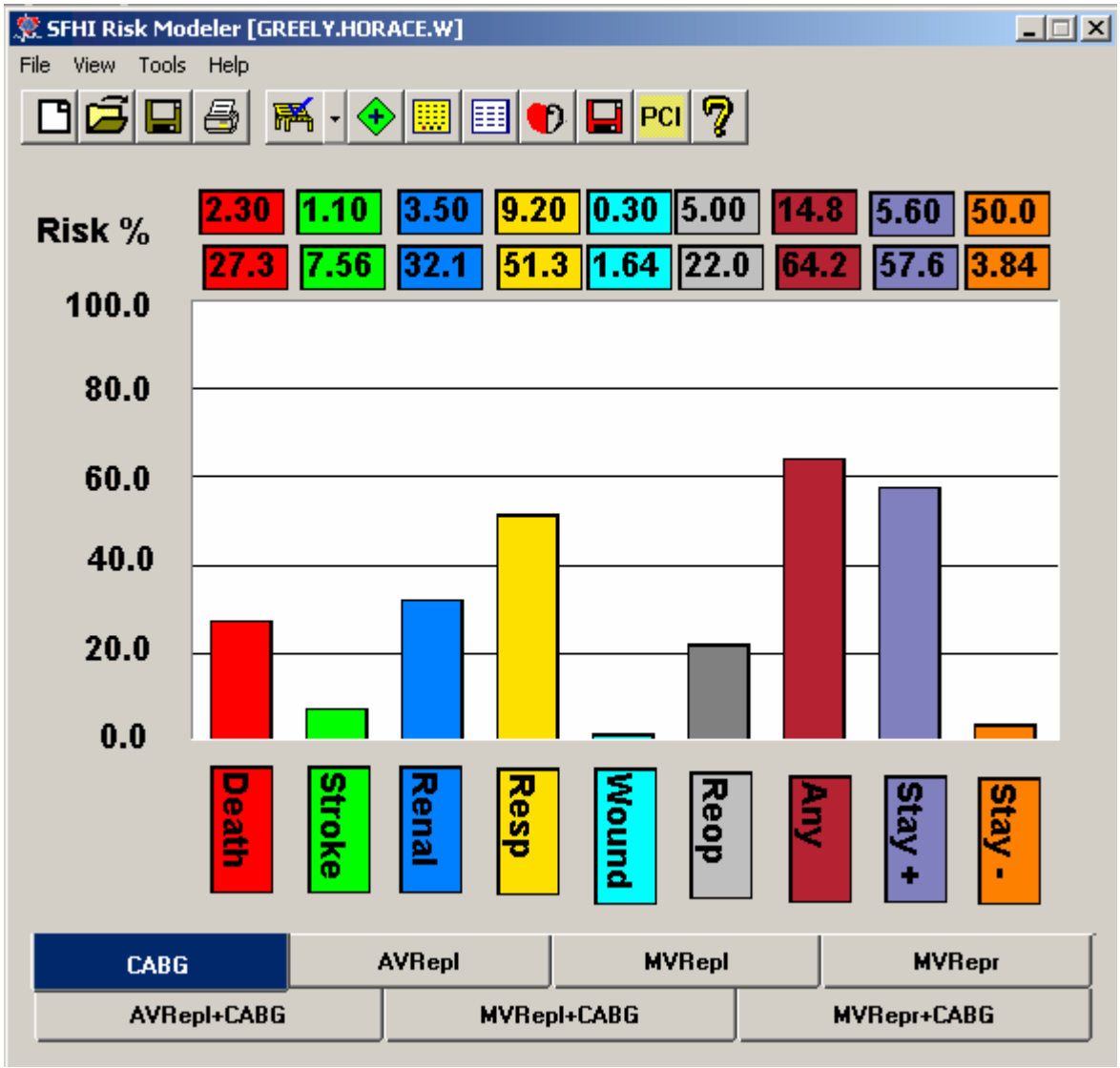
San Francisco Heart & Vascular Institute
At Seton Medical Center

Cardiac Surgery Risk Modeler

By Michael B. Pliam, MD, PhD
2009



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Introduction

Since the beginning of interest in risk modeling for cardiac surgery, the San Francisco Heart & Vascular Institute has maintained a large and detailed database of all of it's cardiac surgical procedures. Data from this database is submitted annually to the Society of Thoracic Surgeons National Cardiac Surgery Database. Through the Duke Clinical Research Center, data from many institutions are collected together, analyzed, and used to produce risk models for various outcome categories and surgical populations. The Society of Thoracic Surgeons' risk models predict the risk of operative mortality and morbidity after adult cardiac surgery on the basis of patient demographic and clinical variables. The models are primarily used to adjust for case mix when comparing outcomes across institutions with different patient populations. Such comparisons are provided in the Database reports received by STS Database participants. The STS models are also used by physicians and patients as tools for understanding the possible risks of surgery. **These risks are solely statistical estimates. They should be supplemented by the professional judgment of the patients' healthcare provider, particularly their cardiologist and cardiac surgeon.**

How To Use the Program

Log On

You must log on to use this program. The log on window appears when you first attempt to run the program. You must supply a username and password which will provided by your Administrator.

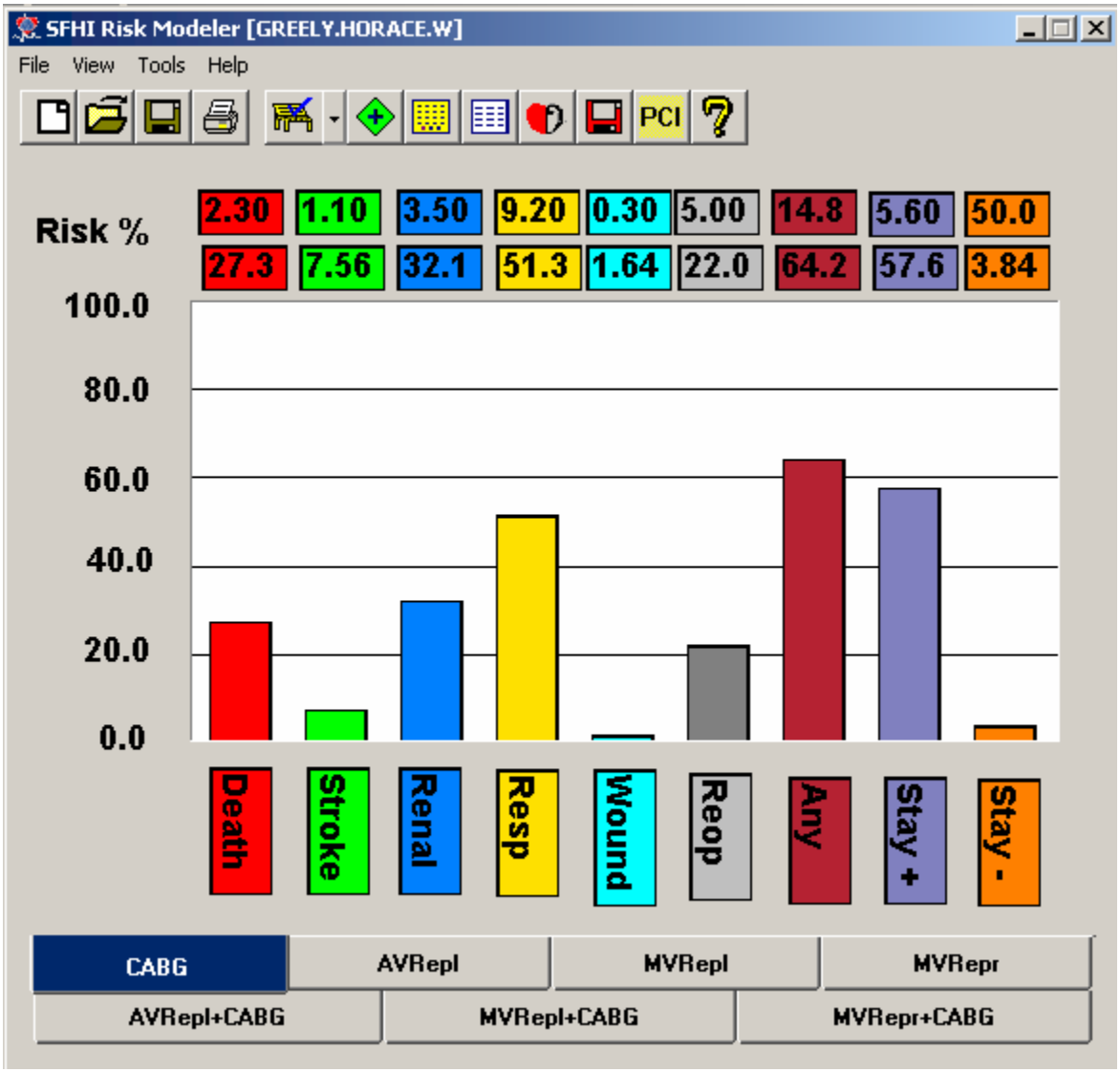
Fill in your username and password, then press Enter. You will be allowed 3 tries before the Log On closes with a message that your attempt to log on has failed and that you should contact your Administrator.

Note that this log on feature prevents unauthorized users from gaining access to sensitive patient information.

Further note that only a single instance of the main application can be run at any one time. This feature is particularly important when the application is run from a server on a local access network, since it prevents users from simultaneously altering the patient database. Should you successfully log into the application in the network that is already being run, you will receive a message that the application is currently unavailable and that you should try again later.

The Main Interface

The main program is an intuitive simple tabbed interface with a menu and tool bar, much like any standard Windows program.



There are 9 outcome models that are calculated for a given patient. These are: Death, Stroke, Resp, Wound, Reop, Stay+ and Stay-. These are indicated by labels at the bottom of the bar graph. They are shown below and defined in Table 1. The colored bars show the relative risk percentages for the 9 models. The scale on the left of the graph indicates the risk percentage. Additionally, respective values for each bar are show above the graph.

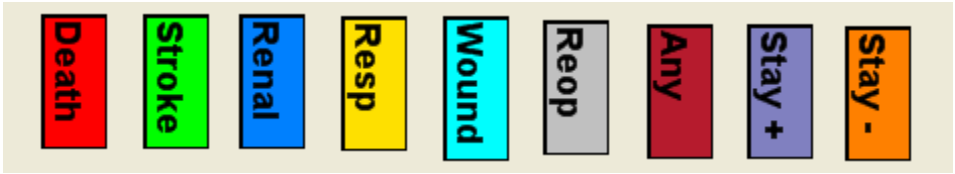
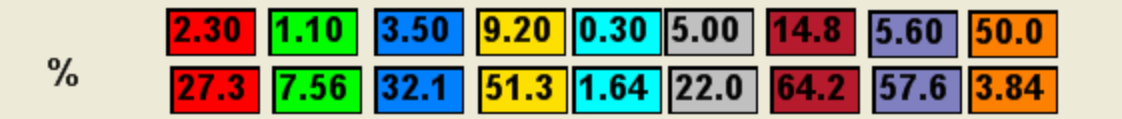


Table 1.

