	<i>Population Group</i>	
	<i>Black</i>	<i>Other</i>
1	5.8	5.6
2	5.9	6.0
3	.	6.2

*Risk-Adjusted Operative Mortality for MV
Replacement - Risk Adjusted Rate*

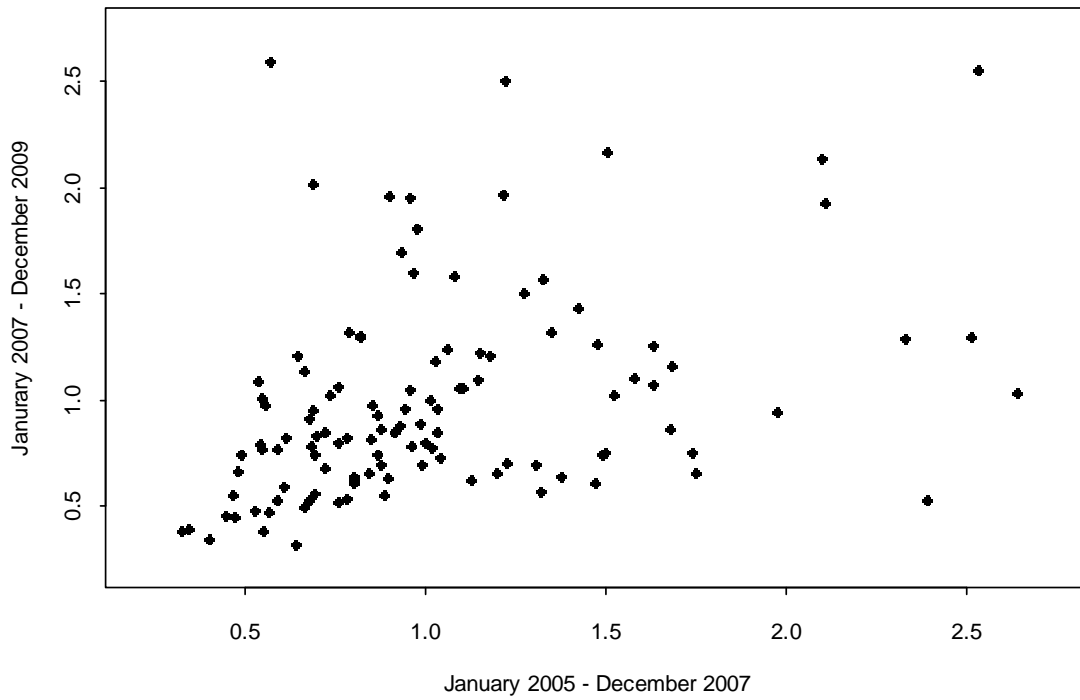
*Population Group
Non-Hispanic*

<i>Measurement</i>	
N	95
Mean	5.5
1 st	2.9
5 th	3.5
10 th	4.2
25 th	4.6
Median	5.4
75 th	6.2
90 th	6.9
95 th	7.9
99 th	9.3
Outlier	3 (3.2%)
High	3
Low	0

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

Testing results: $\rho = 0.37$

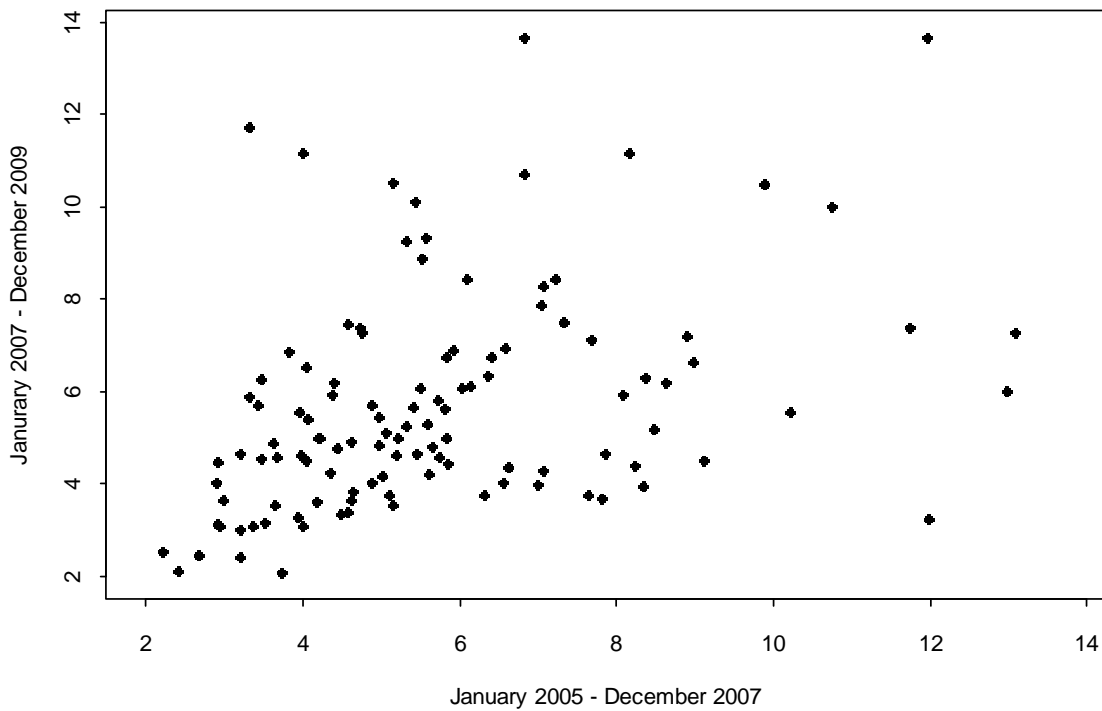
Risk-Adjusted Operative Mortality for Mitral Valve Replacement Surgery ($\rho=0.37$)



Risk Adjusted Rate:

Testing results: $\rho = 0.38$

Risk-Adjusted Operative Mortality for Mitral Valve Replacement Surgery ($\rho=0.38$)



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 meaningful differences in performance*)

Results below are from January 1, 2005-December 31, 2009. Sample contains 106 STS Adult Cardiac Surgery Database Participants who had at least 50 eligible cases for the measure and reported data to STS for at least 36 months in 2005-2009.

<i>Measurement</i>	<i>Risk-Adjusted Operative Mortality for Mitral Valve Replacement Surgery</i>
N	106
Mean	1.0
1 st	2.1
5 th	1.7
10 th	1.4
25 th	1.1
Median	0.9
75 th	0.7
90 th	0.6
95 th	0.5
99 th	0.4
Outlier†	9 (8.5)
High	6
Low	3

Risk Adjusted Rate:

<i>Measurement</i>	<i>Risk-Adjusted Operative Mortality for Mitral Valve Replacement Surgery</i>
N	106
Mean	5.4
1 st	2.3
5 th	3.1
10 th	3.5
25 th	4.2
Median	5.1
75 th	6.3
90 th	7.8
95 th	8.5
99 th	11.1
Outlier†	9 (8.5)
High	6
Low	3

†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 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.

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 participant's annualized volume is calculated as:

$$\text{Participant Annualized Volume} = 12 \times (\# \text{ of surgeries}) / (\# \text{ of months})$$

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 STS Average Annualized Volume is the average value of all of the participant annualized volumes across the entire population of STS participants. The Participant Percentile 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 Distribution of Participant Values 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 “90th 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 Participant Percentile 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 Distribution of Participant Values 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 "90th 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 Observed Participant Rate 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 Distribution of Participant Values 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 "90th 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, 10th percentile, 50th percentile, and 90th percentile. The “Xth” 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.”

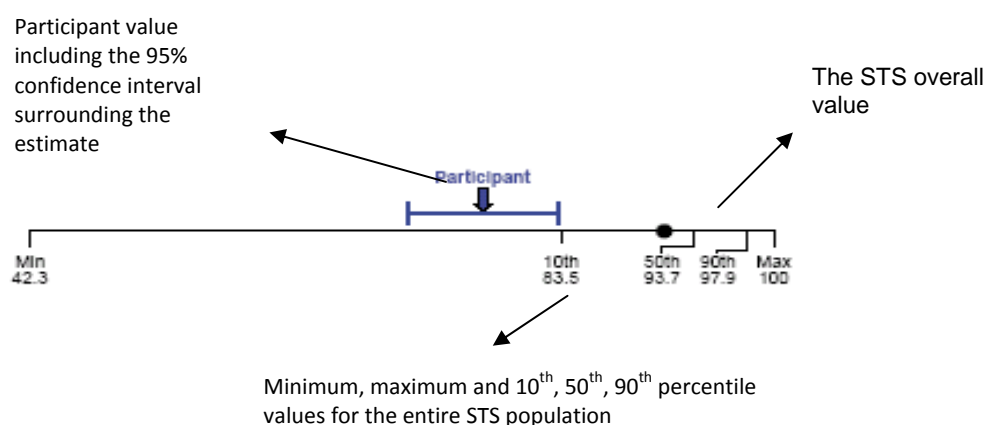
NQF/STS Results Comparison: Participants may see some differences between summaries of their data provided in the NQF section of the report and summaries of their data reported elsewhere in the STS report. These differences are due to subtle variations in variable definitions, patient inclusion and exclusion 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 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 50th 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 50th 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.

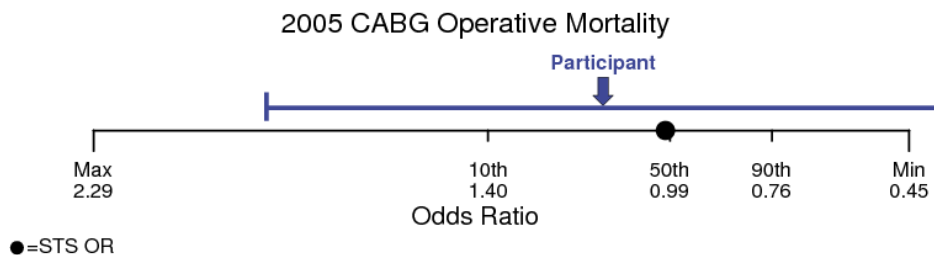
NQF Measure	Eligible Procedures	Participant Estimated OR	Participant Percentile	Participant Observed Rate
2005 CABG Operative Mortality	74	1.14	26.3	5.4%

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
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 ● = Overall STS Usage
Jan 2008 - Dec 2008 Preoperative Beta Blockade Therapy ¹	541	89.3% (86.4 , 91.8)	69.9	82.1%	
Jan 2008 - Dec 2008 Use of IMA ²	536	96.5% (94.5 , 97.9)	63.3	94.2%	
Jan 2008 - Dec 2008 Discharge Anti-Platelet Medication ³	536	98.7% (97.3 , 99.5)	68.7	96.1%	
Jan 2008 - Dec 2008 Discharge Beta Blockade Therapy ⁴	538	96.1% (94.1 , 97.6)	53.4	93.7%	
Jan 2008 - Dec 2008 Discharge Anti-Lipid Treatment ⁴	535	91.8% (89.1 , 94.0)	40.7	91.4%	

¹Excludes v2.61 contraindicated / not indicated records.

²Excludes patients with prior CABG surgery

³Anti-platelet use includes Aspirin and ADP Inhibitors, and excludes in-hospital mortalities. Excludes v2.61 contraindicated / not indicated records.

⁴Excludes in-hospital mortalities. Excludes v2.61 contraindicated / not indicated records.

The Society of Thoracic Surgeons 2008 Cardiac Surgery Risk Models: Part 2—Isolated Valve Surgery

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Background. Adjustment for case-mix is essential when using observational data to compare surgical techniques or providers. That is most often accomplished through the use of risk models that account for preoperative patient factors that may impact outcomes. The Society of Thoracic Surgeons (STS) uses such risk models to create risk-adjusted performance reports for participants in the STS National Adult Cardiac Surgery Database (NCD). Although risk models were initially developed for coronary artery bypass surgery, similar models have now been developed for use with heart valve surgery, particularly as the proportion of such procedures has increased. The last published STS model for isolated valve surgery was based on data from 1994 to 1997 and did not include patients undergoing mitral valve repair. STS has developed new valve surgery models using contemporary data that include both valve repair as well as replacement. Expanding upon existing valve models, the new STS models include several nonfatal complications in addition to mortality.

