

UNDERSTANDING RISK ADJUSTED MORTALITY (RAM) IN THE CATHPCI REGISTRY[®]

The CathPCI Registry[®] is the oldest of several registries in the National Cardiovascular Data Registry[™] (NCDR[™]). Operated by the American College of Cardiology (ACC), which is a professional association for cardiologists, this Registry is a voluntary data registry in which participating hospitals collect and submit data about patients who had a diagnostic coronary catheterization and/or a percutaneous coronary intervention (PCI); in return, the hospitals receive detailed reports comparing their demographics, co-morbid conditions, cardiac status, coronary anatomy as well as process and outcome measures, as compared to aggregated data.

Hospitals' different patient populations reflect differences in patient risk factors prior to PCI; these differences will affect outcomes, notably patient mortality. In a similar fashion, the impact of treatment upon outcomes will vary among hospitals. Thus, variations in outcomes among hospitals make it imperative that mortality outcomes be made comparable using a risk-adjusted mortality (RAM) model.

Since mortality is the most important and widely used indicator of outcomes and quality of care, reporting hospital risk adjusted outcomes is crucial to hospitals' understanding of their treatment quality. The RAM model offers participating hospitals the ability to monitor outcomes of their patients undergoing PCI and to compare their outcomes to the overall experience reported in the Registry. By accounting for patient risk factors and hospital treatment, risk adjustment "levels the playing field" among participating institutions.

The RAM model was first applied to data for the years 1998 to 2000. To assure its validity and reassess clinical variables, it was substantially revised in 2007-2008. This current, substantially revised model was developed by the RAM Work Group, comprised of NCDR committee members who have expertise in epidemiology, biostatistics and coronary interventions. Analysis was performed by the Duke Clinical Research Institute. To develop the model, the Work Group had the following goals:

- Assess the quality of the data collected for the registry;
- Define the patient population for inclusion in the model;
- Select elements/clinical variables associated with PCI mortality;
- Compute a risk score for individual patients based on the presence of elements/clinical variables;
- Aggregate individual patient risk scores into a risk adjustment mortality model.

The new model was developed using patients discharged between January 1, 2004 and March 31, 2006. A total of 309,351 consecutive patients undergoing PCI at 470 hospitals in the United States were entered into the NCDR™ Cath Lab Module, version 3.04.

Upon implementation of the RAM model, several statistics are computed that allow for comparison between your institution and the Registry. In the NCDR report provided to each institution, observed, predicted, and adjusted mortality are presented.

DATA COLLECTION AND DATA QUALITY

The validity of risk adjustment models is almost entirely dependent on the accuracy and completeness of the dataset on which the models are based.

Inclusion criteria assess the level of completeness on key elements/clinical variables used in the model. There are 2 complementary components to Data Quality Program:

- The Data Quality Report (DQR) program: The DQR program assesses the completeness of data submitted by participating hospitals. Hospitals must achieve a high level of completeness (>95% completeness of specific data elements identified as 'core fields' which encompass the variables included in our risk adjustment models) in order to have their data analyzed in the RAM model, and to be included in the aggregated data. The process is iterative, providing hospitals with the opportunity to correct errors and resubmit data for review.
- The Data Audit Program (DAP). The DAP consists of annual on-site chart review and data abstraction. Among participating hospitals, a certain number are randomly selected to participate in the DAP. The audits focus on variables that are associated with PCI mortality including demographics, co morbidities, cardiac status, coronary anatomy, and PCI status. In most audits, the median agreement between submitted and audited values is 92%.

POPULATION DEFINITION

Who is included:

1. Data submissions that passed the data quality completeness checks;
2. Patient admissions with a PCI procedure performed during admission.