Outcome Model	Short Name	Definition
Operative Mortality	Death	Death within the current hospitalization
Permanent Stroke	Stroke	Cerebrovascular accident with permanent residuae
Renal Failure	Renal	Renal failure postoperatively (not relevant for patients preoperatively on dialysis)
Prolonged Ventilatory Support > 24 Hrs	Resp	Postoperative ventilatory support > 24 hours or requiring reintubation
Deep Sternal Wound Infection	Wound	Sternal wound infection and / or dehiscence
Reoperation for Any Reason	Reop	Reoperation for bleeding or any other reason
Any of the Above	Any	One or more of any of the above problems
Prolonged Hospital Stay > 14 Days	Stay +	Hospitalization exceeding 14 days postop
Short Hospital Stay < 6 Days	Stay -	Hospitalization less than 6 days postop

The risk model outcome values can be read directly from the bar graph. For ease of reading, outcome probabilities can be read more precisely from the value indicators immediately above the the bar graph. Indicators are color coded to correspond to distinct bar graph colors that are unique to each model. Should you choose to view them in order to compare your patient with the national averages as supplied by the Society of Thoracic Surgeons, a row of benchmarks can be displayed immediately above the outcome probability row of indicators. These represent the average occurrence of a particular outcome for that entire risk category and procedure. The benchmark indicators can be turned on and off by selecting the Benchmarks item under the Tools menu, or by clicking on the Benchmarks button on the toolbar, or by selecting the menu associated with the Benchmarks button down-arrow on the toolbar. The benchmark indicators will always appear above the current patient outcome probability values. All of these are expressed in percent, that is, the actual probability multiplied by 100.0.



The 7 tabs at the bottom of the interface allow you to select the appropriate surgical procedure category for a patient. These are CABG, AVRepl, MVRepl, MVRepr, AVRepl+CABG, MVRepl+CABG, and MVRepr+CABG. These are shown below and their meanings defined in Table 2.

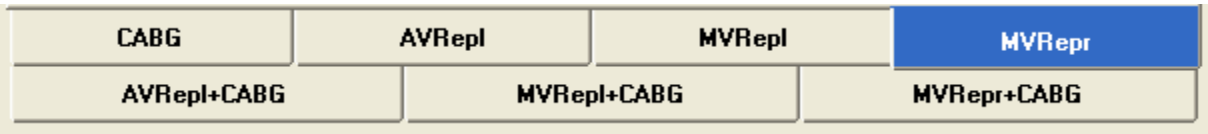


Table 2.

Surgical Procedure Category	Tab Name	Definition
Isolated Coronary Artery Bypass	CABG	Isolated coronary artery bypass only
Isolated Aortic Valve Replacement	AVRepl	Isolated aortic valve replacement only
Isolated Mitral Valve Replacement	MVRepl	Isolated mitral valve replacement only
Isolated Mitral Valve Repair	MVRepr	Isolated mitral valve repair only
Aortic Valve Replacement + CABG	AVRepl+CABG	Combined aortic valve replacement and coronary artery bypass
Mitral Valve Replacement + CABG	MVRepl+CABG	Combined mitral valve replacement and coronary artery bypass
Mitral Valve Repair + CABG	MVRepr+CABG	Combined mitral valve repair and coronary artery bypass

In all, there are 7 procedure categories times 9 outcome models each category, for a total of 63 available risk models. All the risk models use the same patient preoperative variables.

The Toolbar

The toolbar facilitates the rapid execution of most of the menu selection items. It contains ten buttons with mouse-over popup labels. The first 4 buttons are typical Window's program interface buttons to facilitate clearing out the current data (New), Opening a patient file that is stored on disk (Open), saving the currently loaded patient data to disk (Save), and printing the current patient data as text (Print). The right-most button summons the program information box. The function of the remaining six custom button operations are summarized in Table 3.

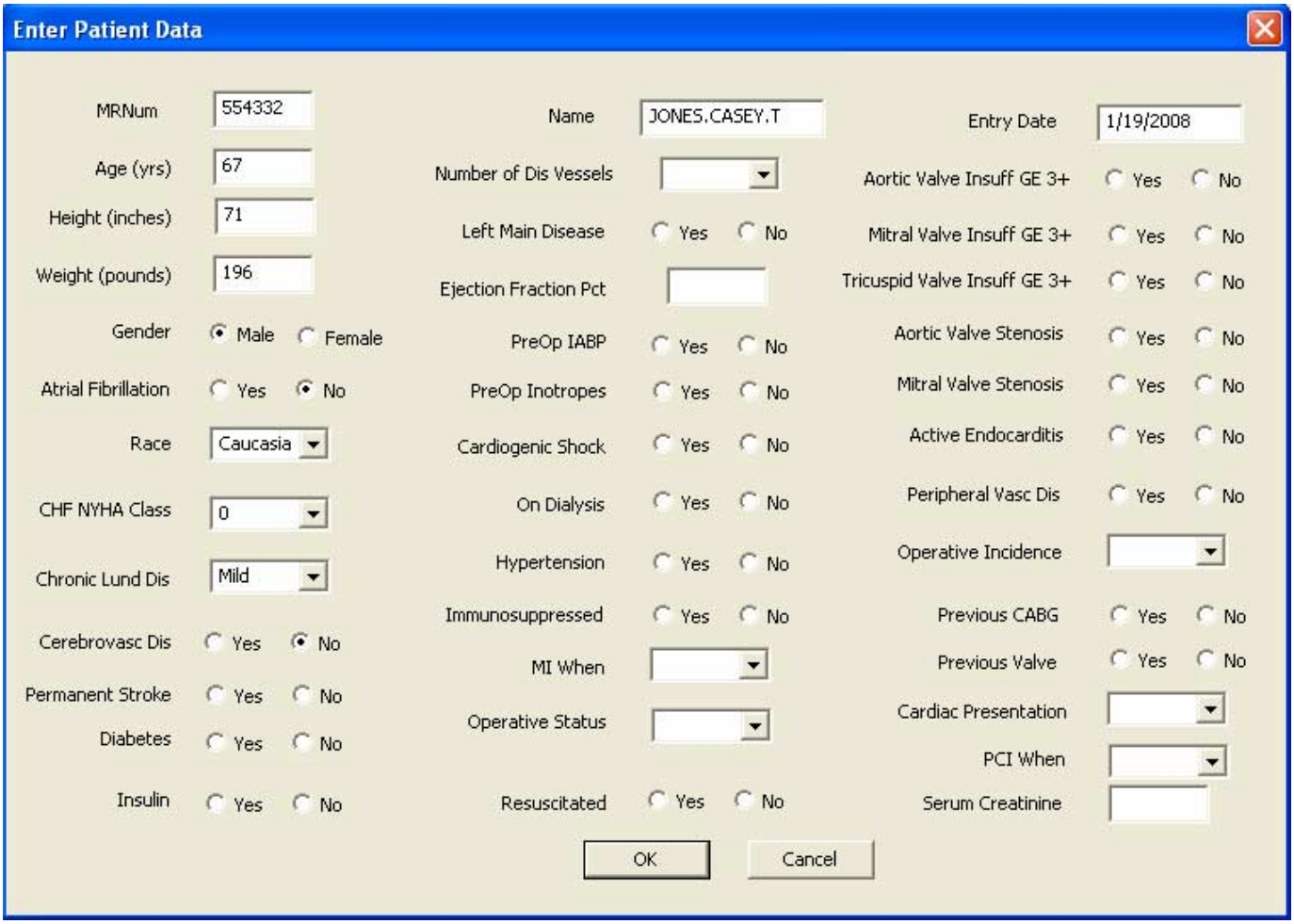
Table 3.

Button	Label	Function

	New	Clears the current patient data from the risk calculator, zeros all the risk values
	Open	Opens a patient data file (smx) from the hard disk
	Save	Saves the existing patient data to a hard disk (smx) file
	Print	Prints the existing patient data and risk profile
	Benchmarks	Turns benchmark indicators on/off with button or arrow and menu
	Edit Patient	Opens the patient data editor filled with current patient entries
	Quick View	Opens the quick data view containing non-editable current patient data for viewing and printing
	Add Patient	Opens a blank patient data editor for entering new patient data
	Data Manager	Opens the database manager for selection and management of patient data
	Save to Database	Save the current data to the patient database
	PCI Risk	Calculate mortality risk for PCI
	About	Displays information about the program