Methods. Using STS data from 2002 to 2006, isolated valve surgery risk models were developed for operative mortality, permanent stroke, renal failure, prolonged ventilation (> 24 hours), deep sternal wound infection, reoperation for any reason, a major morbidity or mortality composite endpoint, prolonged postoperative length of stay, and short postoperative length of stay. The study population consisted of adult patients who underwent one of three types of valve surgery: isolated aortic valve replacement (n = 67,292), isolated mitral valve replacement (n = 21,229), or isolated mitral valve repair (n = 21,238). The

population was divided into a 60% development sample and a 40% validation sample. After an initial empirical investigation, the three surgery groups were combined into a single logistic regression model with numerous interactions to allow the covariate effects to differ across these groups. Variables were selected based on a combination of automated stepwise selection and expert panel review.

Results. Unadjusted operative mortality (in-hospital regardless of timing, and 30-day regardless of venue) for all isolated valve procedures was 3.4%, and unadjusted in-hospital morbidity rates ranged from 0.3% for deep sternal wound infection to 11.8% for prolonged ventilation. The number of predictors in each model ranged from 10 covariates in the sternal infection model to 24 covariates in the composite mortality plus morbidity model. Discrimination as measured by the c-index ranged from 0.639 for reoperation to 0.799 for mortality. When patients in the validation sample were grouped into 10 categories based on deciles of predicted risk, the average absolute difference between observed versus predicted events within these groups ranged from 0.06% for deep sternal wound infection to 1.06% for prolonged postoperative stay.

Conclusions. The new STS risk models for valve surgery include mitral valve repair as well as multiple endpoints other than mortality. Model coefficients are provided and an online risk calculator is publicly available from The Society of Thoracic Surgeons website.

(Ann Thorac Surg 2009;88:S23–42)

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Models for predicting surgical outcomes on the basis of patient preoperative characteristics are valuable tools for research, quality improvement, and clinical prac-

tice. Such models are used by The Society of Thoracic Surgeons (STS) to produce risk-adjusted performance re-

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Abbreviations and Acronyms

AVR	= aortic valve replacement
CABG	= coronary artery bypass graft surgery
CI	= confidence interval
MI	= myocardial infarction
MVR	= mitral valve replacement
MVRepair	= mitral valve repair
NCD	= National Adult Cardiac Surgery Database
QMTF	= Quality Measurement Task Force
STS	= The Society for Thoracic Surgeons

ports for providers participating in the STS National Adult Cardiac Surgery Database (NCD). They are also used by STS surgeons and other physicians for counseling patients about the risk of surgery.

The earliest STS risk models were developed nearly 2 decades ago for isolated coronary artery bypass graft surgery (CABG). Subsequently, similar models have been developed for isolated valve replacement and combined CABG plus valve replacement. Because surgical practice and outcomes are changing rapidly, these models are updated periodically to reflect contemporary experience.

The last published STS model for isolated valve surgery was based on STS data from 1994 to 1997. The reference population included aortic and mitral valve replacements but excluded mitral valve repair, and the endpoint was operative mortality. In the decade since this model was published, many aspects of heart surgery have changed. First, as CABG volumes have decreased with the introduction of coronary stents, valve surgery as a proportion of overall heart surgery volume has increased in most practices. Between 2000 and 2006, the percentage of isolated CABG procedures decreased from 73% to 60% and the percentage of isolated valve procedures increased from 18% to 22%. Thus, in assessing provider performance, it is no longer sufficient only to consider isolated CABG surgery. Second, the frequency of mitral repair as a percentage of all isolated mitral operations in the STS NCD increased from 35% in 2000 to 53% in 2006. Third, during the same time period, the average mortality rate for isolated aortic or mitral surgery also decreased. Finally, efforts to measure and compare surgical performance have intensified and expanded. In addition to measuring operative mortality, performance reports increasingly focus on nonfatal complications as well as resource utilization and efficiency. Such outcomes have not historically been risk-adjusted for valve surgery.

The STS Quality Measurement Task Force (QMTF) has undertaken a complete revision of all STS risk models for adult cardiac surgery, and these new models were implemented in January 2008. This report, Part 2 of 3, describes the new STS models for isolated valve surgery (Part 1 describes the STS isolated CABG models, and Part 3 describes the models for CABG plus valve surgery). Authors of this report are the QMTF members who were involved in this initiative.

Two important features have been incorporated into these new models. First, the population includes mitral valve repair as well as aortic and mitral valve replacement. Second, in addition to operative mortality, the new models include six nonfatal in-hospital morbidity endpoints and two length-of-stay endpoints. In comparison with several other valve models that have recently been published [1–6], the STS models are distinguished by the large size of the development population and the broad spectrum of endpoints included.

Study Population and Endpoints

The population for this analysis consisted of operations on adult patients aged 20 to 100 years who underwent isolated single aortic or mitral valve surgery between January 1, 2002, and December 31, 2006. Only patients undergoing one of the following procedures were included: (1) isolated aortic valve replacement (AVR); (2) isolated mitral valve replacement (MVR); and (3) isolated mitral valve repair (MVRepair).

Because of the relatively small number of pulmonic, tricuspid, multiple valve procedures, and aortic repairs, these cases were not included in the current models. Patients undergoing concomitant CABG were excluded from the current analysis, but these were included in the separate STS valve plus CABG models described in Part 3 of this series. Records with missing data on sex ($n = 44$) were excluded because missing sex is not allowed in the analysis dataset used for creating STS database participant feedback reports. This left a final study population of 109,759 patient operations performed at 809 STS NCD participating groups. Patients on dialysis preoperatively ($n = 2,699$) were not included when developing the risk model for prediction of postoperative renal failure.

Patient characteristics in the study population are presented in Table 1.

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 nine endpoints, identical to those in the STS CABG models. In contrast with the definition of operative mortality, which includes hospital deaths as well as deaths that occur after discharge within 30 days of surgery, the morbidity endpoints only include events that occurred before discharge. However, beginning with version 2.61, sternal infection data will be recorded for as long as 30 days postoperatively. The nine endpoints are as follows: (1) operative mortality: death during the same

Table 1. Distribution of Risk Factors in Overall Study Population Isolated Valve (2002–2006)

Variable	Overall Valve (n = 109,759)		AVR (n = 67,292)		MVR (n = 21,229)		MVRepair (n = 21,238)	
	N	%	N	%	N	%	N	%
Demographics								
Age, years								
< 55	28,147	25.6	13,227	19.66	6,601	31.09	8,319	39.17
55–64	23,258	21.2	12,987	19.30	4,833	22.77	5,438	25.61
65–74	28,145	25.6	18,299	27.19	5,294	24.94	4,552	21.43
≥75	30,209	27.5	22,779	33.85	4,501	21.20	2,929	13.79
Sex								
Male	60,752	55.4	39,209	58.27	9,055	42.65	12,488	58.80
Female	49,007	44.6	28,083	41.73	12,174	57.35	8,750	41.20
Race								
Caucasian	93,522	85.2	58,656	87.17	16,810	79.18	18,056	85.02
Black	7,630	7.0	3,555	5.28	2,383	11.23	1,692	7.97
Hispanic	3,680	3.4	2,344	3.48	889	4.19	447	2.10
Asian	1,538	1.4	719	1.07	437	2.06	382	1.80
Other	2,493	2.3	1,508	2.24	505	2.38	480	2.26
Missing	896	0.8	510	0.76	205	0.97	181	0.85
Risk factors								
Body surface area, m ²								
< 1.50	4,351	4.0	2,341	3.48	1,234	5.81	776	3.65
1.50–1.74	24,577	22.4	13,713	20.38	6,151	28.97	4,713	22.19
1.75–1.99	40,548	36.9	24,744	36.77	7,914	37.28	7,890	37.15
≥ 2.00	39,517	36.0	26,007	38.65	5,768	27.17	7,742	36.45
Missing	766	0.7	487	0.72	162	0.76	117	0.55
Body mass index, kg/m ²								
< 25	35,526	32.4	18,509	27.51	8,447	39.79	8,570	40.35
25–29	39,074	35.6	24,035	35.72	6,992	32.94	8,047	37.89
30–34	20,534	18.7	14,142	21.02	3,318	15.63	3,074	14.47
≥ 35	13,682	12.5	10,008	14.87	2,280	10.74	1,394	6.56
Missing	943	0.9	598	0.89	192	0.90	153	0.72
Diabetes mellitus								
No diabetes	88,709	80.8	52,052	77.35	17,535	82.60	19,122	90.04
Diabetes, noninsulin	14,900	13.6	11,026	16.39	2,412	11.36	1,462	6.88
Diabetes, insulin	5,788	5.3	3,974	5.91	1,216	5.73	598	2.82
Diabetes missing	138	0.1	91	0.14	34	0.16	13	0.06
Treatment missing	224	0.2	149	0.22	32	0.15	43	0.20
Hypertension								
No	41,649	37.9	22,338	33.20	8,859	41.73	10,452	49.21
Yes	67,886	61.9	44,816	66.60	12,326	58.06	10,744	50.59
Missing	224	0.2	138	0.21	44	0.21	42	0.20
Hypercholesterolemia								
No	59,003	53.8	33,156	49.27	12,857	60.56	12,990	61.16
Yes	50,328	45.9	33,865	50.33	8,286	39.03	8,177	38.50
Missing	428	0.4	271	0.40	86	0.41	71	0.33
Past or present smoker								
No	57,609	52.5	33,953	50.46	11,075	52.17	12,581	59.24
Yes	51,910	47.3	33,191	49.32	10,109	47.62	8,610	40.54
Missing	240	0.2	148	0.22	45	0.21	47	0.22
Chronic lung disease								
None	87,826	80.0	53,503	79.51	16,125	75.96	18,198	85.69
Mild	11,184	10.2	6,991	10.39	2,520	11.87	1,673	7.88
Moderate	6,346	5.8	4,022	5.98	1,494	7.04	830	3.91
Severe	3,332	3.0	2,110	3.14	853	4.02	369	1.74
Missing	1,071	1.0	666	0.99	237	1.12	168	0.79