Who is excluded:

1. NCDR Registry patients who did not have a PCI (Patient admissions with a diagnostic cath only during that admission);
2. Data submissions that do not pass the data quality and completeness reports;

3. Procedure variables for subsequent PCIs during the same admission (if the patient had more than one PCI procedure during that admission).
4. Patient admissions with PCI who transferred to another facility on discharge;
5. Patient admissions with PCI who have more than two variables in the risk model that are missing. Note: If one or two variables are missing, the value is imputed for certain characteristics (see appendix 2 of the NCDR CathPCI Registry PCI Risk Adjusted Mortality Model 2008 for more information). If the value is missing for more than two variables, the patient record is excluded. However, in our data quality program, all variables in the risk model have a high "inclusion" criteria. This means that, when a hospital submits data to us, they need to have a high level of completeness (around 99%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk adjusted mortality for the records they submitted for that quarter.

Patients with a first PCI procedure performed during an admission were included in the study population. After excluding 6,334 transfer-out patients and 39 patients who were missing more than 2 candidate variables for the mortality model, 302,958 patients with PCI procedures at 470 participating NCDR centers remained in the analysis population. Sixty percent of patients (n=181,775) were chosen at random for the model development, while the remaining 40% were taken as the first validation sample. The overall population (the development sample plus two validation samples) includes 588,398 admissions at 635 sites.

VARIABLE SELECTION

Before proceeding with developing a multivariate model, univariate analysis was used to identify the factors that had both clinical and statistical (i.e. p-value < 0.05) significance. A multivariate logistic regression with backward selection method was then performed to identify the predictive variables. The selection criterion was set to 0.05.

Weights were assigned to risk factors or variables reflecting the strength of their association to PCI in-hospital mortality. Each patient in a facilities submission is given a risk score to predict risk of in-hospital mortality and accurately report risk adjusted mortality rates during hospitalization.

The most noteworthy risk factors or variables include:

1. ST-segment elevation MI defined as a patient who had a STEMI on admission, with an onset within 24 hours, or the procedure indication was primary, rescue or facilitated PCI.
2. Discharge status (alive or expired). The interaction between this variable with other variables were key in the analysis.
3. The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = $186 \times (\text{last creatinine})^{-1.154} \times (\text{age})^{-0.203} \times (\text{gender factor}) \times (\text{race factor})$ where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others].

4. The body mass index (BMI) (kg/m²) is calculated from height (cm) and weight (kg): $BMI = \text{weight} \times 10000 / (\text{height})^2$.

Variables coded on admission include:

1. Age (\leq or >70),
2. Body mass index (calculated using height and weight),
3. Cardiogenic shock on admission.
4. Previous history of congestive heart failure (CHF),
5. Previous valvular surgery,
6. Cerebrovascular disease,
7. Peripheral vascular disease,
8. Diabetes (and type of control),
9. Chronic lung disease,
10. Previous PCI,
11. Glomerular filtration rate (calculated using creatinine, age, sex and race),
12. Dialysis,
13. NYHA classification

Variables coded during the procedure include:

1. Pre-procedure IABP,
2. Ejection Fraction %;
3. PCI Status (urgent, emergency, salvage);
4. Coronary lesion $>50\%$ with subacute thrombosis;
5. Pre-procedure TIMI flow;
6. Highest lesion risk using SCAI lesion classification;
7. Lesion location (e.g. proximal LAD)

COMPUTING OBSERVED MORTALITY RATES

Observed mortality rates (OMR) represent an unadjusted measure of mortality. OMR was computed by dividing the number of patients who died in the hospital during or following a PCI by the number of patients who had PCI procedures performed during 2004-2006. For example, if an institution had 1,275 procedures in the Registry and 19 patients died, the OMR would be 1.5% (19/1275). Please note that this rate does not account for differences in patient risk.