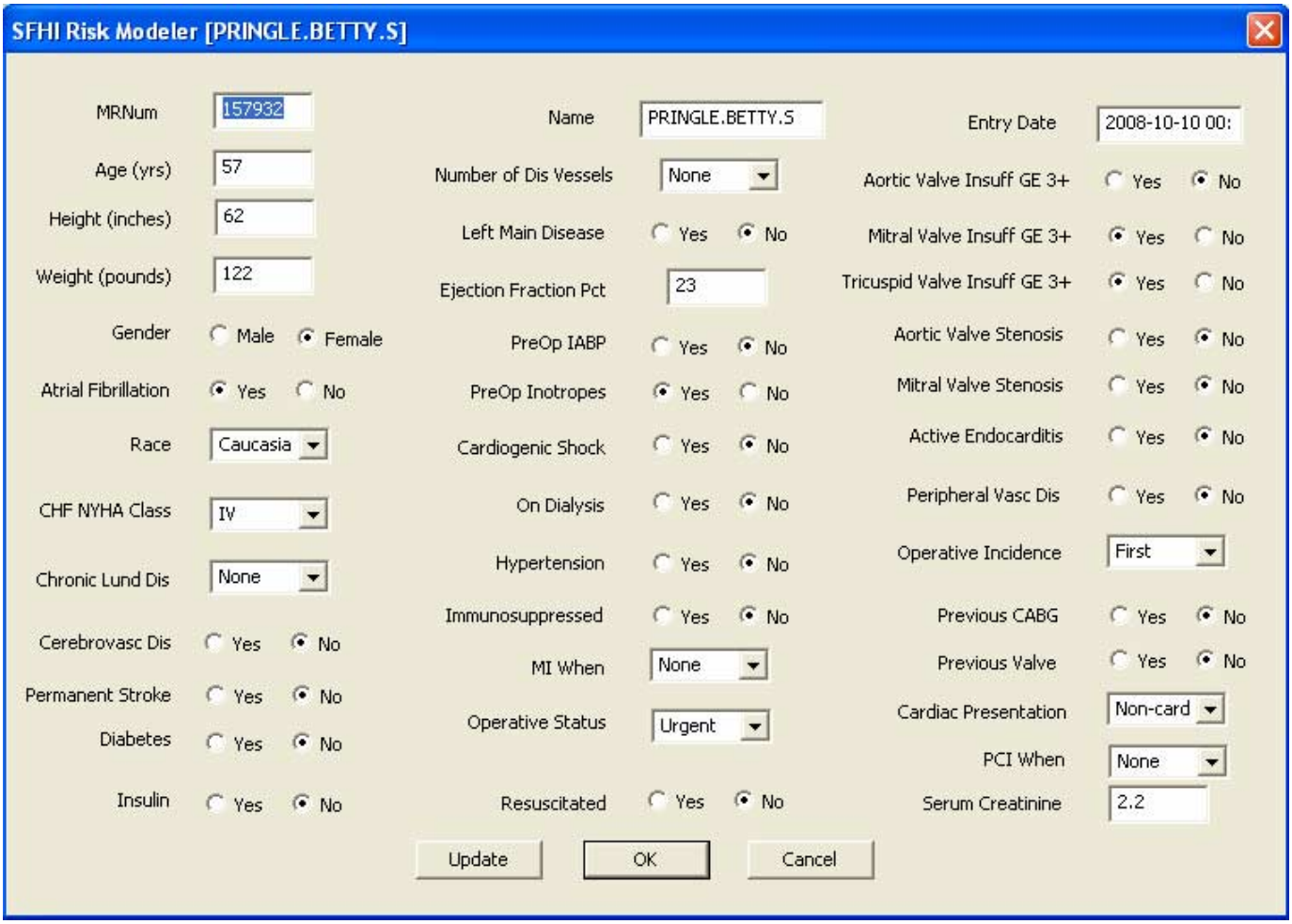
Adding a New Patient

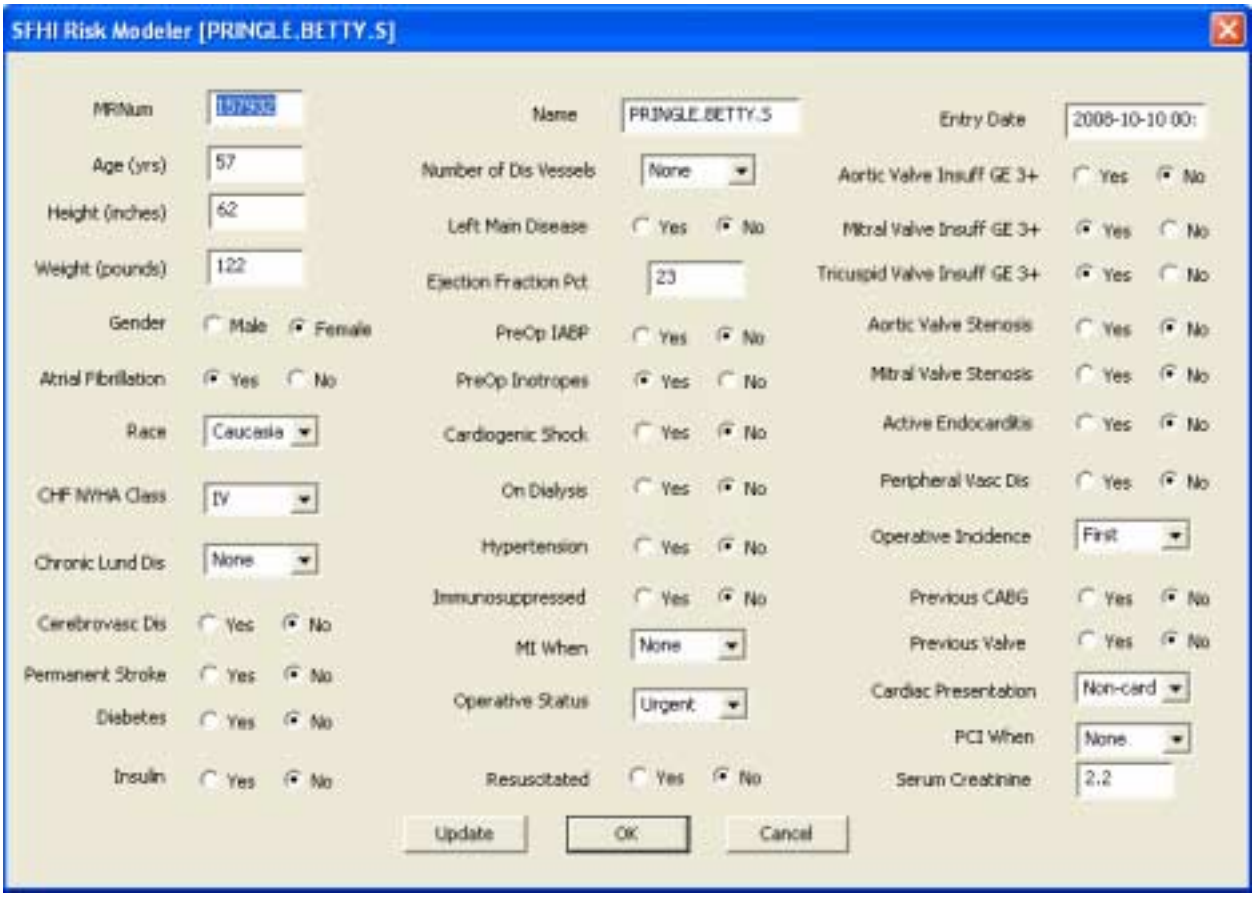
To add a new patient, you must complete the entry fields presented in the Add Patient window. There are 40 fields in all, 37 of which are required to complete the calculation of a risk category. The 3 fields, MRNum, Name, and Entry Date are only required if you wish to enter the new patient in the database. You have the option of saving the patient data to the database, to disk, or to both. If you try to calculate a risk model with one of the required 37 fields is missing, you will receive a message 'Parameter is incorrect', in which case, you should try to fill in the missing data point and try again.



Editing Existing Patient Data

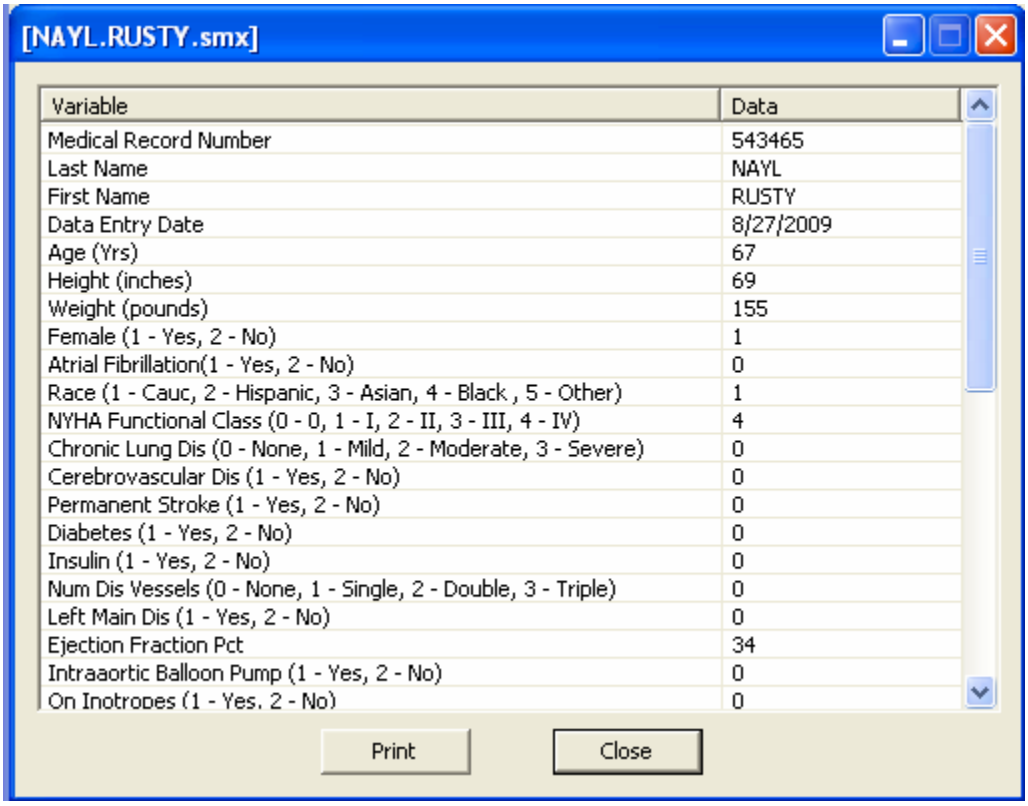
You can change or edit currently loaded patient data. Click the Edit Patient button on the toolbar or make the selection from the Tools menu. The Patient Edit window will appear containing all of the current patient input variables. You can change these variables and, by clicking on the Update button, you can view the effect that the change has on the calculated risk models.