Table 1. Continued

Variable	Overall Valve (n = 109,759)		AVR (n = 67,292)		MVR (n = 21,229)		MVRepair (n = 21,238)	
	N	%	N	%	N	%	N	%
Peripheral vascular disease								
No	101,129	92.1	61,222	90.98	19,550	92.09	20,357	95.85
Yes	8,381	7.6	5,909	8.78	1,641	7.73	831	3.91
Missing	249	0.2	161	0.24	38	0.18	50	0.24
Cerebrovascular disease								
No	96,852	88.2	58,983	87.65	18,158	85.53	19,711	92.81
Yes	12,661	11.5	8,147	12.11	3,033	14.29	1,481	6.97
Missing	246	0.2	162	0.24	38	0.18	46	0.22
CVA								
No CVA	101,631	92.6	62,518	92.91	18,833	88.71	20,280	95.49
Remote CVA (> 2 weeks)	6,926	6.3	4,203	6.25	1,912	9.01	811	3.82
Recent CVA (≤ 2 weeks)	818	0.7	325	0.48	409	1.93	84	0.40
CVA—missing timing	100	0.1	60	0.09	29	0.14	11	0.05
Missing	284	0.3	186	0.28	46	0.22	52	0.24
Endocarditis								
No endocarditis	100,998	92.0	63,257	94.00	17,926	84.44	19,815	93.30
Treated endocarditis	4,197	3.8	1,761	2.62	1,445	6.81	991	4.67
Active endocarditis	4,238	3.9	2,068	3.07	1,791	8.44	379	1.78
Endocarditis—missing type	63	0.1	30	0.04	27	0.13	6	0.03
Missing	263	0.2	176	0.26	40	0.19	47	0.22
Renal failure								
No	102,205	93.1	62,873	93.43	19,016	89.58	20,316	95.66
Yes	7,305	6.7	4,251	6.32	2,173	10.24	881	4.15
Missing	249	0.2	168	0.25	40	0.19	41	0.19
Renal function								
Creatinine < 1.00 mg/dL	42,028	38.3	25,679	38.16	7,754	36.53	8,595	40.47
Creatinine 1–1.49 mg/dL	51,939	47.3	32,058	47.64	9,372	44.15	10,509	49.48
Creatinine 1.50–1.99 mg/dL	8,081	7.4	5,078	7.55	1,875	8.83	1,128	5.31
Creatinine 2.00–2.49 mg/dL	1,946	1.8	1,192	1.77	512	2.41	242	1.14
Creatinine ≥ 2.50 mg/dL	1,294	1.2	750	1.11	390	1.84	154	0.73
Dialysis	2,699	2.5	1,464	2.18	900	4.24	335	1.58
Missing	1,772	1.6	1,071	1.59	426	2.01	275	1.29
Immunosuppressive treatment								
No	106,037	96.6	64,953	96.52	20,356	95.89	20,728	97.60
Yes	3,336	3.0	2,074	3.08	819	3.86	443	2.09
Missing	386	0.4	265	0.39	54	0.25	67	0.32
Previous CV interventions								
Previous coronary artery bypass surgery								
No	98,978	90.2	60,351	89.69	18,564	87.45	20,063	94.47
Yes	10,399	9.5	6,713	9.98	2,569	12.10	1,117	5.26
Missing	382	0.3	228	0.34	96	0.45	58	0.27
Previous valve surgery								
No	100,179	91.3	62,898	93.47	16,857	79.41	20,424	96.17
Yes	9,227	8.4	4,186	6.22	4,285	20.18	756	3.56
Missing	353	0.3	208	0.31	87	0.41	58	0.27
Previous other cardiac surgery								
No	105,686	96.3	65,084	96.72	20,034	94.37	20,568	96.85
Yes	3,662	3.3	1,975	2.93	1,077	5.07	610	2.87
Missing	411	0.4	233	0.35	118	0.56	60	0.28
Number of previous CV surgeries								
No prior CV surgery	91,196	83.1	56,629	84.15	15,239	71.78	19,328	91.01
1 prior CV surgery	15,399	14.0	9,122	13.56	4,775	22.49	1,502	7.07
2 or more prior CV surgeries	2,653	2.4	1,260	1.87	1,069	5.04	324	1.53
Missing	511	0.5	281	0.42	146	0.69	84	0.40

Table 1. Continued

Variable	Overall Valve (n = 109,759)		AVR (n = 67,292)		MVR (n = 21,229)		MVRepair (n = 21,238)	
	N	%	N	%	N	%	N	%
Prior PCI								
No PCI	101,878	92.8	62,145	92.35	19,573	92.20	20,160	94.92
PCI within 6 hours	122	0.1	58	0.09	51	0.24	13	0.06
PCI not within 6 hours	7,100	6.5	4,678	6.95	1,447	6.82	975	4.59
PCI-missing timing	133	0.1	90	0.13	28	0.13	15	0.07
Missing	526	0.5	321	0.48	130	0.61	75	0.35
Preoperative cardiac status								
Acuity status								
Elective	84,052	76.6	51,734	76.88	14,293	67.33	18,025	84.87
Urgent	23,795	21.7	14,670	21.80	6,071	28.60	3,054	14.38
Emergent	1,555	1.4	685	1.02	747	3.52	123	0.58
Emergent salvage	154	0.1	70	0.10	78	0.37	6	0.03
Missing	203	0.2	133	0.20	40	0.19	30	0.14
MI								
No prior MI	99,416	90.6	60,850	90.43	18,716	88.16	19,850	93.46
MI > 21 days	7,785	7.1	4,770	7.09	1,848	8.71	1,167	5.49
MI 8-21 days	719	0.7	480	0.71	170	0.80	69	0.32
MI 1-7 days	1,247	1.1	863	1.28	315	1.48	69	0.32
MI > 6 and < 24 hours	142	0.1	61	0.09	66	0.31	15	0.07
MI ≤ 6 hours	90	0.1	42	0.06	40	0.19	8	0.04
MI-missing timing	127	0.1	79	0.12	33	0.16	15	0.07
Missing	233	0.2	147	0.22	41	0.19	45	0.21
Angina								
No	85,364	77.8	49,573	73.67	17,598	82.90	18,193	85.66
Yes	24,164	22.0	17,577	26.12	3,591	16.92	2,996	14.11
Missing	231	0.2	142	0.21	40	0.19	49	0.23
Cardiogenic shock								
No	108,163	98.5	66,646	99.04	20,460	96.38	21,057	99.15
Yes	1,329	1.2	485	0.72	725	3.42	119	0.56
Missing	267	0.2	161	0.24	44	0.21	62	0.29
Resuscitation								
No	108,958	99.3	66,832	99.32	20,992	98.88	21,134	99.51
Yes	533	0.5	297	0.44	186	0.88	50	0.24
Missing	268	0.2	163	0.24	51	0.24	54	0.25
Arrhythmia								
No arrhythmia	89,779	81.8	57,451	85.38	14,604	68.79	17,724	83.45
AFib/flutter	16,124	14.7	7,569	11.25	5,721	26.95	2,834	13.34
Heart block	1,598	1.5	1,109	1.65	315	1.48	174	0.82
Sustained VT/VF	984	0.9	486	0.72	290	1.37	208	0.98
Arrhythmia-other	688	0.6	324	0.48	175	0.82	189	0.89
Arrhythmia-missing type	312	0.3	175	0.26	74	0.35	63	0.30
Missing	274	0.2	178	0.26	50	0.24	46	0.22
Preoperative IABP								
No	107,945	98.3	66,733	99.17	20,332	95.77	20,880	98.31
Yes	1,431	1.3	342	0.51	809	3.81	280	1.32
Missing	383	0.3	217	0.32	88	0.41	78	0.37
NYHA class								
I	17,413	15.9	10,222	15.19	2,706	12.75	4,485	21.12
II	32,360	29.5	20,295	30.16	4,915	23.15	7,150	33.67
III	40,321	36.7	25,483	37.87	8,205	38.65	6,633	31.23
IV	14,324	13.1	8,104	12.04	4,256	20.05	1,964	9.25
Missing	5,341	4.9	3,188	4.74	1,147	5.40	1,006	4.74

Table 1. Continued

Variable	Overall Valve (n = 109,759)		AVR (n = 67,292)		MVR (n = 21,229)		MVRepair (n = 21,238)	
	N	%	N	%	N	%	N	%
Congestive heart failure								
No	64,608	58.9	41,972	62.37	9,341	44.00	13,295	62.60
Yes	44,934	40.9	25,185	37.43	11,849	55.82	7,900	37.20
Missing	217	0.2	135	0.20	39	0.18	43	0.20
Number of diseased coronary vessels								
None	90,281	82.3	55,072	81.84	17,525	82.55	17,684	83.27
One	8,947	8.2	5,393	8.01	1,498	7.06	2,056	9.68
Two	3,386	3.1	2,180	3.24	735	3.46	471	2.22
Three	5,611	5.1	3,766	5.60	1,147	5.40	698	3.29
Missing	1,534	1.4	881	1.31	324	1.53	329	1.55
Left main disease \geq 50%								
No	106,462	97.0	65,328	97.08	20,495	96.54	20,639	97.18
Yes	1,625	1.5	1,127	1.67	289	1.36	209	0.98
Missing	1,672	1.5	837	1.24	445	2.10	390	1.84
Ejection fraction, %								
< 25	2,694	2.5	1,774	2.64	341	1.61	579	2.73
25–34	5,900	5.4	3,810	5.66	1,052	4.96	1,038	4.89
35–44	10,035	9.1	6,181	9.19	2,208	10.40	1,646	7.75
45–54	20,481	18.7	12,411	18.44	4,382	20.64	3,688	17.37
\geq 55	60,890	55.5	36,584	54.37	11,308	53.27	12,998	61.20
Missing	9,759	8.9	6,532	9.71	1,938	9.13	1,289	6.07
Aortic stenosis								
No	54,457	49.6	13,309	19.78	20,303	95.64	20,845	98.15
Yes	54,681	49.8	53,722	79.83	696	3.28	263	1.24
Missing	621	0.6	261	0.39	230	1.08	130	0.61
Mitral stenosis								
No	100,609	91.7	65,186	96.87	15,383	72.46	20,040	94.36
Yes	8,155	7.4	1,401	2.08	5,676	26.74	1,078	5.08
Missing	995	0.9	705	1.05	170	0.80	120	0.57
Tricuspid stenosis								
No	108,073	98.5	66,243	98.44	20,821	98.08	21,009	98.92
Yes	331	0.3	152	0.23	120	0.57	59	0.28
Missing	1,355	1.2	897	1.33	288	1.36	170	0.80
Pulmonic stenosis								
No	107,512	98.0	65,842	97.85	20,783	97.90	20,887	98.35
Yes	141	0.1	91	0.14	29	0.14	21	0.10
Missing	2,106	1.9	1,359	2.02	417	1.96	330	1.55
Aortic insufficiency								
None	59,905	54.6	25,861	38.43	16,701	78.67	17,343	81.66
Trivial	9,191	8.4	5,916	8.79	1,661	7.82	1,614	7.60
Mild	13,282	12.1	10,014	14.88	1,798	8.47	1,470	6.92
Moderate	9,501	8.7	8,815	13.10	382	1.80	304	1.43
Severe	15,722	14.3	15,529	23.08	109	0.51	84	0.40
Missing	2,158	2.0	1,157	1.72	578	2.72	423	1.99
Mitral insufficiency								
None	43,731	39.8	40,453	60.12	2,283	10.75	995	4.68
Trivial	7,743	7.1	7,285	10.83	388	1.83	70	0.33
Mild	14,455	13.2	13,066	19.42	1,089	5.13	300	1.41
Moderate	10,224	9.3	4,438	6.60	3,246	15.29	2,540	11.96
Severe	31,813	29.0	573	0.85	14,045	66.16	17,195	80.96
Missing	1,793	1.6	1,477	2.19	178	0.84	138	0.65

Table 1. Continued

Variable	Overall Valve (n = 109,759)		AVR (n = 67,292)		MVR (n = 21,229)		MVRepair (n = 21,238)	
	N	%	N	%	N	%	N	%
Tricuspid insufficiency								
None	78,472	71.5	49,976	74.27	14,266	67.20	14,230	67.00
Trivial	8,856	8.1	5,612	8.34	1,381	6.51	1,863	8.77
Mild	13,346	12.2	7,333	10.90	2,788	13.13	3,225	15.19
Moderate	5,167	4.7	2,126	3.16	1,753	8.26	1,288	6.06
Severe	974	0.9	297	0.44	460	2.17	217	1.02
Missing	2,944	2.7	1,948	2.89	581	2.74	415	1.95
Pulmonic insufficiency								
None	97,954	89.2	60,463	89.85	18,837	88.73	18,654	87.83
Trivial	4,161	3.8	2,370	3.52	779	3.67	1,012	4.77
Mild	2,541	2.3	1,340	1.99	573	2.70	628	2.96
Moderate	441	0.4	209	0.31	144	0.68	88	0.41
Severe	76	0.1	34	0.05	30	0.14	12	0.06
Missing	4,586	4.2	2,876	4.27	866	4.08	844	3.97

AFib = atrial fibrillation; AVR = aortic valve replacement; CV = cardiovascular; CVA = cerebrovascular accident (stroke); IABP = intra-aortic balloon pump; MI = myocardial infarction; MVR = mitral valve replacement; MVRepair = mitral valve repair; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; VF = ventricular fibrillation; VT = ventricular tachycardia.

hospitalization as surgery, regardless of timing, or within 30 days of surgery regardless of venue; (2) permanent stroke (cerebrovascular accident [CVA]): 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 greater 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.