COMPUTING EXPECTED MORTALITY RATES

To better assess the probability of death for each PCI patient prior to his or her procedure an expected mortality rate (EMR) was calculated. The EMR for each institution was determined by using a multivariate logistic regression mortality model. This was accomplished by summing the predicted probabilities of death that were calculated for each PCI patient from that institution and dividing by the total number of patients from that institution who had PCI procedures. The resulting rate represents what the model predicted as the mortality rate for an institution given the existence of risk factors for each patient, and the sum of the weights assigned by the model for

those risk factors. Because the regression model had been developed on the only 60% of the registry data (the remaining 40% were taken as the first validation sample), the overall EMR of all the patients in the registry was not exactly but nearly equal to the OMR of the registry (1.2%).

COMPUTING RISK-ADJUSTED MORTALITY RATES

The Risk-Adjusted Mortality Rate (RAMR) represents the mortality, based on the associated logistic regression model, that an institution would be predicted to have if the institution performed PCI on a randomly selected group of patients taken from the Registry experience. Statistically, if one were to randomly select 100 patients having PCI from the 301,118 patients in the Registry, the mortality of this group would be close to 1.2%.

Mathematically, the RAMR was calculated by taking the OMR for each institution and dividing it by the EMR for that institution, and multiplying the resulting ratio by the overall mortality rate for the entire registry (1.2%). Three scenarios are possible; either the institution's RAMR is higher, lower, or about the same as the overall Registry experience. Table 1 provides specific examples of the application of the calculations described above.

Table 1. Risk Adjustment

	INSTITUTION A	INSTITUTION B	INSTITUTION C	NCDR™
# PCI Procedures	1006	2240	968	588,398
# Deaths	20	25	9	7,123
OMR	1.99%	1.12%	0.93%	1.21%
EMR	1.77%	1.43%	0.93%	1.23%
OMR/EMR	1.12	0.783	1.00	0.984
RAMR	$1.12 \times 1.21\%$ 1.36%	$0.783 \times 1.21\%$ 0.95%	$1.00 \times 1.21\%$ 1.21%	$(1.21\%/1.23\%) \times 1.21\%$ 1.19%

INTERPRETING THE RAMR

An explanation of how to interpret your RAMR based on this model is outlined below. All examples refer back to Table 1.

STATISTIC	INTERPRETATION
OMR/EMR > 1	When the ratio of the OMR to EMR is greater than 1, the institution had an observed mortality for its patients that was greater than their expected mortality. In this scenario, adjusting for the risk of a group of patients similar

STATISTIC	INTERPRETATION
	to those found in the Registry, Institution A would have an adjusted mortality greater than 1.21%.
OMR/EMR <1	<p>When the ratio of the OMR to EMR is less than 1, the institution had an observed mortality for its patients that was less than their expected mortality.</p> <p>In this scenario, adjusting for the risk of a group of patients similar to those found in the Registry, Institution B would have an adjusted mortality lower than 1.21%.</p>
OMR/EMR =1	<p>When the ratio of the OMR to EMR is close to 1, the institution had an observed mortality for its patients that was exactly what was expected.</p> <p>In this scenario, adjusting for the risk of a group of patients similar to those found in the Registry, Institution C would have an adjusted mortality rate of 1.21%.</p>

LIMITATIONS

While the new NCDR model can provide quite accurate assessment of PCI mortality risks in the modern era and have application for informed clinical decision making as well as for appropriate risk adjusted hospital outcome comparisons, there are limitations. Some limitations include voluntary participation, limited auditing of data source (fewer than 5% of participating hospitals), no external validation of model, standardized angiographic data, no data on functional status and outcomes limited to in-hospital mortality. The factors used and the weights obtained from this analysis are model-specific. That is, the adjusted mortality from this analysis may not correspond exactly to that generated from other models. As a corollary, the absence of reported deaths will affect the RAMR.