SFHI Risk Modeler [PRINGLE.BETTY.S]
MRNum
157932
Age (yrs)
57
Height (inches)
62
Weight (pounds)
122
Gender
Male
Female
Atrial Fibrillation
Yes
No
Race
Caucasia
CHF NYHA Class
IV
Chronic Lund Dis
None
Cerebrovasc Dis
Yes
No
Permanent Stroke
Yes
No
Diabetes
Yes
No
Insulin
Yes
No
Name
PRINGLE.BETTY.S
Number of Dis Vessels
None
Left Main Disease
Yes
No
Ejection Fraction Pct
23
PreOp IABP
Yes
No
PreOp Inotropes
Yes
No
Cardiogenic Shock
Yes
No
On Dialysis
Yes
No
Hypertension
Yes
No
Immunosuppressed
Yes
No
MI When
None
Operative Status
Urgent
Resuscitated
Yes
No
Update
OK
Cancel
Entry Date
2008-10-10 00:
Aortic Valve Insuff GE 3+
Yes
No
Mitral Valve Insuff GE 3+
Yes
No
Tricuspid Valve Insuff GE 3+
Yes
No
Aortic Valve Stenosis
Yes
No
Mitral Valve Stenosis
Yes
No
Active Endocarditis
Yes
No
Peripheral Vasc Dis
Yes
No
Operative Incidence
First
Previous CABG
Yes
No
Previous Valve
Yes
No
Cardiac Presentation
Non-card
PCI When
None
Serum Creatinine
2.2



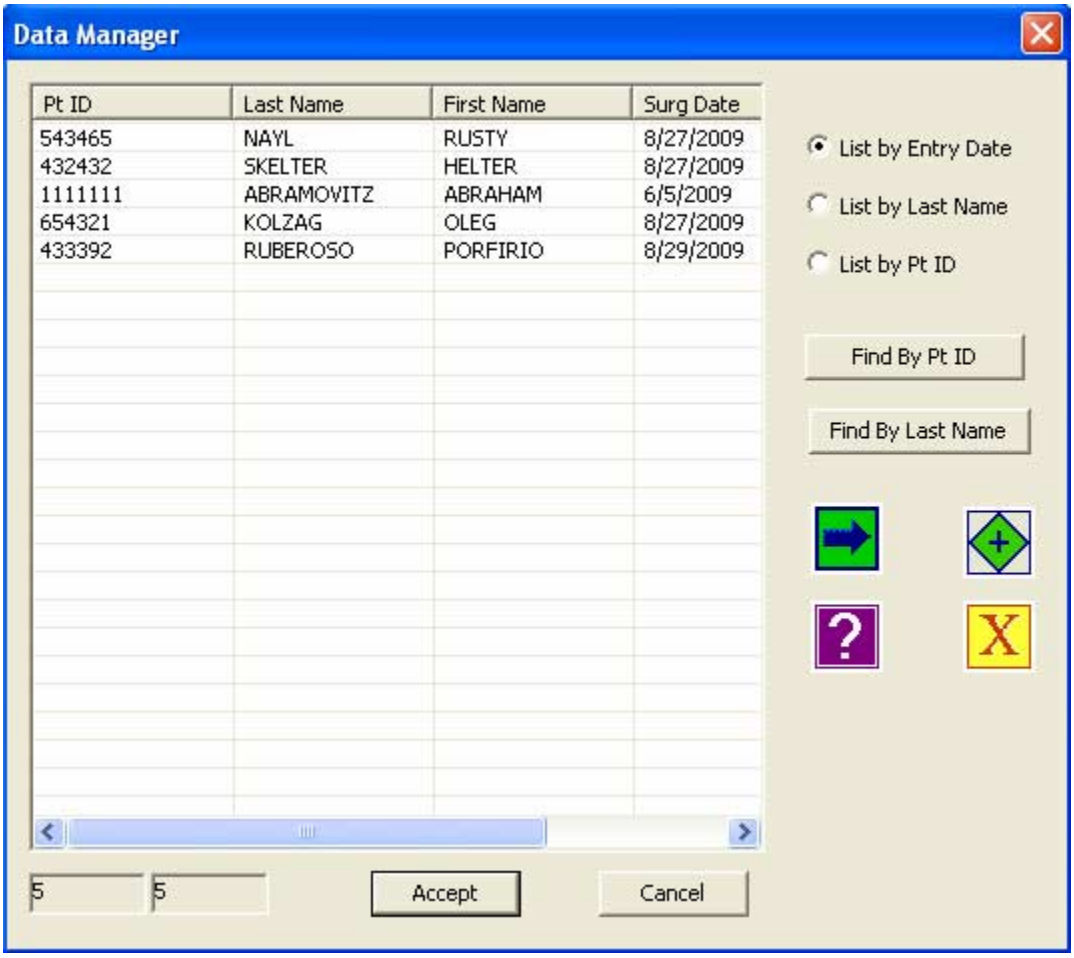
The Quick Viewer

This window allows you to quickly review data of the current patient. You cannot edit the data from this window. (For editing data, use the Patient Editor). However, you can print the Quick Viewer data to a text file. Note that the print function will print both the current patient data and the results of the 9 risk models for the selected procedure category.



The Data Manager

It may be more convenient for some users to store patients in a database rather than to a hard disk as a file. To facilitate this, the program provides a database interface, the Data Manager. The Data Manager window allows for loading, adding, deleting, searching and ordering of an MS Access database.



Patients are listed by their identification number (Pt ID), Name, Entry Date, and Age. The list can be sorted by Pt ID, Name, or Entry Date by clicking on the desired ordering mode check button. The list can be searched for a specific patient by either Pt ID or Name through the use of the two buttons provided. Four buttons control loading patient data, adding a new patient to the database, deleting a patient from the database, and seeking online help (see Table 4). Any patient listed in the database can be loaded onto the Risk Calculator by either double-clicking on the list name, or by selecting them from the list and clicking on OK or the Load Selected Patient button.

Table 4.

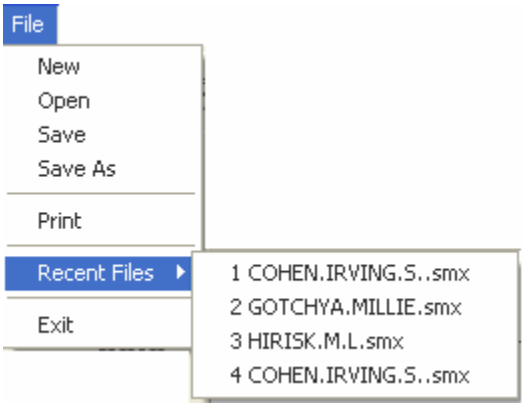
Button	Label	Function
	Load Selected Patient	Loads the selected patient data into the main risk modeler program
	Add New Patient	Opens the patient data entry interface to add a new patient to the database

	Delete Selected Patient	Deletes the selected patient data from the database
	Data Manager Help	Opens Database Manager help (this file)

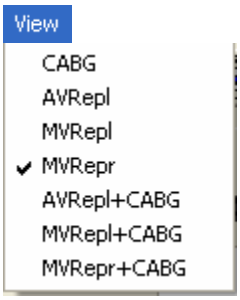
The Main Menu

The Main Menu is a typical Windows menu that consists of four main selections, File, View, Tools, and Help. These are largely intuitive and self-explanatory.

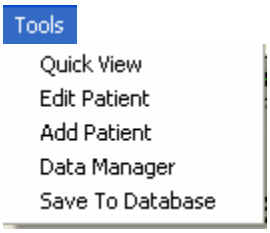
The File menu subitems allow input and output of patient data files. In this application, these files are of the type SMX. These SMX files are binary files that can only be opened using this application.



The View menu subitems allow for selection of specific procedure categories. The current selection is checked on the menu and the corresponding tab is highlighted.



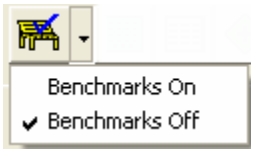
The Tools menu subitems correspond to the Toolbar buttons



The Help menu subitems offer choices for online help contents and information about the program.

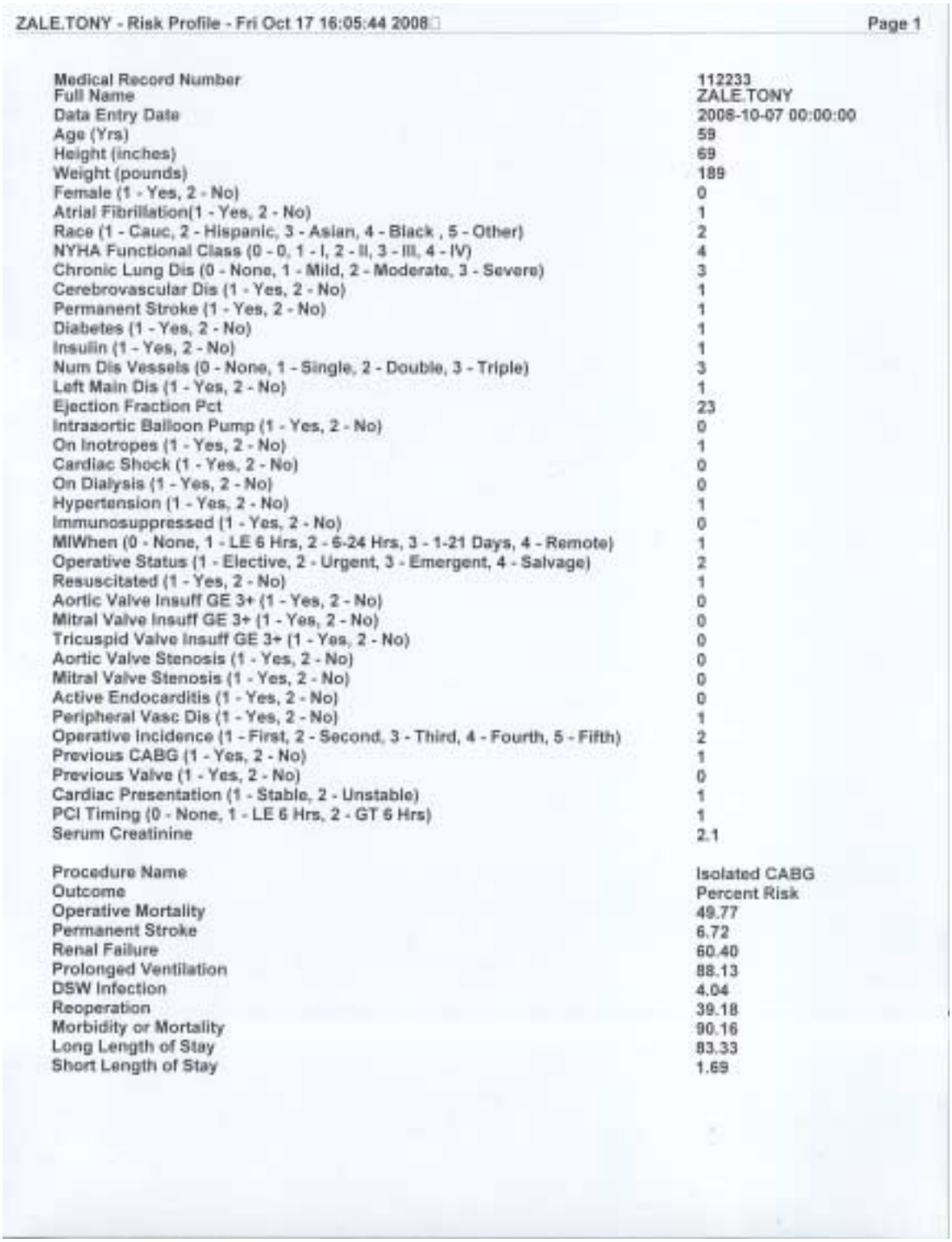
The Toolbar Menu

The Benchmark toolbar button is associated with a down-arrow button which, when clicked, displays a popup menu that allows you to quickly show or hide the benchmark indicators.