Table 2 summarizes the endpoint frequencies in the study population.

Single Versus Multiple Models

Two issues required particularly careful consideration: whether to construct separate models for the AVR and MVR populations, and how best to further subdivide the mitral population into repair versus replacement.

Because of the large size of the STS NCD, separate

Table 2. Frequency of Endpoints in Overall Study Population 2002 to 2006

	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
All isolated valve (AVR, MVR, MVRepair)									
N	109,759	109,759	107,060	109,759	109,759	109,759	109,759	109,759	109,759
Events	3,706	1,751	4,673	12,892	307	9,164	20,074	9,718	41,214
%	3.4	1.6	4.3	11.8	0.3	8.4	18.3	8.9	37.6
AVR									
N	67,292	67,292	65,828	67,292	67,292	67,292	67,292	67,292	67,292
Events	2,157	1,007	2,774	7,323	197	5,369	11,706	5,308	26,144
%	3.2	1.5	4.1	10.9	0.3	8.0	17.4	7.9	38.9
MVR									
N	21,229	21,229	20,329	21,229	21,229	21,229	21,229	21,229	21,229
Events	1,210	447	1,348	4,015	71	2,450	5,675	3,244	4,727
%	5.7	2.1	6.4	18.9	0.3	11.5	26.7	15.3	22.3
MVRepair									
N	21,238	21,238	20,903	21,238	21,238	21,238	21,238	21,238	21,238
Events	339	297	551	1,554	39	1,345	2,693	1,166	10,343
%	1.6	1.4	2.6	7.3	0.2	6.3	12.7	5.5	48.7

AVR = aortic valve replacement; Comp = composite adverse event (any); CVA = cerebrovascular accident (stroke); DSWI = deep sternal wound infection; Mort = mortality; MVR = mitral valve replacement; MVRepair = mitral valve repair; PLOS = prolonged length of stay; Reop = reoperation; RF = renal failure; SLOS = short length of stay; Vent = prolonged ventilation.

models for AVR, MVR, and MVRRepair initially seemed both feasible and appropriate. However, because the endpoints of interest are rare events, we recognized the possibility that the number of such events would be too small to support reliable estimation of the model coefficients.

To assess this tradeoff, we conducted a pilot study to compare two alternative strategies for developing risk models for isolated valve surgery. The first strategy involved developing models separately for three subpopulations (AVR, MVR, and MVRRepair). The second strategy involved modeling all three subpopulations together in a single model; several interaction terms were included to allow the effect of selected risk factors to differ across the subpopulations. Both strategies were pilot tested by developing risk models for two endpoints: operative mortality and permanent stroke. These pilot models were developed in a 60% development sample and tested in a separate 40% validation sample. Each model was assessed by calculating the c-index and the generalized R^2 index of Nagelkerke [7] in the validation sample for each combination of subpopulation and endpoint (3 subpopulations \times 2 endpoints = 6 combinations). With the exception of AVR operative mortality, the combined model with interactions resulted in better discrimination. With the exception of MVR and MVRRepair operative mortality, the combined model also captured more variation as measured by the generalized R^2 statistic.

Because the combined model strategy performed better in the majority of cases, and because a single combined model was consistent with the previous STS valve model, the combined model strategy was selected. To avoid assuming that the weighting of each risk factor was exactly constant across the three populations, we included interactions between surgery type and several key predictor variables. In principle, fitting a single model with several interactions is advantageous because it allows for pooling information across related groups without making an a priori assumption that all of the covariate effects are exactly constant across groups.

Selection of Candidate Predictor Variables

Our general approach to variable selection is discussed in Part 1 of this series describing the development of the 2008 STS isolated CABG risk models. Briefly, we initially identified potential candidate variables by reviewing four versions of the STS data collection instrument (data versions 2.35, 2.41, 2.52.1, and 2.61) as well as previously published STS and similar cardiac risk models [1–6]. A panel of cardiac surgeons and health policy experts reviewed the initial variables for face validity and to be certain that no important predictor variables available in (or mappable to) STS NCD data version 2.61 had been excluded.

Final candidate explanatory variables and their coding are summarized in Table 3. The variables were identical to the CABG model candidate variables with the following differences: (1) percutaneous coronary intervention conducted within 6 hours or less of surgery was not a candidate variable because it was present in only 122 patients (0.1%) in the valve model population; (2) infec-

tious endocarditis was included. This risk factor was rarely present among isolated CABG patients (0.09%), but was not uncommon (7.7%) among patients undergoing valve surgery; (3) mitral stenosis was included; this risk factor was rarely present among isolated CABG patients (0.35%) but was common (7.4%) among patients undergoing valve surgery; and (4) an indicator for surgery type (AVR, MVR, MVRRepair) was included in the valve models.

Coding of Explanatory Variables

The coding of continuous and categorical variables was identical to the CABG models, except for the following differences: (1) age was modeled as a linear spline truncated from below at 50 years and with a change of slope at 75; (2) creatinine was modeled as a linear term with values less than 0.5 and greater than 5.0 mapped to those values respectively (approximately the 1st and 99th percentiles of the empirical distribution); (3) previous myocardial infarction (MI) was modeled as three categories (< 24 hours, 1 to 21 days, and > 21 days or no MI); the first two categories were subsequently combined after expert panel review; (4) race was modeled as three categories: black, Hispanic, Caucasian/other; and (5) chronic lung disease was modeled as linear across four categories (none, mild, moderate, severe).

In general, these differences reflect a slightly simpler coding scheme (fewer parameters) for the valve models compared with the isolated CABG models.

Repair Versus Replacement

In addition to a number of variables whose inclusion or coding were noted to be problematic during development of the 2008 STS isolated CABG models (Part 1 of this series), the approach to modeling mitral valve repair versus replacement was of some concern in the valve models. From a methodologic perspective, models used for risk-adjustment should include all patient preoperative risk factors that vary in prevalence between institutions and that substantially impact the probability of an adverse outcome. Such models should include variables that reflect the patient's baseline condition but should not include intraoperative events (eg, unexpected hemorrhage) or discretionary care processes (eg, use of a mechanical versus bioprosthetic valve). Adjusting for intraoperative events is not appropriate because these may be a reflection of the surgeon's performance. Adjusting for discretionary care processes may likewise mask differences in performance if the surgeon's choice of procedures has a substantial impact on outcomes. The same patient may receive valve repair if treated by one surgeon and replacement if treated by another. Adjusting for repair versus replacement will potentially conceal the outcomes of surgeons who achieve excellent results by repairing technically challenging valves that might otherwise be replaced if treated by a surgeon with less skill or tenacity. Importantly, there is considerable evidence to suggest the superiority of valve repair whenever feasible.

However, in addition to such discretionary factors, the decision to repair rather than replace the mitral valve is

Table 3. List of Final Candidate Variables and Their Coding for STS Valve Models

Candidate Variables	Coding
Continuous variables	
Age ^a	Linear spline truncated from below at 50 and with knot at 75
Ejection fraction	Linear, values > 50 mapped to 50
Body surface area ^a	Quadratic polynomial modeled separately for males and females. Note: body surface area < 1.4 and > 2.6 mapped to those values, respectively.
Creatinine	Linear (only for patients not on dialysis). Note: creatinine < 0.5 and > 5.0 mapped to those values, respectively.
Time trend ^a	Ordinal categorical variable with separate category for each 6-month harvest interval. Modeled as linear across categories.
Binary variables	
Active infectious endocarditis	Yes/no
Dialysis	Yes/no
Preoperative atrial fibrillation	Yes/no
Shock	Yes/no
Female ^a	Yes/no
Hypertension	Yes/no
Immunosuppressive treatment	Yes/no
Preoperative IABP or inotropes	Yes/no
Peripheral vascular disease	Yes/no
Unstable angina (no MI < 7 days)	Yes/no
Left main disease	Yes/no
Aortic stenosis	Yes/no
Mitral 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	Modeled as linear across categories (none, mild, moderate, severe)
CVD/CVA	3 groups: no CVD, CVD no CVA, CVD + CVA
Diabetes mellitus	3 groups: insulin diabetes, noninsulin diabetes, other or no diabetes
Number diseased coronary vessels	3 groups: < 2, 2, 3. Modeled as linear across the categories
MI	3 groups: < 24 hr, 1–21 days, > 21 days or no MI (groups 1 and 2 were subsequently collapsed)
Race	3 groups: Black; Hispanic; Other including Caucasian
Status	4 groups: elective, urgent, emergent—no resuscitation, salvage or emergent with resuscitation
Previous cardiovascular operations	3 groups: 0 previous, 1 previous, ≥2 previous
CHF and NYHA class	3 groups: no CHF, CHF not NYHA IV, CHF+NYHA IV
Surgery type	3 groups: AVR, MVR, MVRRepair
Interaction terms	
Age by reoperation ^a	
Age by emergent status ^a	
Surgery type by each of the following:	Age, diabetes, dialysis, creatinine, reoperation, endocarditis, emergent status, CLD, CHF, EF, sex, shock, IABP/inotropes, mitral insufficiency, aortic insufficiency, mitral stenosis, aortic stenosis

^a These variables were forced into each model.

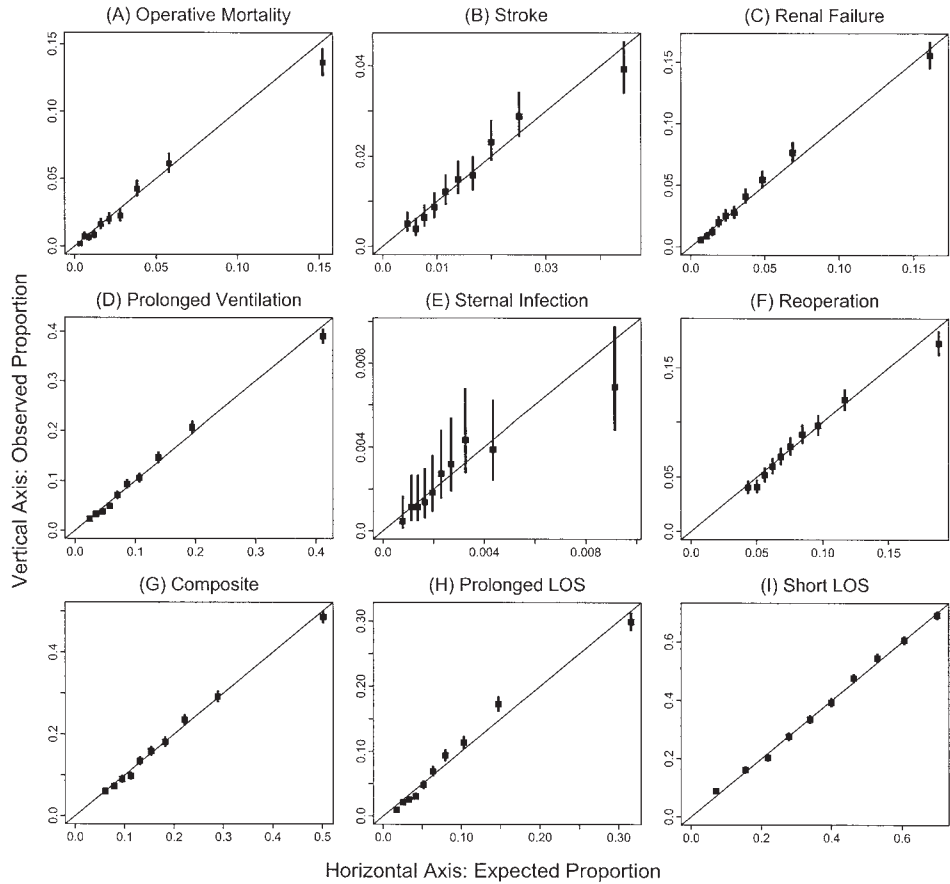
AVR = aortic valve replacement; CHF = congestive heart failure; CLD = chronic lung disease; CVA = cerebrovascular accident (stroke); CVD = cardiovascular disease; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; MVR = mitral valve replacement; MVRRepair = mitral valve repair; NYHA = New York Heart Association.

also dependent upon the patient's preoperative valve disease etiology, anatomy, and pathophysiology. On average, patients amenable to valve repair have less extensive valve pathology and a relatively favorable postoperative prognosis (the mortality rate for valve repair is 1.6%

compared with 5.7% for replacement). Ignoring these anatomical differences can introduce bias when comparing institutions, especially because these variables are not captured elsewhere on the STS data collection form.