There are challenges in interpreting the RAMR that must be kept in mind when reviewing your institutional results. Variation in volume from one institution to the next may influence that institution's EMR. For example, very high mortality rates may occur due to chance alone. This is particularly true for low volume institutions. Large differences between observed and expected mortality rates at institutions with small sample sizes may be due primarily to sampling variability. In addition, these risk-adjusted rates may be misleading because the overall pre-procedural severity of illness may not be accurately estimated if significant risk factors are missing. In contrast to cardiac surgery, the occurrence of the outcome of interest (in-hospital mortality) occurs very infrequently. This makes it extremely difficult to develop stable risk adjustment models and hinders the ability to apply these models to local datasets. Any risk-adjustment analysis and comparison will need to consider the number of cases upon which the predictions are based and refrain from over-interpreting results based on small sample sizes.

USING RISK ADJUSTED DATA - WHAT DOES IT MEAN?

How should risk adjusted data be used by participants? Obviously, most concern is generated when an institution has a RAMR that is substantially higher than the overall Registry mortality. The ratio between OMR and EMR for most institutions will vary somewhere between 0.7 and 1.3.

For institutions with OMR/EMR ratios greater than 1.3, there are a number of things the institutions might consider. First and foremost, the institution should not assume there is a problem with the quality of their program or the quality of the physicians involved with their program. The institution must embark on a systematic analysis of the data that was submitted to the NCDR. Three major areas should be addressed:

1. Missing Data

- Are there substantial amounts of missing data on the factors used in the regression model? If so, are there ways to obtain that data on the current patients and insure that these variables are collected in the future?

2. Data Accuracy

- The second level of analysis should involve the accuracy of the data. If a risk factor is missing when in fact the patient actually had the risk factor, the expected mortality will be lower and the adjusted mortality will be higher than it should be. One approach to evaluate this situation is to take a random sample of cases and determine if the risk factors were coded correctly on these patients. If variance is found, what is the source of the variance? Are there ways to correct this problem? Is more education of coders necessary? Are definitions not being interpreted correctly? It is also possible that in settings where multiple people complete the data forms that some coders are applying the definitions differently than others. In this situation, it may be helpful to have ongoing meetings to discuss definitions and periodically have everyone code test cases and compare the results. Additionally, the NCDR™ Core Data Element FAQ is an important resource for data collectors while they interpret the definitions for differing case scenarios.

3. Data Collection and Entry

- The third level of analysis should involve the processes around collection and entry of the data into the local database. Are the forms correct, but mistakes are being made on data entry? Is the database dependent on electronic interfaces from other data sources that may be incorrect? Are the interfaces populating data correctly in the local database? All of these areas are sources of error that can have significant impact on the accuracy of the data collected.

It is likely that any serious problems in one or more of the three areas above could have a substantial impact on the calculation of RAMR. The institution should contact the NCDR to discuss these issues and determine a course of action for future submissions to the Registry.

It is also important to remember that all mortality estimates are based on three years of data. We recommend that institutions refrain from making any major program decisions based on these results until several years of data are available for comparison.

Institutions that have a ratio of OMR/EMR of 0.7 or less also need to approach the use of this information with caution. As was stated earlier, chance variation related to sampling may affect these models. It is recommended that institutions wait for several years of data and observe their results over time.

As the overall Registry experience grows and the quality of the data improve, these risk adjustment models will become more stable and the results for individual institutions will be based on a larger volume of cases.

For other questions about PCI RAM, contact our CathPCI Registry Support Center at ncdr@acc.org; or (800) 257-4737.

Specifications for the Updated 2009 NCDR® CathPCI Registry® PCI In-Hospital Risk Adjusted Mortality Measure