Printing a Report

Load patient data, select the desired procedure category, and from the File menu select Print. A typical patient printout will appear as that example below.



ZALE.TONY - Risk Profile - Fri Oct 17 16:05:44 2008 Page 1

Medical Record Number	112233
Full Name	ZALE.TONY
Data Entry Date	2008-10-07 00:00:00
Age (Yrs)	59
Height (inches)	69
Weight (pounds)	189
Female (1 - Yes, 2 - No)	0
Atrial Fibrillation(1 - Yes, 2 - No)	1
Race (1 - Cauc, 2 - Hispanic, 3 - Asian, 4 - Black , 5 - Other)	2
NYHA Functional Class (0 - 0, 1 - I, 2 - II, 3 - III, 4 - IV)	4
Chronic Lung Dis (0 - None, 1 - Mild, 2 - Moderate, 3 - Severe)	3
Cerebrovascular Dis (1 - Yes, 2 - No)	1
Permanent Stroke (1 - Yes, 2 - No)	1
Diabetes (1 - Yes, 2 - No)	1
Insulin (1 - Yes, 2 - No)	1
Num Dis Vessels (0 - None, 1 - Single, 2 - Double, 3 - Triple)	3
Left Main Dis (1 - Yes, 2 - No)	1
Ejection Fraction Pct	23
Intraaortic Balloon Pump (1 - Yes, 2 - No)	0
On Inotropes (1 - Yes, 2 - No)	1
Cardiac Shock (1 - Yes, 2 - No)	0
On Dialysis (1 - Yes, 2 - No)	0
Hypertension (1 - Yes, 2 - No)	1
Immunosuppressed (1 - Yes, 2 - No)	0
MIWhen (0 - None, 1 - LE 6 Hrs, 2 - 6-24 Hrs, 3 - 1-21 Days, 4 - Remote)	1
Operative Status (1 - Elective, 2 - Urgent, 3 - Emergent, 4 - Salvage)	2
Resuscitated (1 - Yes, 2 - No)	1
Aortic Valve Insuff GE 3+ (1 - Yes, 2 - No)	0
Mitral Valve Insuff GE 3+ (1 - Yes, 2 - No)	0
Tricuspid Valve Insuff GE 3+ (1 - Yes, 2 - No)	0
Aortic Valve Stenosis (1 - Yes, 2 - No)	0
Mitral Valve Stenosis (1 - Yes, 2 - No)	0
Active Endocarditis (1 - Yes, 2 - No)	0
Peripheral Vasc Dis (1 - Yes, 2 - No)	1
Operative Incidence (1 - First, 2 - Second, 3 - Third, 4 - Fourth, 5 - Fifth)	2
Previous CABG (1 - Yes, 2 - No)	1
Previous Valve (1 - Yes, 2 - No)	0
Cardiac Presentation (1 - Stable, 2 - Unstable)	1
PCI Timing (0 - None, 1 - LE 6 Hrs, 2 - GT 6 Hrs)	1
Serum Creatinine	2.1

Procedure Name	Isolated CABG
Outcome	Percent Risk
Operative Mortality	49.77
Permanent Stroke	6.72
Renal Failure	60.40
Prolonged Ventilation	88.13
DSW Infection	4.04
Reoperation	39.18
Morbidity or Mortality	90.16
Long Length of Stay	83.33
Short Length of Stay	1.69

Definitions

A
Arrhythmia Type-Afib/Aflutter
C
CAB
Cardiac Presentation on Admission
Classification-NYHA
H
Heart Failure
Height (cm)
Hemo Data-EF
Hispanic or Latino Ethnicity
I
IABP-When Inserted
Incidence
L
Left Main Dis >= 50%
M
Meds-Inotropes
MI-When
N
Num Dis Vessels
O
Other Card
Other Card-Ao Aneur
Other Card-Arrhythmia Correction Surgery
Other Card-ASD
Other Card-Atrial Fibrillation Correction Surgery
Other Card-Batista
Other Card-Card Tx
Other Card-Cardiac Trauma
Other Card-Congenital
Other Card-LVA
Other Card-Other
Other Card-Surgical Ventricular Restoration
Other Card-Transmyocardial Laser Revascularization
Other Card-VSD
Other Non Card
P
Patient Age
Prev CAB
Prev Oth Card-PCI-Interval
Prev Valve
R

Arrhythmia Type-Afib/Aflutter
Indicate whether atrial fibrillation or flutter is present within two weeks of the procedure.

CAB
Indicate whether coronary artery bypass grafting was done.

Cardiac Presentation on Admission
Indicate the type of angina present prior to this surgical intervention.
1- No Symptoms or Angina.
2- Symptoms Unlikely to be Ischemia: Pain, pressure or discomfort in the chest, neck or

arms not clearly exertional or not otherwise consistent with pain or discomfort of myocardial ischemic origin. This includes patients with non-cardiac pain (e.g. pulmonary embolism, musculoskeletal, or esophageal discomfort), or cardiac pain not caused by myocardial ischemia (e.g., acute pericarditis).
3- Stable Angina: Angina without a change in frequency or pattern for the six weeks prior to this surgical intervention. Angina is controlled by rest and/or oral or transcutaneous medications.
4- Unstable Angina - There are three principal presentations of unstable angina: 1) rest angina, 2) new -onset (less than 2 months) angina, and 3) increasing angina (in intensity, duration and/or frequency).
5- Non-ST Elevation MI (Non-STEMI) - The patient was hospitalized for a non-ST elevation myocardial infarction as documented in the medical record. Non-STEMIs are characterized by the presence of both criteria: A. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I, and/or myoglobin) exceed the upper limit of normal according to the individual hospital's laboratory parameters with a clinical presentation which is consistent or suggestive of ischemia. ECG changes and/or ischemic symptoms may or may not be present. B. Absence of ECG changes diagnostic of a STEMI (see STEMI).
6- ST Elevation MI (STEMI) - The patient presented with a ST elevation myocardial infarction as documented in the medical record. STEMIs are characterized by the presence of both criteria: A. ECG evidence of STEMI: New or presumed new ST-segment elevation or new left bundle branch block not documented to be resolved within 20 minutes. ST-segment elevation is defined by new or presumed new sustained ST-segment elevation (0.1 mV in magnitude) in two or more contiguous electrocardiogram (ECG) leads. If no exact ST-elevation measurement is recorded in the medical chart, physician?s written documentation of ST-elevation is acceptable. If only one ECG is performed, then the assumption that the ST elevation persisted at least the required 20 minutes is acceptable. Left bundle branch block (LBBB) refers to LBBB that was not known to be old on the initial ECG. For purposes of the Registry, ST elevation in the posterior chest leads (V7 through V9), or ST depression in V1 and V2 demonstrating posterior myocardial infarction is considered a STEMI equivalent and qualifies the patient for reperfusion therapy. B. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I, and/or myoglobin) exceed the upper limit of normal according to the individual hospital's laboratory parameters a clinical presentation which is consistent or suggestive of ischemia which is consistent or suggestive of ischemia.

Classification-NYHA
Indicate the patient's highest New York Heart Association (NYHA) classification within 2 weeks prior to surgery. NYHA classification represents the overall functional status of the patient in relationship to both heart failure and angina. Choose one of the following:
- Class I: Patient has cardiac disease but without resulting limitations of ordinary physical activity. Ordinary physical activity (e.g., walking several blocks or climbing stairs) does not cause undue fatigue, palpitation, dyspnea, or anginal pain. Limiting symptoms may occur with marked exertion. - Class II: Patient has cardiac disease resulting in slight limitation of ordinary physical activity. Patient is comfortable at rest.

Ordinary physical activity such as walking more than two blocks or climbing more than one flight of stairs results in limiting symptoms (e.g., fatigue, palpitation, dyspnea, or anginal pain). - Class III: Patient has cardiac disease resulting in marked limitation of physical activity. Patient is comfortable at rest. Less than ordinary physical activity (e.g., walking one to two level blocks or climbing one flight of stairs) causes fatigue, palpitation, dyspnea, or anginal pain. - Class IV: Patient has dyspnea at rest that increases with any physical activity. Patient has cardiac disease resulting in inability to perform any physical activity without discomfort. Symptoms may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Heart Failure
Indicate whether, within 2 weeks prior to the initial surgical procedure, a physician has diagnosed that the patient is currently in heart failure (HF). HF can be diagnosed based on careful history and physical exam, or by one of the following criteria: 1. Paroxysmal nocturnal dyspnea (PND); 2. Dyspnea on exertion (DOE) due to heart failure; 3. Chest X-ray (CXR) showing pulmonary congestion; 4. Pedal edema or dyspnea, and receiving diuretics; or 5. Pulmonary edema. Note: A low ejection fraction without clinical presentation does not qualify for history of heart failure.

Height (cm)
Indicate the height of the patient in centimeters.

Hemo Data-EF
Indicate the percentage of the blood emptied from the ventricle at the end of the contraction. Use the most recent determination prior to the surgical intervention documented on a diagnostic report. Enter a percentage in the range of 1 - 99. If a percentage range is reported, report a whole number using the "mean" (i.e., 50-55%, is reported as 53%). Values reported as: Normal = 60% Good function = 50% Mildly reduced = 45% Fair function = 40% Moderately reduced = 30% Poor function = 25% Severely reduced = 20% NOTE: If no diagnostic report is in the medical record, a value documented in the progress record is acceptable.

Hispanic or Latino Ethnicity
Indicate if the patient is of Hispanic or Latino ethnicity as determined by the patient / family. Hispanic or Latino ethnicity includes patient report of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race.

IABP-When Inserted
Indicate when the IABP was inserted. Choose one of the following: Preoperatively Intraoperatively Postoperatively

Incidence
Indicate if this is the patient's: -first cardiovascular surgery -first re-op cardiovascular surgery -second re-op cardiovascular surgery -third re-op cardiovascular surgery -fourth or more re-op cardiovascular surgery.

Left Main Dis >= 50%
Indicate whether the patient has Left Main Coronary Disease. Left Main Coronary Disease is present when there is >= 50% compromise of vessel diameter preoperatively.