A related difficulty in adjusting for repair versus re-

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



placement is that the former approach may sometimes be abandoned intraoperatively by the surgeon and converted to MVR. That may sometimes occur because of unforeseen technical problems that would prevent most surgeons from completing the repair, but in other instances, a more skilled surgeon might persist and achieve successful valve repair. Effectively separating these two scenarios is problematic from available data.

Ultimately, it was elected to include an indicator for mitral valve repair versus replacement in the valve risk models, consistent with the approach in a number of existing valve surgery models. We acknowledge that available data make it impossible to determine whether patient differences or surgical skill and judgment are the most important factors in determining between-provider variation in the proportion of valves repaired.

Recognizing the potential limitations of this modeling approach, the decision to adjust for repair versus replacement may be reassessed in future versions of the STS risk models. Beginning with data in version 2.61, the database will capture whether or not repair was attempted, and repair versus replacement may be analyzed based on an intention-to-treat principle.

Missing Data

Model variables with more than 1% missing data in the study sample were ejection fraction (8.9%), NYHA class

(4.9%), tricuspid insufficiency (2.7%), aortic insufficiency (2.0%), mitral insufficiency (1.6%), left main disease (1.5%), creatinine/dialysis (1.6%), and number of diseased vessels (1.4%). The method of imputing missing data was identical to that employed in the isolated CABG models and described in Part 1 of this series. Briefly, binary risk factors were modeled as yes versus no or missing (ie, missing values were analyzed as if the endpoint did not occur). Missing data on categorical variables were imputed to the lowest risk value, typically the mode, and outcomes were typically similar for missing data and lowest risk patients. Missing data on continuous variables were imputed by grouping patients into strata and assigning the stratum-specific median value. For example, ejection fraction was imputed by grouping on sex and congestive heart failure and calculating the median ejection fraction among patients with nonmissing ejection fraction in each group.

Although multiple imputation is generally preferable to single imputation [8], single imputation was chosen for this analysis mainly because of practical considerations. Furthermore, because of the small fraction of missing data, the impact of single versus multiple imputation was considered to be inconsequential. Subsequent sensitivity analyses confirmed that the choice between single versus multiple imputation had little impact on the final regression coefficients, risk estimates, and confidence intervals. A summary of these sensitivity analyses, including coef-

Table 4. Discrimination of Models in Development and Validation Samples

	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Overall									
Development sample	0.805	0.694	0.782	0.770	0.704	0.643	0.721	0.770	0.738
Validation sample	0.799	0.691	0.762	0.762	0.659	0.639	0.718	0.773	0.734
AVR									
Development sample	0.779	0.679	0.766	0.748	0.710	0.630	0.698	0.752	0.713
Validation sample	0.759	0.689	0.749	0.736	0.637	0.619	0.694	0.759	0.713
MVR									
Development sample	0.794	0.679	0.767	0.772	0.591	0.642	0.735	0.748	0.726
Validation sample	0.802	0.702	0.748	0.772	0.656	0.634	0.738	0.729	0.710
MVRepair									
Development sample	0.855	0.736	0.813	0.765	0.774	0.616	0.703	0.777	0.733
Validation sample	0.844	0.672	0.788	0.773	0.714	0.646	0.712	0.800	0.725

AVR = aortic valve replacement; Comp = composite adverse event (any); CVA = cerebrovascular accident (stroke); DSWI = deep sternal wound infection; Mort = mortality; MVR = mitral valve replacement; MVRepair = mitral valve repair; PLOS = prolonged length of stay; Reop = reoperation; RF = renal failure; SLOS = short length of stay; Vent = prolonged ventilation.

ficients and covariance matrices, is available at www.sts.org/riskmodels.

Final Variable Selection Procedure

Variables were initially selected using an automated stepwise model selection algorithm. The stepwise procedure began with a model that included all of the final candidate variables except for interaction terms. Age, sex, body surface area, and month of surgery were forced into each model. Other variables were selected in a stepwise fashion using a significance criterion of 0.05 for entry and removal. This criterion was less stringent than that employed in development of the CABG models, because the sample size in the former was so much larger than that which was used for the valve models. The stepwise procedure was performed separately for each endpoint. The results were then reviewed by an expert panel of surgeons, and the following changes were made based on their feedback: (1) "MI less than 24 hours" and "MI 1 to 21 days" were collapsed into a single category; (2) preoperative atrial fibrillation was forced into the model for stroke (CVA); and (3) an indicator variable for dialysis was forced into any model that included creatinine level.

Interaction Terms

In addition to including main effects, we tested the interaction between surgery group (AVR, MVR, MVRepair) and each of the following variables: age, diabetes mellitus, dialysis, creatinine, reoperation, endocarditis, emergent status, chronic lung disease, congestive heart failure, ejection fraction, sex, shock, intra-aortic balloon pump/inotropes, mitral insufficiency, aortic insufficiency, mitral stenosis, and aortic stenosis. These interaction terms allowed the effect of these selected risk factors to differ across the surgery populations.

Four additional sets of interactions were also included in the models: (1) sex by body surface area (BSA); (2) sex by BSA²; (3) age by reoperation; and (4) age by emergent status. These interaction terms were preselected and were

not tested as part of the backward selection algorithm. Additional technical details are provided in the Appendix. For reasons described in Part 1 of this series (isolated CABG risk models), an extensive automated search for additional interaction terms was not conducted.

Adjustment for Time Trends

Surgery date was included in each model to adjust for changes in the frequency of adverse outcomes over the 5-year study period. Although surgery date is not itself a variable of interest, we adjusted for it to reduce potential confounding by time trends when estimating regression coefficients for the variables that are of primary interest (ie, patient preoperative risk factors). An example is provided in Part 1 of this series.

Surgery date was categorized into 6-month intervals (corresponding to the biannual STS data harvests) and modeled as a linear trend across the ordinal categories. Because it is a nuisance variable, surgery date is not included in the final risk prediction algorithm. Thus, a patient's predicted risk does not depend on the patient's surgery date. As described in the Appendix, the published intercept parameter has been adjusted to incorporate the time trend. The adjusted intercept reflects the baseline risk for a reference period of July to December 2006.

Results

Assessment of Model Fit and Discrimination

Because of the relatively large size of our sample, the Hosmer-Lemeshow test is uninformative and would invariably result in a significant *p* value [9]. As an alternative, model fit was assessed graphically by plotting observed versus predicted rates of each endpoint across deciles of predicted risk in the development and validation samples. This was done in the overall population and in subgroups based on surgery type (AVR, MVR, MVRepair); age (< 60, 60 to 79, ≥ 80 years); sex (male, female); diabetes mellitus (yes/no); status (elective, nonelective); and ejection fraction

Table 5. Odds Ratios (95% Confidence Intervals) for the Final Selected Models

A. Odds ratios for variables that do not interact with surgery group

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Preoperative AFib	1.20 (1.10, 1.31)	1.06 (0.93, 1.20)	NA	1.18 (1.11, 1.25)	NA	1.11 (1.04, 1.18)	1.12 (1.07, 1.18)	1.17 (1.10, 1.24)	0.74 (0.70, 0.78)
BSA 1.6 versus 2.0 among females	1.19 (1.09, 1.30)	1.18 (1.03, 1.35)	0.95 (0.87, 1.04)	1.15 (1.08, 1.22)	0.42 (0.27, 0.68)	1.26 (1.18, 1.34)	1.17 (1.12, 1.23)	1.11 (1.04, 1.17)	0.99 (0.95, 1.04)
BSA 1.6 versus 2.0 among males	1.75 (1.48, 2.07)	1.17 (0.92, 1.47)	1.33 (1.12, 1.58)	1.56 (1.41, 1.74)	0.94 (0.49, 1.84)	1.34 (1.21, 1.49)	1.44 (1.33, 1.57)	1.39 (1.25, 1.56)	0.73 (0.68, 0.79)
BSA 1.8 versus 2.0 among females	0.99 (0.95, 1.04)	1.08 (0.99, 1.17)	0.90 (0.86, 0.94)	1.00 (0.97, 1.03)	0.65 (0.54, 0.77)	1.07 (1.03, 1.11)	1.02 (0.99, 1.04)	0.99 (0.96, 1.02)	1.05 (1.03, 1.08)
BSA 1.8 versus 2.0 among males	1.21 (1.14, 1.29)	1.07 (0.98, 1.16)	1.07 (1.00, 1.14)	1.14 (1.10, 1.19)	0.90 (0.70, 1.14)	1.12 (1.08, 1.16)	1.12 (1.09, 1.16)	1.10 (1.06, 1.15)	0.92 (0.89, 0.94)
BSA 2.2 versus 2.0 among females	1.21 (1.11, 1.33)	0.94 (0.80, 1.10)	1.30 (1.21, 1.41)	1.15 (1.09, 1.21)	1.57 (1.26, 1.96)	1.02 (0.95, 1.09)	1.12 (1.07, 1.16)	1.14 (1.08, 1.21)	0.85 (0.81, 0.88)
BSA 2.2 versus 2.0 among males	0.98 (0.93, 1.03)	0.95 (0.88, 1.03)	1.09 (1.05, 1.14)	1.05 (1.02, 1.08)	1.32 (1.17, 1.48)	0.95 (0.93, 0.98)	1.02 (0.99, 1.04)	1.03 (1.00, 1.07)	0.94 (0.93, 0.96)
Creatinine per 1 unit	1.55 (1.46, 1.64)	1.34 (1.22, 1.47)	2.04 (1.93, 2.16)	1.58 (1.51, 1.65)	NA	1.27 (1.20, 1.33)	1.64 (1.57, 1.71)	1.58 (1.51, 1.65)	0.64 (0.61, 0.68)
CVD with CVA	NA	1.81 (1.56, 2.10)	1.22 (1.09, 1.37)	1.28 (1.18, 1.38)	NA	1.14 (1.05, 1.24)	1.20 (1.12, 1.28)	1.40 (1.29, 1.52)	0.77 (0.72, 0.83)
CVD without CVA	NA	1.32 (1.11, 1.57)	1.23 (1.10, 1.37)	1.14 (1.05, 1.23)	NA	1.06 (0.96, 1.17)	1.08 (1.01, 1.15)	NA	0.80 (0.73, 0.88)
No. diseased coronary vessels (2 versus 1 or 3 versus 2)	NA	1.10 (1.01, 1.20)	NA	1.07 (1.02, 1.11)	NA	NA	1.04 (1.00, 1.08)	1.03 (0.98, 1.08)	0.90 (0.86, 0.94)
EF per 10-unit decrease	1.09 (1.05, 1.14)	NA	1.04 (1.00, 1.09)	1.12 (1.09, 1.15)	1.26 (1.12, 1.41)	1.08 (1.04, 1.11)	1.10 (1.07, 1.12)	1.12 (1.08, 1.15)	0.87 (0.85, 0.90)
Hypertension	1.12 (1.03, 1.22)	1.19 (1.07, 1.33)	1.35 (1.25, 1.45)	1.11 (1.06, 1.17)	NA	NA	1.11 (1.07, 1.15)	NA	0.94 (0.91, 0.97)
Immunosuppressive treatment	1.42 (1.21, 1.67)	NA	1.39 (1.19, 1.62)	NA	NA	NA	1.16 (1.06, 1.27)	1.31 (1.17, 1.47)	NA
Left main disease	1.19 (0.98, 1.46)	NA	1.19 (0.98, 1.44)	NA	2.17 (1.13, 4.16)	NA	NA	NA	NA
Active infectious endocarditis	1.95 (1.68, 2.27)	1.87 (1.52, 2.29)	2.17 (1.88, 2.50)	2.15 (1.95, 2.36)	NA	1.55 (1.39, 1.73)	1.97 (1.80, 2.15)	2.79 (2.51, 3.09)	0.34 (0.30, 0.38)
Mitral insufficiency, moderate/severe	NA	1.26 (1.14, 1.39)	NA	NA	NA	NA	NA	NA	NA
Tricuspid insufficiency, moderate/severe	NA	NA	1.14 (1.01, 1.29)	1.14 (1.04, 1.25)	NA	1.09 (1.00, 1.20)	1.21 (1.12, 1.30)	1.17 (1.05, 1.31)	0.82 (0.73, 0.92)
Peripheral vascular disease	1.25 (1.12, 1.38)	1.29 (1.11, 1.49)	NA	NA	NA	1.22 (1.12, 1.32)	1.14 (1.07, 1.21)	1.17 (1.09, 1.25)	0.83 (0.78, 0.88)
Aortic stenosis		NA	NA	0.90 (0.83, 0.97)	NA	0.90 (0.84, 0.96)	0.93 (0.87, 0.98)	0.86 (0.80, 0.92)	1.07 (1.02, 1.13)
Mitral stenosis	1.24 (1.08, 1.41)	NA	NA	NA	NA	NA	NA	NA	NA
MI ≤ 21 days	1.14 (0.98, 1.34)	NA	NA	1.37 (1.22, 1.55)	NA	1.04 (0.91, 1.18)	1.28 (1.16, 1.41)	1.21 (1.06, 1.37)	0.81 (0.72, 0.91)
Time trend, per 6-month harvest interval	0.98 (0.97, 0.99)	0.98 (0.96, 1.00)	1.01 (0.99, 1.02)	1.02 (1.01, 1.03)	0.97 (0.93, 1.01)	1.00 (0.99, 1.01)	1.01 (1.00, 1.02)	1.00 (0.99, 1.01)	1.00 (0.99, 1.01)
Race black	NA	1.33 (1.13, 1.57)	1.51 (1.34, 1.69)	1.42 (1.27, 1.58)	NA	1.27 (1.15, 1.40)	1.37 (1.27, 1.49)	1.45 (1.31, 1.60)	0.64 (0.59, 0.70)
Race Hispanic	NA	0.87 (0.64, 1.19)	1.16 (0.97, 1.38)	1.07 (0.94, 1.22)	NA	1.14 (1.00, 1.30)	1.09 (0.98, 1.22)	1.16 (0.98, 1.38)	0.82 (0.72, 0.93)
Status urgent	1.29 (1.19, 1.40)	NA	1.21 (1.11, 1.33)	1.29 (1.20, 1.39)	NA	1.17 (1.10, 1.25)	1.22 (1.15, 1.29)	1.42 (1.33, 1.51)	0.70 (0.66, 0.74)
Unstable angina	1.21 (1.04, 1.41)	NA	NA	NA	NA	NA	NA	NA	NA