Measure Specifications	
Numerator	Patients with a PCI procedure performed during admission who expired
Denominator	Patients with a PCI procedure performed during admission
Inclusion Criteria	Data submissions that passed the data quality completeness checks. Patient admissions with a PCI procedure performed during admission.
Exclusion Criteria	<ol style="list-style-type: none"> 1. NCDR Registry patients who did not have a PCI (Patient admissions with a diagnostic cath only during that admission); 2. Data submissions that do not pass the data quality and completeness reports; 3. Procedure variables for subsequent PCIs during the same admission (if the patient had more than one PCI procedure during that admission). 4. Patient admissions with PCI who transferred to another facility on discharge; 5. Patient admissions with PCI who have more than two variables in the risk model that are missing. Note: If one or two variables are missing, the value is imputed for certain characteristics (see appendix 2 of the NCDR CathPCI Registry PCI Risk Adjusted Morality Model 2008 for more information). If the value is missing for more than two variables, the patient record is excluded. However, in our data quality program, all variables in the risk model have a high "inclusion" criteria. This means that, when a hospital submits data to us, they need to have a high level of completeness (around 99%) for those variables. If they are not able to meet the criteria in our data quality program, they do not receive risk adjusted mortality for the records they submitted for that quarter.
Period of Assessment	Quarterly, to include previous four quarters of data
Source of Data	CathPCI Registry – v3
Method of Reporting	ACC-NCDR® CathPCI Registry™ Institutional Reports
Clinical Rationale/ Recommendation	<p>Although death in patients with serious heart disease is not completely unexpected, that rate (adjusted for case mix/patient risk factors) is sensitive to a number of controllable factors such as case selection, procedural judgment and operator skill, as well as institutional support and overall quality of care.</p> <p>The ACC-NCDR® risk adjustment model analyzes multiple elements to account for patient risk factors that are present prior to PCI. Risk adjustment “levels the playing field” among participating institutions and adjusts the “actual” mortality rate based on these factors. In other words, if you have several very sick patients die, your risk adjusted mortality rate would be lower than your actual mortality rate. If you had several very healthy patients die unexpectedly, your risk adjusted mortality rate would be higher than your actual mortality rate. Please refer to the detail section of the report and the risk adjustment technical notes for more information.</p> <p>Weights were assigned to risk factors or variables reflecting the strength of their association to PCI in-hospital mortality. Each patient</p>

Measure Specifications	
	<p>in a facilities submission is given a risk score to predict risk of in-hospital mortality and accurately report risk adjusted mortality rates during hospitalization.</p> <p>The most noteworthy risk factors or variables in the model include:</p> <ol style="list-style-type: none"> 1. ST-segment elevation MI defined as a patient who had a STEMI on admission, with an onset within 24 hours, or the procedure indication was primary, rescue or facilitated PCI. 2. Discharge status (alive or expired). The interaction between this variable with other variables were key in the analysis. 3. The glomerular filtration rate (GFR) variable is calculated using abbreviated MDRD formula [GFR = $186 \times (\text{last creatinine})^{-1.154} \times (\text{age})^{-0.203} \times (\text{gender factor}) \times (\text{race factor})$ where (gender factor) = 1 for male and 0.742 for female, (race factor) = 1.21 for black and 1 for others]. 4. The body mass index (BMI) (kg/m²) is calculated from height (cm) and weight (kg): BMI = weight × 10000 / (height)². <p>Other variables:</p> <p>Variables coded on admission: Age (<= or >70), Body mass index, Cardiogenic shock on admission. Previous history of CHF, previous valvular surgery, cerebrovascular disease, peripheral vascular disease, diabetes (and type of control), chronic lung disease, previous PCI, glomerular filtration rate, dialysis, NYHA</p> <p>Variables coded during the procedure – Pre-procedure IABP, Ejection Fraction %; PCI Status; Coronary lesion >50% with subacute thrombosis; Pre-procedure TIMI flow; Lesion risk using SCAI lesion classification; lesion location (e.g. proximal LAD)</p>
Relevant Citations	Refer to the document: NCDR CathPCI Registry PCI Risk Adjusted Morality Model 2008 for further description of the model.
Background	The risk adjusted mortality model was first developed in 2002 using NCDR data from 1998-2000. That model was revised in 2008. A committee of ACC physicians provided independent oversight and input to the Duke Clinical Research Institute who developed and tested the revised model, which is being implemented in 2009 institutional reports.