Meds-Inotropes
Indicate whether the patient received IV inotropic agents within 48 hours preceding surgery, or if it was contraindicated or not indicated. The contraindication must be documented in the medical record by a physician, nurse practitioner, or physician assistant.

MI-When
Indicate the time period between the last documented myocardial infarction and surgery.

Num Dis Vessels
Indicate the number of diseased major native coronary vessel systems: LAD system, Circumflex system, and/or Right system with >= 50% narrowing of any vessel preoperatively. NOTE: Left main disease (>=50%) is counted as TWO vessels (LAD and Circumflex, which may include a Ramus Intermedius). For example, left main and RCA would count as three total. Select from the following: None (no significant coronary obstructive disease) One Two Three

Other Card
Indicate whether an other cardiac procedure was done (other than CABG and/or Valve procedures).

Other Card-Ao Aneur
Indicate whether the patient underwent an aortic aneurysm repair either in conjunction with, or as the primary surgical procedure. This includes dissections, non-dissections and ruptures of the aorta.

Other Card-Arrhythmia Correction Surgery

Indicate if one of the following arrhythmia correction devices was surgically placed either in conjunction with, or as the primary surgical procedure: None Permanent Pacemaker: an internal electronic generator that controls the heart rate. Permanent Pacemaker with Cardiac Resynchronization Therapy (CRT): an internal permanent pacemaker that uses biventricular electrical stimulation to synchronize ventricular contraction. Automatic Implanted Cardioverter Defibrillator (AICD): an internal device that defibrillates the heart. AICD with CRT: an internal AICD that uses biventricular electrical stimulation to synchronize ventricular contraction.

Other Card-ASD
Indicate whether the patient had an Atrial Septal Defect Repair either in conjunction with, or as the primary surgical procedure including but not limited to ASD, Secundum; ASD, Sinus venosus; and PFO.

Other Card-Atrial Fibrillation Correction Surgery
Indicate if one of the following atrial fibrillation correction surgeries was performed either in conjunction with, or as the primary surgical procedure. The intent of both surgeries is to preclude the atria from fibrillating by disrupting the abnormal reentry pathways of electronic signals that lead to atrial fibrillation. Standard Surgical Maze Procedure: Surgical procedure in which full thickness incisions are made in the atria of the heart. Sutures are then used to reapproximate the incised tissue. The resulting lesion disrupts the abnormal reentry pathways of electronic signals that lead to atrial fibrillation. Other Surgical Ablative Procedure: Surgical procedure in which lesions are created in the atria of the heart by an energy source. The lesion disrupts the abnormal reentry pathways of electronic signals that lead to atrial fibrillation. Combination of Standard Surgical Maze Procedure and Other Surgical Ablative Procedure.

Other Card-Batista
Indicate whether the patient had a Left Ventricular Reduction Myoplasty either in conjunction with, or as the primary surgical procedure. Left Ventricular Reduction Myoplasty is a procedure whereby left ventricular myocardium is excised to reduce left ventricular volume in patients with a dilated cardiomyopathy, with or without mitral valve replacement or repair. If a concomitant valve procedure is performed, please check that category also.

Other Card-Card Tx
Indicate whether the patient had a Heterotopic or Orthotopic heart transplantation either in conjunction with, or as the primary surgical procedure.

Other Card-Cardiac Trauma
Indicate whether the patient had a surgical procedure for an injury due to Cardiac

Trauma either in conjunction with, or as the primary surgical procedure.

Other Card-Congenital
Indicate whether the patient had a congenital defect repair either in conjunction with, or as the primary surgical procedure.

Other Card-LVA
Indicate whether the patient had a Left Ventricular Aneurysm Repair either in conjunction with, or as the primary surgical procedure.

Other Card-Other
Indicate whether the patient had an other cardiac procedure performed either in conjunction with, or as the primary surgical procedure that is not included within this section. Includes, but is not limited to those procedures listed on the STS Data Manager's section of the STS Web Site.

Other Card-Surgical Ventricular Restoration
Indicate whether the patient had a Surgical Ventricular Restoration either in conjunction with, or as the primary surgical procedure. Surgical Ventricular Restoration are procedures that restore the geometry of the heart after an anterior MI. They include the Dor procedure or the SAVER procedure. This SVR procedure is distinct from an anterior left ventricular aneurysmectomy (LVA) and from a Batista procedure (left ventricular volume reduction procedure).

Other Card-Transmyocardial Laser Revascularization
Indicate whether the patient underwent the creation of multiple channels in left ventricular myocardium with a laser fiber either in conjunction with, or as the primary surgical procedure.

Other Card-VSD
Indicate whether the patient had a Ventricular Septal Defect Repair either in conjunction with, or as the primary surgical procedure.

Other Non Card
Indicate whether a non-cardiac procedure was done.

Patient Age
Indicate the patient's age in years, at time of surgery. This should be calculated from the

date of birth and the date of surgery, according to the convention used in the USA (the number of birthdate anniversaries reached by the date of surgery). If age is less than 18, the data record will be accepted into the database, but will not be included in the national analysis and report.

Prev CAB
Indicate whether the patient had a previous Coronary Bypass Graft prior to the current admission.

Prev Oth Card-PCI-Interval
Indicate the interval of time between the previous PCI and the current surgical procedure.

Prev Valve
Indicate whether the patient had a previous surgical replacement and/or surgical repair of a cardiac valve. This may also include percutaneous valve procedures.

Race - Black / African American
Indicate whether the patient's race, as determined by the patient or family, includes Black / African American. This includes a person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American." Definition source: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity : The minimum categories for data on race and ethnicity for Federal statistics, program administrative reporting, and civil rights compliance reporting. (www.whitehouse.gov/omb/fedreg/1997standards.html)

Race - Asian
Indicate whether the patient's race, as determined by the patient or family, includes Asian. This includes a person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. Definition source: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity : The minimum categories for data on race and ethnicity for Federal statistics, program administrative reporting, and civil rights compliance reporting. (www.whitehouse.gov/omb/fedreg/1997standards.html)

Resuscitation
Indicate whether the patient required cardiopulmonary resuscitation within one hour before the start of the operative procedure.

RF - Peripheral Arterial Disease
Indicate whether the patient has a history of peripheral arterial disease (includes upper and lower extremity, renal, mesenteric, and abdominal aortic systems). This can include: 1. Claudication , either with exertion or at rest, 2. Amputation for arterial vascular insufficiency, 3. Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (excluding dialysis fistulas and vein stripping), 4. Documented aortic aneurysm with or without repair, 5. Positive noninvasive test (e.g., ankle brachial index =< 0.9, ultrasound, magnetic resonance or computed tomography imaging of > 50% diameter stenosis in any peripheral artery, i.e., renal, subclavian, femoral, iliac). Peripheral arterial disease excludes disease in the carotid or cerebrovascular arteries.

RF-Cerebrovascular Dis
Indicate whether the patient has Cerebro-Vascular Disease, documented by any one of the following: CVA (symptoms > 24 hrs after onset, presumed to be from vascular etiology); TIA (recovery within 24 hrs); Non-invasive carotid test with > 79% diameter occlusion.; or Prior carotid surgery. Does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy.

RF-Chronic Lung Dis
Indicate whether the patient has chronic lung disease, and the severity level according to the following classification: No; Mild: FEV1 60% to 75% of predicted, and/or on chronic inhaled or oral bronchodilator therapy. Moderate: FEV1 50% to 59% of predicted, and/or on chronic steroid therapy aimed at lung disease. Severe: FEV1 <50% predicted, and/or Room Air pO2 < 60 or Room Air pCO2 > 50.

RF-CVA
Indicate whether the patient has a history of stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in cerebral blood supply) that did not resolve within 24 hours.

RF-Diabetes
Indicate whether the patient has a history of diabetes, regardless of duration of disease or need for anti-diabetic agents. Includes on admission or preoperative diagnosis. Does not include gestational diabetes.

RF-Diabetes-Control
Indicate the method of diabetic control. Code the control method patient presented with on admission. Patients placed on a pre-operative diabetic pathway of Insulin drip but at admission were controlled with NONE, diet or oral method are not coded as insulin

dependent. Choices are: None = No treatment for diabetes. Diet = Diet treatment only. Oral = Oral agent treatment (includes oral agent with/without diet treatment). Insulin = Insulin treatment (includes any combination with insulin). Other = Other adjunctive therapy

RF-Hypertension
Indicate whether the patient has a diagnosis of hypertension, documented by one of the following: a. Documented history of hypertension diagnosed and treated with medication, diet and/or exercise b. Prior documentation of blood pressure >140 mmHg systolic or 90 mmHg diastolic for patients without diabetes or chronic kidney disease, or prior documentation of blood pressure >130 mmHg systolic or 80 mmHg diastolic on at least 2 occasions for patients with diabetes or chronic kidney disease c. Currently on pharmacologic therapy to control hypertension

RF-Immunosuppressive Rx
Indicate whether the patient has used any form of immunosuppressive therapy within 30 days preceding the operative procedure. This includes, but is not limited to inhaled or systemic steroid therapy and chemotherapy. This does not include topical applications, one time systemic therapy, or preoperative protocol.

RF-Infect Endocard Type
Indicate the type of endocarditis the patient has. If the patient is currently being treated for endocarditis, the disease is considered active. If no antibiotic medication (other than prophylactic medication) is being given at the time of surgery, then the infection is considered treated.

RF-Last Creat Lvl
Indicate the creatinine level closest to the date and time prior surgery. A creatinine level should be collected on all patients, even if they have no prior history. A creatinine value is a high predictor of a patient's outcome and is used in the predicted risk models.

RF-Renal Fail-Dialysis
Indicate whether the patient is currently undergoing dialysis.

Sex
Indicate the patient's sex at birth as either male or female.

Status
Indicate the clinical status of the patient prior to entering the operating room: Elective:

The patient's cardiac function has been stable in the days or weeks prior to the operation. The procedure could be deferred without increased risk of compromised cardiac outcome. Urgent: Procedure required during same hospitalization in order to minimize chance of further clinical deterioration. Examples include but are not limited to: Worsening, sudden chest pain, CHF, acute myocardial infarction (AMI), anatomy, IABP, unstable angina (USA) with intravenous (IV) nitroglycerin (NTG) or rest angina. Emergent: Patients requiring emergency operations will have ongoing, refractory (difficult, complicated, and/or unmanageable) unrelenting cardiac compromise, with or without hemodynamic instability, and not responsive to any form of therapy except cardiac surgery. An emergency operation is one in which there should be no delay in providing operative intervention. The patient?s clinical status includes any of the following: a. Ischemic dysfunction (any of the following): (1) Ongoing ischemia including rest angina despite maximal medical therapy (medical and/or IABP)); (2) Acute Evolving Myocardial Infarction within 24 hours before surgery; or (3) pulmonary edema requiring intubation. b. Mechanical dysfunction (either of the following): (1) shock with circulatory support; or (2) shock without circulatory support. Emergent Salvage: The patient is undergoing CPR en route to the OR or prior to anesthesia induction.