Table 5. Continued

B. Odds ratios for aortic valve replacement									
Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50	1.43 (1.34, 1.52)	1.48 (1.38, 1.59)	1.38 (1.30, 1.47)	1.31 (1.26, 1.36)	1.52 (1.31, 1.76)	1.16 (1.12, 1.21)	1.23 (1.19, 1.26)	1.31 (1.25, 1.37)	0.75 (0.73, 0.77)
Age 70 versus 50	2.04 (1.79, 2.32)	2.19 (1.90, 2.52)	1.90 (1.68, 2.16)	1.71 (1.59, 1.84)	2.31 (1.72, 3.10)	1.35 (1.25, 1.46)	1.50 (1.42, 1.59)	1.71 (1.55, 1.87)	0.57 (0.54, 0.60)
Age 80 versus 50	3.34 (2.84, 3.93)	3.21 (2.70, 3.81)	2.88 (2.46, 3.37)	2.31 (2.12, 2.52)	2.73 (1.95, 3.80)	1.59 (1.44, 1.76)	1.97 (1.82, 2.12)	2.50 (2.24, 2.79)	0.34 (0.32, 0.36)
CHF, not NYHA IV	1.29 (1.18, 1.42)	NA	1.24 (1.14, 1.34)	1.33 (1.24, 1.43)	NA	NA	1.20 (1.13, 1.27)	1.25 (1.17, 1.34)	0.86 (0.81, 0.91)
CHF, NYHA IV	1.83 (1.62, 2.07)	NA	1.61 (1.44, 1.81)	1.92 (1.77, 2.08)	NA	1.25 (1.17, 1.35)	1.62 (1.51, 1.73)	1.54 (1.40, 1.68)	0.72 (0.65, 0.79)
Diabetes, insulin	1.62 (1.43, 1.83)	NA	1.91 (1.70, 2.14)	1.42 (1.31, 1.55)	1.56 (1.05, 2.31)	1.20 (1.10, 1.31)	1.39 (1.29, 1.50)	1.68 (1.55, 1.83)	0.64 (0.59, 0.69)
Diabetes, noninsulin	1.27 (1.15, 1.39)	NA	1.45 (1.34, 1.57)	1.12 (1.04, 1.20)	NA	NA	1.12 (1.06, 1.18)	1.22 (1.15, 1.30)	0.85 (0.81, 0.88)
Dialysis versus no dialysis and creatinine = 1.0	2.85 (2.35, 3.45)	1.65 (1.34, 2.03)	NA	3.07 (2.74, 3.43)	NA	1.79 (1.60, 2.01)	2.42 (2.21, 2.66)	2.94 (2.64, 3.27)	0.29 (0.24, 0.34)
Preoperative IABP/ inotropes	1.47 (1.26, 1.71)	NA	1.34 (1.15, 1.57)	1.78 (1.55, 2.05)	1.69 (1.08, 2.65)	1.14 (1.02, 1.29)	1.75 (1.59, 1.94)	1.46 (1.30, 1.63)	0.56 (0.48, 0.66)
Shock	1.62 (1.29, 2.03)	1.65 (1.21, 2.25)	NA	2.09 (1.77, 2.47)	NA	1.32 (1.11, 1.58)	2.11 (1.80, 2.49)	1.74 (1.37, 2.21)	NA
Female versus male (at BSA = 1.8)	1.23 (1.10, 1.36)	1.25 (1.09, 1.43)	0.97 (0.88, 1.07)	1.29 (1.21, 1.38)	0.98 (0.72, 1.33)	0.86 (0.81, 0.93)	1.03 (0.98, 1.08)	1.25 (1.16, 1.35)	0.69 (0.66, 0.73)
CLD (moderate versus mild, or severe versus moderate)	1.27 (1.21, 1.33)	NA	1.18 (1.13, 1.23)	1.26 (1.22, 1.30)	1.27 (1.13, 1.42)	1.09 (1.06, 1.12)	1.17 (1.14, 1.20)	1.29 (1.24, 1.34)	0.81 (0.79, 0.83)
Reoperation, 1 previous operation ^a	2.11 (1.78, 2.49)	2.09 (1.64, 2.65)	1.55 (1.31, 1.84)	1.83 (1.64, 2.05)	NA	1.31 (1.16, 1.49)	1.55 (1.42, 1.70)	1.42 (1.27, 1.59)	0.67 (0.62, 0.72)
Reoperation, ≥ 2 previous operations ^a	2.48 (1.99, 3.08)	2.36 (1.76, 3.16)	1.66 (1.33, 2.07)	2.49 (2.14, 2.90)	NA	1.41 (1.19, 1.67)	1.96 (1.73, 2.22)	1.76 (1.52, 2.03)	0.50 (0.43, 0.58)
Status emergent, no resuscitation ^a	3.77 (2.75, 5.16)	2.78 (1.85, 4.17)	3.10 (2.21, 4.35)	4.54 (3.54, 5.83)	NA	1.63 (1.31, 2.03)	3.23 (2.66, 3.93)	2.45 (2.02, 2.97)	0.33 (0.25, 0.42)
Status emergent, with resuscitation or salvage ^a	7.94 (5.40, 11.66)	2.11 (1.06, 4.19)	3.47 (2.19, 5.51)	3.50 (2.41, 5.08)	NA	NA	3.38 (2.36, 4.84)	NA	0.32 (0.19, 0.54)

Table 5. Continued

C. Odds ratios for mitral valve replacement									
Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50	1.65 (1.53, 1.78)	1.48 (1.38, 1.59)	1.35 (1.26, 1.44)	1.31 (1.26, 1.36)	1.52 (1.31, 1.76)	1.25 (1.19, 1.31)	1.33 (1.29, 1.39)	1.26 (1.21, 1.33)	0.71 (0.68, 0.74)
Age 70 versus 50	2.71 (2.33, 3.17)	2.19 (1.90, 2.52)	1.81 (1.60, 2.06)	1.71 (1.59, 1.84)	2.31 (1.72, 3.10)	1.56 (1.42, 1.71)	1.78 (1.65, 1.92)	1.60 (1.45, 1.76)	0.50 (0.46, 0.55)
Age 80 versus 50	5.14 (4.15, 6.37)	3.21 (2.70, 3.81)	2.67 (2.23, 3.20)	2.31 (2.12, 2.52)	2.73 (1.95, 3.80)	1.97 (1.72, 2.26)	2.54 (2.27, 2.84)	2.27 (2.00, 2.58)	0.28 (0.25, 0.32)
CHF, not NYHA IV	1.29 (1.18, 1.42)	NA	1.24 (1.14, 1.34)	1.19 (1.07, 1.32)	NA	NA	1.11 (1.01, 1.21)	1.25 (1.17, 1.34)	0.96 (0.87, 1.06)
CHF, NYHA IV	1.83 (1.62, 2.07)	NA	1.61 (1.44, 1.81)	1.72 (1.55, 1.91)	NA	1.25 (1.17, 1.35)	1.49 (1.36, 1.64)	1.54 (1.40, 1.68)	0.80 (0.71, 0.91)
Diabetes, insulin	1.62 (1.43, 1.83)	NA	1.91 (1.70, 2.14)	1.66 (1.47, 1.86)	1.56 (1.05, 2.31)	1.20 (1.10, 1.31)	1.67 (1.52, 1.83)	1.68 (1.55, 1.83)	0.64 (0.59, 0.69)
Diabetes, noninsulin	1.27 (1.15, 1.39)	NA	1.45 (1.34, 1.57)	1.30 (1.16, 1.45)	NA	NA	1.34 (1.22, 1.47)	1.22 (1.15, 1.30)	0.85 (0.81, 0.88)
Dialysis versus no dialysis and creatinine = 1.0	4.59 (3.65, 5.77)	1.65 (1.34, 2.03)	NA	3.07 (2.74, 3.43)	NA	1.79 (1.60, 2.01)	2.42 (2.21, 2.66)	2.94 (2.64, 3.27)	0.23 (0.16, 0.33)
Preoperative IABP/ inotropes	1.47 (1.26, 1.71)	NA	1.34 (1.15, 1.57)	2.21 (1.90, 2.56)	1.69 (1.08, 2.65)	1.14 (1.02, 1.29)	1.75 (1.59, 1.94)	1.46 (1.30, 1.63)	0.63 (0.51, 0.77)
Shock	1.62 (1.29, 2.03)	1.65 (1.21, 2.25)	NA	2.09 (1.77, 2.47)	NA	1.32 (1.11, 1.58)	2.11 (1.80, 2.49)	1.05 (0.85, 1.31)	NA
Female versus male (at BSA=1.8)	1.11 (0.97, 1.27)	1.25 (1.09, 1.43)	0.97 (0.88, 1.07)	1.06 (0.98, 1.16)	0.98 (0.72, 1.33)	0.79 (0.72, 0.87)	1.03 (0.98, 1.08)	1.09 (0.99, 1.19)	0.69 (0.66, 0.73)
CLD (moderate versus mild, or severe versus moderate)	1.08 (1.01, 1.16)	NA	1.18 (1.13, 1.23)	1.26 (1.22, 1.30)	1.27 (1.13, 1.42)	1.09 (1.06, 1.12)	1.17 (1.14, 1.20)	1.16 (1.11, 1.22)	0.81 (0.79, 0.83)
Reoperation, 1 previous operation ^a	2.11 (1.78, 2.49)	2.09 (1.64, 2.65)	1.55 (1.31, 1.84)	1.50 (1.34, 1.67)	NA	1.31 (1.16, 1.49)	1.55 (1.42, 1.70)	1.42 (1.27, 1.59)	0.67 (0.62, 0.72)
Reoperation, ≥ 2 previous operations ^a	2.48 (1.99, 3.08)	2.36 (1.76, 3.16)	1.66 (1.33, 2.07)	2.03 (1.76, 2.35)	NA	1.41 (1.19, 1.67)	1.96 (1.73, 2.22)	1.76 (1.52, 2.03)	0.50 (0.43, 0.58)
Status emergent, no resuscitation ^a	2.74 (1.99, 3.78)	2.78 (1.85, 4.17)	2.20 (1.59, 3.05)	3.19 (2.41, 4.23)	NA	1.63 (1.31, 2.03)	3.23 (2.66, 3.93)	2.45 (2.02, 2.97)	0.33 (0.25, 0.42)
Status emergent, with resuscitation or salvage ^a	5.78 (3.77, 8.85)	2.11 (1.06, 4.19)	2.46 (1.56, 3.88)	2.46 (1.66, 3.65)	NA	NA	3.38 (2.36, 4.84)	NA	0.32 (0.19, 0.54)

Table 5. Continued

D. Odds ratios for mitral valve repair

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Age 60 versus 50	1.80 (1.62, 2.00)	1.48 (1.38, 1.59)	1.55 (1.41, 1.71)	1.31 (1.26, 1.36)	1.52 (1.31, 1.76)	1.20 (1.13, 1.27)	1.31 (1.26, 1.37)	1.50 (1.41, 1.60)	0.62 (0.60, 0.65)
Age 70 versus 50	3.24 (2.63, 4.00)	2.19 (1.90, 2.52)	2.42 (2.00, 2.92)	1.71 (1.59, 1.84)	2.31 (1.72, 3.10)	1.44 (1.29, 1.62)	1.73 (1.58, 1.89)	2.25 (1.98, 2.55)	0.39 (0.36, 0.42)
Age 80 versus 50	6.72 (5.00, 9.04)	3.21 (2.70, 3.81)	4.11 (3.14, 5.38)	2.31 (2.12, 2.52)	2.73 (1.95, 3.80)	1.75 (1.48, 2.07)	2.42 (2.12, 2.76)	3.78 (3.17, 4.51)	0.19 (0.17, 0.22)
CHF, not NYHA IV	1.29 (1.18, 1.42)	NA	1.24 (1.14, 1.34)	1.16 (0.99, 1.35)	NA	NA	1.11 (0.99, 1.24)	1.25 (1.17, 1.34)	0.92 (0.80, 1.05)
CHF, NYHA IV	1.83 (1.62, 2.07)	NA	1.61 (1.44, 1.81)	1.67 (1.43, 1.95)	NA	1.25 (1.17, 1.35)	1.50 (1.33, 1.68)	1.54 (1.40, 1.68)	0.76 (0.65, 0.90)
Diabetes, insulin	1.62 (1.43, 1.83)	NA	1.91 (1.70, 2.14)	1.68 (1.42, 1.97)	1.56 (1.05, 2.31)	1.20 (1.10, 1.31)	1.57 (1.36, 1.81)	1.68 (1.55, 1.83)	0.64 (0.59, 0.69)
Diabetes, noninsulin	1.27 (1.15, 1.39)	NA	1.45 (1.34, 1.57)	1.31 (1.11, 1.55)	NA	NA	1.26 (1.10, 1.45)	1.22 (1.15, 1.30)	0.85 (0.81, 0.88)
Dialysis versus no dialysis and creatinine = 1.0	6.24 (4.19, 9.30)	1.65 (1.34, 2.03)	NA	3.07 (2.74, 3.43)	NA	1.79 (1.60, 2.01)	2.42 (2.21, 2.66)	2.94 (2.64, 3.27)	0.26 (0.19, 0.37)
Preoperative IABP/ inotropes	1.47 (1.26, 1.71)	NA	1.34 (1.15, 1.57)	2.90 (2.28, 3.70)	1.69 (1.08, 2.65)	1.14 (1.02, 1.29)	1.75 (1.59, 1.94)	1.46 (1.30, 1.63)	0.49 (0.38, 0.64)
Shock	1.62 (1.29, 2.03)	1.65 (1.21, 2.25)	NA	2.09 (1.77, 2.47)	NA	1.32 (1.11, 1.58)	2.11 (1.80, 2.49)	2.50 (1.51, 4.12)	NA
Female versus male (at BSA = 1.8)	0.97 (0.77, 1.21)	1.25 (1.09, 1.43)	0.97 (0.88, 1.07)	1.23 (1.10, 1.38)	0.98 (0.72, 1.33)	0.90 (0.80, 1.02)	1.03 (0.98, 1.08)	1.28 (1.12, 1.47)	0.69 (0.66, 0.73)
CLD (moderate versus mild, or severe versus moderate)	1.23 (1.09, 1.39)	NA	1.18 (1.13, 1.23)	1.26 (1.22, 1.30)	1.27 (1.13, 1.42)	1.09 (1.06, 1.12)	1.17 (1.14, 1.20)	1.26 (1.15, 1.40)	0.81 (0.79, 0.83)
Reoperation, 1 previous operation ^a	2.11 (1.78, 2.49)	2.09 (1.64, 2.65)	1.55 (1.31, 1.84)	2.06 (1.73, 2.45)	NA	1.31 (1.16, 1.49)	1.55 (1.42, 1.70)	1.42 (1.27, 1.59)	0.67 (0.62, 0.72)
Reoperation ≥ 2 previous operations ^a	2.48 (1.99, 3.08)	2.36 (1.76, 3.16)	1.66 (1.33, 2.07)	2.80 (2.32, 3.37)	NA	1.41 (1.19, 1.67)	1.96 (1.73, 2.22)	1.76 (1.52, 2.03)	0.50 (0.43, 0.58)
Status emergent, no resuscitation ^a	8.73 (4.84, 15.74)	2.78 (1.85, 4.17)	3.03 (1.69, 5.43)	6.12 (3.96, 9.46)	NA	1.63 (1.31, 2.03)	3.23 (2.66, 3.93)	2.45 (2.02, 2.97)	0.33 (0.25, 0.42)
Status emergent, with resuscitation or salvage ^a	18.39 (9.68, 34.96)	2.11 (1.06, 4.19)	3.39 (1.76, 6.54)	4.72 (2.71, 8.23)	NA	NA	3.38 (2.36, 4.84)	NA	0.32 (0.19, 0.54)

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

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; Comp = composite adverse event (any); CVA = cerebrovascular accident (stroke); CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; MI = myocardial infarction; Mort = mortality; NA = not applicable; NYHA = New York Heart Association; PLOS = prolonged length of stay; Reop = reoperation; RF = renal failure; SLOS = short length of stay; Vent = prolonged ventilation.

(≤ 40 , > 40). Calibration plots (observed versus expected) based on the overall validation sample are presented in Figure 1. The average absolute difference between observed versus predicted event rates within deciles of predicted risk ranged from 0.06% for deep sternal wound infection to 1.06% for prolonged postoperative stay. Analogous figures were produced for specific valve procedures and numerous subgroups, and these are available at www.sts.org/riskmodels.

Model fit appeared to be adequate for each endpoint with the possible exception of deep sternal wound infection, which revealed some overfitting within certain subgroups. A modest degree of overfitting was expected for this endpoint given the relatively small number of infections and large number of candidate predictors.

Discrimination was assessed by the c-statistic, also known as the area under the receiver operating characteristic (ROC) curve. Table 4 presents the discrimination of each model in the development and validation samples for all patients combined and for subgroups consisting of AVR, MVR, and MVRepair. In the validation sample, c-statistics for the operative mortality model were 0.799 (overall), 0.759 (AVR), 0.802 (MVR), and 0.844 (MVRepair). C-statistics in the validation sample for other endpoints ranged from 0.619 for reoperation in the AVR subgroup to 0.800 for prolonged length of stay in the MVRepair subgroup.

Final Models

After validating the models in the 40% validation sample, the development and validation samples were then combined, and the final model coefficients were estimated using the overall 100% combined sample. The final logistic regressions were estimated using generalized estimating equations with empirical (sandwich) standard error estimates to account for clustering of patients within institutions [10]. An independence working correlation matrix was used to apply the generalized estimating equations methodology. 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 the clustered data structure.

Odds Ratios

Odds ratios and 95% confidence intervals (CI) for the final selected models are presented in Table 5. "Not applicable" indicates that the specific predictor was not included in a particular risk model. Because several variables interact with surgery type, the odds ratios for these variables differ depending on the type of surgery (AVR, MVR, MVRepair). For example, in the operative mortality model, the odds ratio for emergent status is 3.77 (95% CI: 2.75, 5.16) for AVR, 2.74 (95% CI: 1.99, 3.78) for MVR, and 8.73 (95% CI: 4.84, 15.74) for MVRepair. Odds ratios that do not interact with surgery type are summarized in Table 5, Part A. Odds ratios that differ by surgery type for at least one endpoint are presented in Table 5, Parts B, C, and D.

Final Model Intercept and Coefficients

The final risk prediction algorithms, including all coefficients and intercepts, are presented in the Appendix.

Limitations

The limitations for these valve models are similar to those for the CABG models and are thoroughly discussed in Part 1 of this series (2008 STS CABG risk models).

Conclusion

The STS Quality Measurement Task Force has developed and tested nine new risk-adjustment models for isolated valve surgery using the STS NCD. This report includes a detailed exposition of the model development process, including not only statistical issues but also the many clinical and pragmatic judgments that were required. An online risk calculator is also available through a link from the STS website.