STS Cardiogenic Shock
Indicate whether the patient was, at the time of procedure, in a clinical state of hypoperfusion sustained for greater than 30 minutes, according to either of the following criteria: 1. Systolic BP < 80 and/or Cardiac Index < 1.8 despite maximal treatment; 2. IV inotropes and/or IABP necessary to maintain Systolic BP > 80 and/or CI > 1.8.

VAD
Indicate whether a ventricular assist device (VAD) was implanted.

Valve
Indicate whether a surgical procedure was done on the Aortic, Mitral, Tricuspid or Pulmonic valves.

VD-Insuff-Aortic
Indicate whether there is evidence of Aortic valve regurgitation. Enter level of valve function associated with highest risk (i.e., worst performance). Enter the highest level recorded in the chart. "Moderately severe" should be coded as "Severe". If data not available or study suboptimal, enter N/A.

VD-Insuff-Mitral
Indicate whether there is evidence of Mitral valve regurgitation. Enter level of valve function associated with highest risk (i.e., worst performance). Enter the highest level recorded in the chart. "Moderately severe" should be coded as "Severe". If data not

available or study suboptimal, enter N/A.

VD-Insuff-Tricuspid
Indicate whether there is evidence of Tricuspid valve regurgitation. Enter level of valve function associated with highest risk (i.e., worst performance). Enter the highest level recorded in the chart. "Moderately severe" should be coded as "Severe". If data not available or study suboptimal, enter N/A.

VD-Stenosis-Aortic
Indicate whether Aortic Stenosis is present. If not documented or not done, indicate as N/A.

VD-Stenosis-Mitral
Indicate whether Mitral Stenosis is present. If not documented or not done, indicate as N/A.

VS-Aortic Proc-Procedure
Indicate whether a surgical procedure was done or not done on the Aortic Valve. Select one of the following: a. No b. Replacement c. Repair/Reconstruction d. Root Reconstruction with Valve Conduit e. Replacement + Aortic Graft Conduit (not a valve conduit) f. Root Reconstruction w/ Valve Sparing g. Resuspension Aortic Valve with Replacement of Ascending aorta h. Resuspension Aortic Valve without Replacement of Ascending aorta i. Resection Sub-Aortic Stenosis

VS-Mitral Proc-Procedure
Indicate whether a surgical procedure was done or not done on the Mitral Valve. Select one of the following: a. No b. Annuloplasty only c. Replacement d. Reconstruction with Annuloplasty e. Reconstruction without Annuloplasty

VS-Pulmonic Proc-Procedure
Indicate whether a surgical procedure was done or not done on the Pulmonic Valve. Select one of the following: a. No b. Replacement c. Reconstruction

VS-Tricuspid Proc-Procedure
Indicate whether a surgical procedure was done or not done on the Tricuspid Valve. Select one of the following: a. No b. Annuloplasty Only c. Replacement d. Reconstruction with Annuloplasty e. Reconstruction without Annuloplasty f. Valvectomy

Weight (kg)
Indicate the weight of the patient in kilograms closest to the date of surgery.

FAQ

Which fields can prevent the calculation from taking place?

Risk values are calculated for the following procedures categories only:

CABG Only
Aortic Valve Replacement (AVRepl)
Mitral Valve Replacement (MVRepl)
Mitral Valve Repair (MVRepr)
AVRepl+CABG
MVRepl+CABG
MVRepr+CABG

Note that at the present time there is no model for double valve replacements .

What eligibility criteria must be met in order to calculate risk scores?

Date of Surgery must be greater than 1/1/2000.
For CABG Only Renal Failure, the Dialysis field must be No.

How should I interpret the results?

The results of the various risk model calculations need to be interpreted with caution. Several reasons for this can be given.

Statistical models should only be used to evaluate situations in conjunction with the model's underlying statistical significance. No statistical parameters, other than outcome, are presented here.

Even with large databases, certain combinations of risk factors seldom if ever occur together. When combined randomly within a given model, curious and misleading results might occur that may bear little resemblance to reality.

Models are, at best, only an approximation of the real situation. They are useful for examining interrelationships between risk factors and for comparing one type of model with another. They should never be used as the sole criteria to make life and death decisions concerning the delivery of health care.

What are the minimum operating system requirements to be able to run the risk modeler?

Windows 2000K, Windows XP Pro, Windows Vista operating systems. Microsoft Access must be installed.

What algorithms are used to calculate the risk values?

The algorithms are primarily the risk algorithms described by the STS detailed in the 2.61 software specifications. For more information, please contact the San Francisco Heart & Vascular Institute.

Is this program HIPPA compliant ?

Yes. The patient database is both encrypted and password enabled. The database password is hard-coded in the program so that it is not possible for anyone to access the patient database accept through the use of the software.

References

Block PC, Peterson EC, Krone R, Kessler K, Hannan E, O'Conner GT, Detre K. Identification of variables needed to risk adjust outcomes of coronary interventions: evidence-based guidelines for efficient data collection. J Am Coll Cardiol 1998;32:275-82.

Brier GW. Verification of forecasts expressed in terms of probability. Monthly Weather Review 1950;75:1-3.

Chassin MR, Galvin RW. The urgent need to improve health care quality. JAMA 1998;280:1000-1005.

Clark RE. Report of the first presentation of the National Database. Ann Thorac Surg 1991;52:414.

Clark RE. The Society of Thoracic Surgeons national database status report. Ann Thorac Surg 1994;57:20-6.

Clark RE. The STS cardiac surgery national database: An update. Ann Thorac Surg 1995;59:1376-81.

Clark RE, Edwards FH, Schwartz M. Profile of preoperative characteristics of patients having CABG over the past decade. Ann Thorac Surg 1994;58:1863-5.

Dziuban SW Jr, McIlduff JB, Miller SJ, Dal Col RH. How a New York cardiac surgery program uses outcomes data. Ann Thorac Surg 1994;58:1871-6.

DuBois EF. In Basal Metabolism in Health and Disease, 3rd Edition, Philadelphia, 1936, Lea & Febiger.

Edwards FH, Albus RA, Zajtchuk R, et al. Use of a Bayesian statistical model for risk assessment in coronary artery surgery. Ann Thorac Surg 1988;45:437-40.

Edwards FH, Albus RA, Zajtchuk R, et al. A quality assurance model of operative mortality in coronary artery surgery. Ann Thorac Surg 1989;47:646-9.

Edwards FH, Cohen AJ, Bellamy RF, et al. Risk assessment in urgent/emergent coronary artery surgery. Chest 1990;97:1125-9.

Edwards FH, Clark RE, Schwartz M. Coronary artery bypass grafting: the Society of Thoracic Surgeons national database experience. Ann Thorac Surg 1994;57:12-9.

Edwards FH, Clark RE, Schwartz M. Impact of internal mammary artery conduits on operative mortality in coronary revascularization. Ann Thorac Surg 1994;57:27-32.

Edwards FH, Clark RE, Schwartz M. Practical considerations in the management of large multiinstitutional databases. Ann Thorac Surg 1994;58:1841-4.

Edwards FH, Graeber GM. The theorem of Bayes as a clinical research tool. Surg Gynecol Obstet 1987;165:127-9.

Edwards FH, Peterson ED, The Duke Clinical Research Institute, Data Analyses of the Society of Thoracic Surgeons National Adult Cardiac Surgery Database, April 2008.

Edwards FH, Peterson RJ, Bridges C, Ceithaml EL. Use of a Bayesian statistical model for risk assessment in coronary artery surgery. Update. Ann Thorac Surg 1995;59:1611-2.

Fisher LD, Van Belle G. In “Biostatistic: A Methodology for the Health Sciences”, Chapter 8. Nonparametric, distribution-free and permutation models: robust procedures., New York, 1993, John Wiley & Sons, Inc., pp 327-8.

Frankel HM. Determination of body mass index. JAMA 1986;225:125.

Grover FL, Johnson RR, Shroyer ALW, et al. The Veterans Affairs continuous improvement in cardiac surgery study. Ann Thorac Surg 1994;58:1845-51.

Hadorn DC, Draper D, Rogers WH, et al. Cross validation performance of mortality prediction models. Statistics in Medicine 1992; 11:475-89.

Hadorn DC, Keeler EB, Rogers WH, Brook RH. Assessing the performance of mortality prediction models. Santa Monica, CA:RAND/UCLA/Harvard Center for Health Care Financing Policy Research. 1993;:1-41.

Hammermeister KE. Participatory continuous improvement. Ann Thorac Surg 1994;58:1815-21.

Hammermeister KE, Daley J, Grover FL. Using outcomes data to improve clinical practice: what we have learned. Ann Thorac Surg 1994;58:1809-11.

Hammermeister KE, Johnson R, Marshall G, et al. Continuous assessment and improvement in quality of care: a model from the Department of Veterans Affairs cardiac surgery. Ann Surg 1994;219:281-9.

Hanley JA, McNeil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. Radiology 1982;143:29-36.

Hannan EL, Kumar K, Racz M, et al. New York State's cardiac surgery reporting system: four years later. Ann Thorac Surg 1994;58:1852-7.

Higgins Tl, Estafanous FG, Loop FD, et al. Stratification of morbidity and mortality

outcome by preoperative risk factors in coronary artery bypass patients. a clinical severity score. JAMA 1992;267:2344-8.

Hosmer DW, Taber S, Lemeshow S. The importance of assessing the fit of logistic regression models: a case study. Am J Pub Health 1991;81:12;1630-5.

Katz D, Foxman B. How well do prediction equations predict? using a receiver operating characteristic curves and accuracy curves to compare validity and generalizability. Epidemiology, 1993;4:319-26.

Marshall G, Grover FL, Henderson WG, et al. Assessment of predictive models for binary outcomes: an empirical approach using operative death from cardiac surgery. Statistics Med 1994;13:1501-11.

Marshall G, Shroyer LW, Grover FL, et al. Bayesian-logit model for risk assessment in coronary artery bypass grafting. Ann Thorac Surg 1994;57:1492-500.