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Appendix

Regression Coefficients and Variable Definitions for STS 2008 Valve Models

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

$$\text{Predicted Risk} = \frac{e^{(\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \dots + \beta_n x_n)}}{1 + e^{(\beta_0 + \beta_1 x_1 + \beta_2 x_2 + \dots + \beta_n x_n)}}$$

where x_1, x_2, \dots, x_n denote patient preoperative risk factors (eg, quantitative variables such as age, and comorbidities coded as 1 = present, 0 = absent); and $\beta_0, \beta_1, \dots, \beta_n$ denote regression coefficients (numerical constants). Regression coefficients for each endpoint are presented in Appendix Table 1. The variables x_1, x_2, \dots, 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

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Intercept	-5.78680	-5.83957	-5.52789	-3.96796	-7.11095	-3.08816	-3.06527	-4.30676	1.25115
Atrial fibrillation	0.18074	0.05524	0.00000	0.16527	0.00000	0.10305	0.11403	0.15530	-0.30247
Age function 1	0.03557	0.03909	0.03219	0.02683	0.04180	0.01512	0.02041	0.02670	-0.02834
Age function 3	0.02804	-0.00132	0.01809	0.00629	-0.05024	0.00218	0.01282	0.02315	-0.04637
Age by reoperation function	-0.01308	-0.02043	-0.00551	-0.00840	-0.00939	-0.00697	-0.00684	-0.00485	0.00927
Age by status function	-0.02495	-0.02987	-0.00721	-0.01377	0.00277	0.00102	-0.00677	-0.00379	-0.00795
Age by MVR function	0.01436	0.00000	-0.00245	0.00000	0.00000	0.00715	0.00848	-0.00324	-0.00603
Age by MVRepair function	0.02326	0.00000	0.01190	0.00000	0.00000	0.00315	0.00685	0.01378	-0.01883
BSA function 1	-1.40168	-0.38619	-0.71012	-1.11750	0.14188	-0.73553	-0.91858	-0.82801	0.77317
BSA function 2	2.16782	0.23148	1.92875	2.29127	2.04603	0.83644	1.65638	1.65423	-1.76728
CHF but not NYHA IV	0.25590	0.00000	0.21233	0.28353	0.00000	0.00000	0.17974	0.22508	-0.15108
CHF and NYHA IV	0.60544	0.00000	0.47812	0.65056	0.00000	0.22686	0.48025	0.42957	-0.33521
CHF by MVR function	0.00000	0.00000	0.00000	-0.11007	0.00000	0.00000	-0.07864	0.00000	0.11503
CHF by MVRepair function	0.00000	0.00000	0.00000	-0.13792	0.00000	0.00000	-0.07731	0.00000	0.06468
CLD function	0.23846	0.00000	0.16629	0.22816	0.23817	0.08406	0.16044	0.25263	-0.21022
CLD by MVR function	-0.15906	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.10092	0.00000
CLD by MVRepair function	-0.03243	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.01795	0.00000
Creatinine function 1	0.43909	0.29230	0.71439	0.45646	0.00000	0.23562	0.49230	0.45631	-0.44178
CVD without prior CVA	0.00000	0.27837	0.20531	0.12726	0.00000	0.05830	0.07684	0.00000	-0.22223
CVD and prior CVA	0.00000	0.59220	0.20018	0.24512	0.00000	0.13200	0.18343	0.33480	-0.25595
Diabetes, noninsulin	0.23563	0.00000	0.37172	0.11040	0.00000	0.00000	0.11355	0.19843	-0.16630
Diabetes, insulin	0.48368	0.00000	0.64648	0.35367	0.44389	0.18293	0.33165	0.51913	-0.45093
Diabetes by MVR function	0.00000	0.00000	0.00000	0.15051	0.00000	0.00000	0.17990	0.00000	0.00000
Diabetes by MVRepair function	0.00000	0.00000	0.00000	0.16260	0.00000	0.00000	0.11734	0.00000	0.00000
Dialysis	1.48666	0.79199	0.00000	1.57690	1.19109	0.81972	1.37741	1.53351	-1.69019
Dialysis by MVR function	0.47550	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.20998
Dialysis by MVRepair function	0.78385	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.07964
Ejection fraction function	0.00904	0.00000	0.00407	0.01107	0.02308	0.00734	0.00925	0.01111	-0.01348
Endocarditis, active	0.66737	0.62434	0.77276	0.76318	0.00000	0.43876	0.67810	1.02521	-1.08299
Female	0.20372	0.21925	-0.03031	0.25668	-0.02355	-0.14567	0.03066	0.22437	-0.36400
Female by MVR function	-0.10089	0.00000	0.00000	-0.19465	0.00000	-0.08773	0.00000	-0.14211	0.00000
Female by MVRepair function	-0.23812	0.00000	0.00000	-0.04564	0.00000	0.04424	0.00000	0.02470	0.00000
Female by BSA function 1	0.96491	-0.02257	0.83074	0.77598	2.00214	0.16707	0.52716	0.57195	-0.75434
Female by BSA function 2	0.18084	-0.07419	0.08397	-0.58460	-1.87036	0.25158	-0.09063	-0.12289	0.35123
Hypertension	0.11372	0.17789	0.29770	0.10799	0.00000	0.00000	0.10361	0.00000	-0.06504
IABP or inotropes	0.38682	0.00000	0.29606	0.57608	0.52474	0.13432	0.56046	0.37621	-0.57115
IABP by MVR function	0.00000	0.00000	0.00000	0.21517	0.00000	0.00000	0.00000	0.00000	0.10760
IABP by MVRepair function	0.00000	0.00000	0.00000	0.48870	0.00000	0.00000	0.00000	0.00000	-0.13850

Appendix Table 1. Continued

Variable	Mort	CVA	RF	Vent	DSWI	Reop	Comp	PLOS	SLOS
Immunosuppressive treatment	0.35022	0.00000	0.32828	0.00000	0.00000	0.00000	0.14887	0.27152	0.00000
Insufficiency mitral	0.00000	0.23253	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Insufficiency tricuspid	0.00000	0.00000	0.13159	0.12973	0.00000	0.08969	0.18929	0.15846	-0.20027
Left main disease	0.17593	0.00000	0.17280	0.00000	0.77557	0.00000	0.00000	0.00000	0.00000
MI ≤ 21 days	0.13276	0.00000	0.00000	0.31706	0.00000	0.03495	0.24687	0.18812	-0.20961
MVR	0.10284	0.00000	0.40455	0.44639	0.00000	0.12852	0.13795	0.58004	-0.61402
MVRepair	-0.65440	0.00000	-0.23666	-0.19726	0.00000	-0.22398	-0.23002	-0.37618	0.25710
No. diseased vessel function	0.00000	0.09556	0.00000	0.06299	0.00000	0.00000	0.03700	0.03312	-0.10126
Peripheral vascular disease	0.21980	0.25236	0.00000	0.00000	0.00000	0.19758	0.13174	0.15342	-0.18903
Race black	0.00000	0.28378	0.40941	0.34795	0.00000	0.23856	0.31567	0.37161	-0.44177
Race Hispanic	0.00000	-0.13774	0.14968	0.06720	0.00000	0.12816	0.08581	0.15128	-0.20068
Reop, 1 previous operation	0.74484	0.73489	0.43804	0.60704	0.00000	0.27365	0.44052	0.35252	-0.40042
Reop, ≥ 2 previous operations	0.90625	0.85841	0.50595	0.91229	0.00000	0.34233	0.67201	0.56294	-0.69765
Reop by MVR function	0.00000	0.00000	0.00000	-0.20333	0.00000	0.00000	0.00000	0.00000	0.00000
Reop by MVRepair function	0.00000	0.00000	0.00000	0.11559	0.00000	0.00000	0.00000	0.00000	0.00000
Shock	0.47961	0.50213	0.00000	0.73670	0.00000	0.28068	0.74786	0.55376	0.00000
Shock by MVR function	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	-0.50071	0.00000
Shock by MVRepair function	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.36096	0.00000
Status urgent	0.25552	0.00000	0.19344	0.25714	0.00000	0.15548	0.19858	0.35184	-0.36106
Status emergent	1.32597	1.02109	1.13199	1.51294	0.00000	0.49075	1.17360	0.89480	-1.12373
Status salvage	2.07144	0.74530	1.24544	1.25342	0.00000	0.00000	1.21823	0.00000	-1.13785
Status by MVR function	-0.31729	0.00000	-0.34380	-0.35206	0.00000	0.00000	0.00000	0.00000	0.00000
Status by MVRepair function	0.84051	0.00000	-0.02373	0.29927	0.00000	0.00000	0.00000	0.00000	0.00000
Stenosis aortic	0.00000	0.00000	0.00000	-0.10782	0.00000	-0.10852	-0.07479	-0.15434	0.06873
Stenosis mitral	0.21309	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000
Unstable angina	0.18950	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000	0.00000

BSA = body surface area; CHF = congestive heart failure; CLD = chronic lung disease; Comp = composite adverse event (any); CVA = cerebrovascular accident (stroke); CVD = cerebrovascular disease; DSWI = deep sternal wound infection; EF = ejection fraction; IABP = intra-aortic balloon pump; Mort = mortality; MVR = mitral valve replacement; MVRepair = mitral valve repair; NYHA = New York Heart Association; 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 Valve Models

Variable	Definition
Intercept	= 1 for all patients
Atrial fibrillation	= 1 if patient has history of preop atrial fibrillation, = 0 otherwise
Age function 1	= max (age – 50, 0)
Age function 3	= max (age – 75, 0)
Age by reoperation 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
Age by MVR function	= Age function 1 if operation is MVR, = 0 otherwise
Age by MVRepair function	= Age function 1 if operation is MVRepair, = 0 otherwise
BSA function 1	= max (1.4, min [2.6, BSA]) – 1.8
BSA function 2	= (BSA 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
CHF by MVR function	= 1 if patient has CHF and operation is MVR, = 0 otherwise
CHF by MVRepair function	= 1 if patient has CHF and operation is MVRepair, = 0 otherwise
CLD function	= 0 if no CLD, = 1 if mild CLD, = 2 if moderate CLD, = 3 if severe CLD
CLD by MVR function	= CLD function if operation is MVR, = 0 otherwise
CLD by MVRepair function	= CLD function if operation is MVRepair, = 0 otherwise
Creatinine function 1	= max (0.5, min [creatinine, 5.0]) if patient is not on dialysis, = 0 otherwise
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
Diabetes by MVR function	= 1 if patient has diabetes and operation is MVR, = 0 otherwise
Diabetes by MVRepair function	= 1 if patient has diabetes and operation is MVRepair, = 0 otherwise
Dialysis	= 1 if patient requires dialysis preoperatively, = 0 otherwise
Dialysis by MVR function	= 1 if patient has history of dialysis and operation is MVR, = 0 otherwise
Dialysis by MVRepair function	= 1 if patient has history of dialysis and operation is MVRepair, = 0 otherwise
Ejection fraction function	= max (50–ejection fraction, 0)
Endocarditis, active	= 1 if patient has active endocarditis, = 0 otherwise
Female	= 1 if patient is female, = 0 otherwise
Female by MVR function	= 1 if female and operation is MVR, = 0 otherwise
Female by MVRepair function	= 1 if female and operation is MVRepair, = 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
IABP by MVR function	= 1 if patient requires preop IABP/inotropes and operation is MVR, = 0 otherwise
IABP by MVRepair function	= 1 if patient requires preop IABP/inotropes and operation is MVRepair, = 0 otherwise
Immunosuppressive treatment	= 1 if patient received immunosuppressive therapy within 30 days, = 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 ≤ 21 days	= 1 if patient has history of MI within 21 days of surgery, = 0 otherwise
MVR	= 1 if valve operation is mitral valve replacement, = 0 otherwise
MVRepair	= 1 if valve operation is mitral valve repair, = 0 otherwise
No. diseased vessel function	= 2 if triple-vessel disease, = 1 if double-vessel disease, = 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
Reop, 1 prior operation	= 1 if patient has had exactly 1 previous CV surgery, = 0 otherwise
Reop, ≥ 2 prior operations	= 1 if patient has had 2 or more previous CV surgeries, = 0 otherwise
Reop by MVR function	= 1 if surgery is a reoperation and operation is MVR, = 0 otherwise
Reop by MVRepair function	= 1 if surgery is a reoperation and operation is MVRepair, = 0 otherwise

Appendix Table 2. Continued

Variable	Definition
Shock	= 1 if patient was in shock at time of procedure, = 0 otherwise
Shock by MVR function	= 1 if shock and operation is MVR, = 0 otherwise
Shock by MVRRepair function	= 1 if shock and operation is MVRRepair, = 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
Status by MVR function	= 1 if status is emergent or salvage and operation is MVR, = 0 otherwise
Status by MVRRepair function	= 1 if status is emergent or salvage and operation is MVRRepair, = 0 otherwise
Stenosis aortic	= 1 if patient has aortic stenosis, = 0 otherwise
Stenosis mitral	= 1 if patient has mitral stenosis, = 0 otherwise
Unstable angina	= 1 if patient has unstable angina, no MI within 7 days of surgery, = 0 otherwise

Note: See www.sts.org for exact definitions of terms used above.

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; MVR = mitral valve replacement; MVRRepair = mitral valve repair; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PLOS = prolonged length of stay; Preop = preoperative; Reop = reoperation; Comp = composite adverse event (any); RF = renal failure; SLOS = short length of stay; STS = The Society of Thoracic Surgeons; Vent = prolonged ventilation.