Menard S. In “Applied Logistic Regression”, Chapter 2. Summary statistics for evaluating the logistic regression model, Iowa City, IA, 1995; Sage Publications, Inc., pp 17-37.

Mick MJ, Piedmonte MR, Arnold AM, Simpfendorfer C. Risk stratification for long-term outcome after elective coronary angioplasty: a multivariate analysis of 5,000 patients. J Am Coll Cardiol 1994;24:74-80.

Millenson, ML. "Demanding Medical Excellence: Doctors and Accountability in the Information Age", University of Chicago Press, 1997.

National Institutes of Health Consensus Development Panel. Health implications of obesity: National Institutes of Health Consensus Development Conference statement. Ann Intern Med 1985;103:147-51.

Nugent WC, Schults WC. Playing by the numbers: how collecting outcomes data changed my life. Ann Thorac Surg 1994;58:1866-70.

Orr RK, Maini BS, Sottile FD, Dumas EM, O’Mara P. A comparison of four severity-adjusted models to predict mortality after coronary artery bypass graft surgery. Arch Surg 1995;130:301-306.

Parsonnet V, Dean D, Bernstein AD. A method of uniform stratification of risk for evaluating the results of surgery in acquired adult heart disease. Circulation 1989;79 (Suppl 1):I3-12.

Pliam MB, Shaw RE, Zapolanski A. Comparative analysis of coronary surgery risk stratification models. J Invas Cardiol 1997;9:203-22.

Selker HP, Griffith JL, D'Agostino RB. A tool for judging coronary care unit admission appropriateness, valid for both real-time and retrospective use: a time-insensitive predictive instrument (TIPI) for acute cardiac ischemia: a multicenter study. Med Care 1991;29:7;610-7.

"SPSS Reference Guide", 1990, SPSS Inc., Chicago, IL.

Steen PM. Approaches to predictive modeling. Ann Thorac Surg 1994;58:1836-40.

Walker SH, Duncan DB. Estimation of the probability of an event as a function of several independent variables. Biometrika 1967;54:167-79.

Ward ME. Estimation of capitation expense for specialty services. Ann Thorac Surg 1996;62:S26-S30.

Yates JF. External correspondence: decomposition of the mean probability score. Organization Behavior and Human Performance 1981;30:132-56.

STS National Database and Risk Calculator

The Society of Thoracic Surgeons offers outcome programs in the areas of Adult Cardiac, General Thoracic and Congenital surgery. By committing to collecting outcomes data to the STS National Database, surgeons are committing to improving the quality of care that their cardiothoracic surgery patients receive.

Since 1994, more than 40 publications have come from the STS National Databases. These studies have been published in a variety of professional journals and textbooks. The STS National Database has recently served as the basis for a federally funded national quality improvement randomized trial, as well as research in targeted areas of cardiac surgery.

This site contains information for both potential and current participants in any of the STS National Databases. It also contains an online risk calculator at http://www.sts.org/sections/stsnationaldatabase/riskcalculator/

The STS Risk Calculator allows a user to calculate a patient's risk of mortality and other morbidities, such as long length of stay and renal failure. The Risk Calculator incorporates the STS risk models that are designed to serve as statistical tools to account for the impact of patient risk factors on operative mortality and morbidity.

Benchmarks

Benchmarks for various procedures outcomes are available. The Society of Thoracic Surgeons collects data from hundreds of hospitals each year and makes the results available the average observed results available. Some of these are shown in the following tables.

Table 1. Results for in hospital mortality and operative mortality for year 2007

	In Hospital	Operative *		95 % C.I. *	
PROCEDURE	Mortality %	Mortality %	N	Lower	Upper
Isolated CABG	2.0	2.3	154188	2.22	2.37
Isolated Aortic Valve Replacement	2.5	3.0	17592	2.75	5.52
Isolated Mitral Valve Replacement	5.4	6.0	4251	5.29	1.31
Aortic Valve Replacement + CABG	4.3	4.8	14957	4.46	8.23
Mitral Valve Replacement + CABG	10.0	10.7	2427	9.47	2.23
Mitral Valve Repair	1.6	1.8	5076	1.43	4.46
Mitral Valve Repair + CABG	5.5	6.1	4566	5.41	13.0

* Operative Mortality = death within 30 days of the operation

Table 2. Results for permanent stroke for year 2007

			95 % C.I.	
PROCEDURE	Stroke %	N	Lower	Upper
Isolated CABG	1.1	154188	1.05	1.15
Isolated Aortic Valve Replacement	1.4	17592	1.23	1.57
Isolated Mitral Valve Replacement	2.1	4251	1.67	2.53
Aortic Valve Replacement + CABG	2.3	14957	2.06	2.54
Mitral Valve Replacement + CABG	3.4	2427	2.68	4.12
Mitral Valve Repair	1.3	5076	0.99	1.61
Mitral Valve Repair + CABG	2.4	4566	1.96	2.84

Table 3. Results for renal failure for year 2007

			95 % C.I.	
PROCEDURE	Renal Failure %	N	Lower	Upper
Isolated CABG	3.5	154188	3.41	3.59
Isolated Aortic Valve Replacement	4.4	17592	4.10	4.70
Isolated Mitral Valve Replacement	6.6	4251	4.85	7.35
Aortic Valve Replacement + CABG	7.5	14957	7.08	7.92
Mitral Valve Replacement + CABG	12.2	2427	10.90	13.50
Mitral Valve Repair	2.6	5076	2.16	3.04
Mitral Valve Repair + CABG	10.3	4566	9.42	11.18

Table 4. Results for prolonged ventilatory support (> 24 hrs) for year 2007

			95 % C.I.	
PROCEDURE	Prolonged Vent Support %	N	Lower	Upper
Isolated CABG	9.2	154188	9.06	9.34
Isolated Aortic Valve Replacement	10.2	17592	9.75	10.65
Isolated Mitral Valve Replacement	19.4	4251	18.21	20.59
Aortic Valve Replacement + CABG	16.3	14957	15.71	16.89
Mitral Valve Replacement + CABG	33.1	2427	31.23	34.97
Mitral Valve Repair	7.7	5076	6.97	8.43
Mitral Valve Repair + CABG	25.0	4566	2.37	2.63

Table 5. Results for deep sternal wound infection for year 2007

			95 % C.I.	
PROCEDURE	Sternal Wound %	N	Lower	Upper
Isolated CABG	0.3	154188	0.27	0.33
Isolated Aortic Valve Replacement	0.3	17592	0.22	0.38
Isolated Mitral Valve Replacement	0.4	4251	0.21	0.59
Aortic Valve Replacement + CABG	0.6	14957	0.48	0.72
Mitral Valve Replacement + CABG	0.7	2427	0.37	1.03
Mitral Valve Repair	0.2	5076	0.08	0.32
Mitral Valve Repair + CABG	0.9	4566	0.63	1.17

Table 6. Results for reoperation for year 2007

			95 % C.I.	
PROCEDURE	Reop %	N	Lower	Upper
Isolated CABG	5.0	154188	4.89	5.11
Isolated Aortic Valve Replacement	8.0	17592	7.60	8.40
Isolated Mitral Valve Replacement	12.3	4251	11.31	13.29
Aortic Valve Replacement + CABG	10.0	14957	9.52	10.48
Mitral Valve Replacement + CABG	15.5	2427	14.06	16.94
Mitral Valve Repair	6.5	5076	5.82	7.18
Mitral Valve Repair + CABG	11.3	4566	10.38	12.22

Table 7. Results for any one or more of the above for year 2007

			95 % C.I.	
PROCEDURE	Any %	N	Lower	Upper
Isolated CABG	14.8	154188	14.62	14.98
Isolated Aortic Valve Replacement	18.2	17592	17.63	18.77
Isolated Mitral Valve Replacement	29.3	4251	27.93	30.67
Aortic Valve Replacement + CABG	25.8	14957	25.10	26.50
Mitral Valve Replacement + CABG	45.2	2427	43.22	47.18
Mitral Valve Repair	13.6	5076	12.66	14.54
Mitral Valve Repair + CABG	34.1	4566	32.72	35.48

Table 8. Results for prolonged hospital stay (> 14 days) for year 2007

			95 % C.I.	
PROCEDURE	Prolonged Stay %	N	Lower	Upper
Isolated CABG	5.6	154188	5.49	5.71
Isolated Aortic Valve Replacement	8.5	17592	8.09	8.91
Isolated Mitral Valve Replacement	16.1	4251	15.00	17.20
Aortic Valve Replacement + CABG	13.2	14957	12.66	13.74
Mitral Valve Replacement + CABG	24.6	2427	22.89	26.31
Mitral Valve Repair	6.2	5076	5.54	6.86
Mitral Valve Repair + CABG	18.7	4566	17.57	19.83

Table 9. Results for short hospital stay (< 6 days) for year 2007

			95 % C.I.	
PROCEDURE	Prolonged Stay %	N	Lower	Upper
Isolated CABG	50.0	154188	49.75	50.25
Isolated Aortic Valve Replacement	37.9	17592	37.18	38.62
Isolated Mitral Valve Replacement	21.7	4251	20.46	22.94
Aortic Valve Replacement + CABG	26.0	14957	25.30	26.70
Mitral Valve Replacement + CABG	15.0	2427	13.58	16.42
Mitral Valve Repair	48.4	5076	47.03	49.77
Mitral Valve Repair + CABG	19.5	4566	18.35	20.65

Security

In order to insure the secure storage of patient information, all patient information is stored in a PliaTech XML™ database that is both encrypted and password enabled. In addition, any patient information stored on hard disk in the application-specific smx files, are stored in binary file format that is encrypted using the Advanced Encryption Standard with a 256-bit key, making those files more than adequately secure. You have the option to use disk files, to store patient information in the patient database, or both. Note that patient information contained in both the disk files and in the application patient database can only be accessed through the current application software. Obviously, access to the software is critical to the security of the contained patient data. Securing your copy of the software on your computer is entirely your responsibility.

HIPAA Compliant

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Credits

This application was developed by Michael B. Pliam, MD, PhD, as an independent consultant for the San Francisco Heart & Vascular Institute at Seton Medical Center, a Daughters Of Charity Hospital.

The general plan of the 9 risk models and 7 procedural categories follows that devised by the Society of Thoracic Surgeons (STS) Risk Calculator. The risk algorithms used to calculate the outcomes risk have been modified by the author in order to correspond to data currently available in the SFHI database. Further, detailed information regarding the risk calculations were generously provided by Mr. Nick Gawrit of Heartbase ™.

The application was compiled using Microsoft Visual Studio 2005.

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