

## Original Studies

# Quality Assessment and Improvement in Interventional Cardiology: A Position Statement of the Society of Cardiovascular Angiography and Interventions, Part II: Public Reporting and Risk Adjustment

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## INTRODUCTION

As described in Part I of this Position Statement [1], programmatic assessment of percutaneous coronary intervention (PCI) outcomes is fundamental to the delivery of high quality care. Quality improvement requires documenting clinical outcomes and modifying behaviors based on the data. Part II addresses public reporting, current risk models utilized in PCI, recommendations for their proper use and interpretation, and limitations in current methodologies.

Currently, PCI quality is often judged based on advertising, Internet health grades, and public reporting of raw mortality rates. These sources lack sufficient detail and the expertise needed to provide accurate evaluations of facilities or individual operator quality. We propose that PCI quality appraisals be based on the development and use of risk-adjusted models that meaningfully assess clinical outcomes.

## PUBLIC REPORTING

### Principles of Public Reporting

Public reporting, appropriately performed, promotes informed choice among health care consumers, facilitates quality improvement and increases health care transparency. Conversely, it may emphasize the individual physician operator disproportionately over the clinical team and institutional PCI processes. Public

reporting may predispose to the selection of low-risk cases and avoidance of higher-risk cases [2].

SCAI concurs with the 2008 American College of Cardiology Foundation statement of principles

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**TABLE I. Principles and Standards Regarding Public Reporting**

| Public reporting programs should  |
|---|
| 1) Be designed to promote quality improvement   |
| 2) Utilize performance measures that are scientifically validated   |
| 3) Develop reporting measures and procedures in partnership with physicians   |
| 4) Employ standardized covariates to assess performance that are audited periodically for data accuracy   |
| 5) Incorporate a uniform submission process across all public reporting programs  |
| 6) Report performance at the appropriate level of accountability  |
| 7) Include a formal process for evaluating the impact of the program on the quality and cost of health care, including an assessment of unintended consequences |
| 8) Integrate quality and cost   |
| 9) Use valid cost measurement and analysis methods  |
| 10) Provide no incentive for poor quality care  |

See Refs. 3 and 4.

regarding public reporting of quality of care [3]. SCAI also agrees with a multi-societal statement [4] regarding the four standards that should be used for public reporting. These principles are summarized in Table I.

Public reporting is categorized as voluntary or compulsory. An example of voluntary reporting is a hospital's marketing of its outcomes as part of public relations efforts. Submission of data to health insurance payers for the purpose of ranking and assignment as a "center of excellence" is another example.

Compulsory public reporting programs include the Center for Medicare and Medicaid Services (CMS) report on annual case volume and median Medicare reimbursement for PCI procedures, door-to-balloon times within 90 min for primary PCI for STEMI, post-infarct mortality and post-infarct 30-day readmission rates [5]. Several states use proprietary databases to report annual PCI volume and outcomes [6–14].

The use of claims data for public reporting of PCI outcomes is not recommended, since these administrative databases lack sufficient clinical detail for accurate risk adjustment. Self-reporting is also an inherently inaccurate method [15].

### Measures of Quality Used in Public Reporting

Publicly reported measures of quality should include specific definitions that are easily recognized by data collectors, thus avoiding inaccurate data collection [16]. One example is the variability in the assessment of cardiac biomarkers post-PCI, rendering "post-PCI myocardial infarction" a misleading quality metric. After discharge, 30-day mortality is often difficult to ascertain. The lack of standardized definitions also decreases the value of vascular complications and transfusions as quality metrics.

Accurate apportionment of accountability to facilities versus individual operators is essential. Community hospitals providing primary PCI without on-site cardiac surgery often transfer their sickest patients immediately post-PCI to tertiary referral centers, thus avoiding reporting subsequent adverse events. Tertiary facilities using LV assist devices for high-risk PCI accept high-risk patients in transfer, giving them a high-risk case mix. Therefore, simple reporting of mortality without risk adjustment is misleading and may not accurately reflect site quality.

Public reporting of high mortality rates has affected patient selection in unintended and deleterious ways. After the initiation of public reporting in New York, patients undergoing PCI were less likely to be in cardiogenic shock, have heart failure, or have acute myocardial infarction than patients in Michigan [17,18]. This suggests a purposeful avoidance of high-risk procedures [2,19–24]. Termed "risk avoidance creep" [2], operator case selection intended to limit the risk of complications suggests that reporting of unadjusted mortality may not be a reliable guide to quality nor good for patient care.

The position of the Society is that it may be able to support some instances of public reporting which conform to the standards discussed in this two-part quality position statement. Certainly the Society recognizes that the public has a right to know the competency of those individuals they may choose to perform their PCI procedures. However, the reporting of raw outcomes without risk adjustment is likely to be misleading to the public, and the Society cannot support that method of public reporting. Unless case selection is adequately addressed, the reporting and comparison of unadjusted outcomes may lead to incorrect conclusions regarding relative quality. The outcome measures the Society supports are the risk adjustment models discussed below.

### Public Reporting of PCI Volume

Annual operator and institutional PCI volumes have been proposed as a method of assessing PCI quality. Based on the intuitive concept that "practice makes perfect" and supported by the demonstration of such relations with surgical procedures, the linkage of operator and institutional volume to PCI quality has been assumed [25–33].

The use of an arbitrarily defined annual operator volume to define quality has been the subject of controversy for two decades [34]. Individual operator volume is a longstanding quality indicator in the AHA/ACC/SCAI PCI Guidelines [25], a position which the Society has endorsed. A caseload of  $\geq 75$  PCI cases/year is the minimal number of PCI procedures suggested to

**TABLE II. Stent Era Evaluations of Associations Between Operator Volume and Outcomes**

| Author          | Institution            | Reference | Year | Univariate association |       |      |
|-----------------|------------------------|-----------|------|------------------------|-------|------|
|                 |                        |           |      | None                   | Death | CABG |
| Malenka, et al  | Northern New England   | 26        | 1999 | x                      |       |      |
| McGrath, et al  | Medicare               | 27        | 2000 |                        |       | x    |
| Harjai, et al   | Beaumont               | 28        | 2004 | x                      |       |      |
| Hannan, et al   | New York               | 29        | 2005 |                        |       | x    |
| Moscucci, et al | University of Michigan | 30        | 2005 |                        |       | x    |
| Mustafa, et al  | New Jersey             | 31        | 2005 | x                      |       |      |
| Cantor, et al   | Canada                 | 32        | 2006 | x                      |       |      |

**TABLE III. Factors Predictive of Clinical Outcomes Following PCI**

|   |
|---|
| Case selection  |
| Patient-specific risk factors   |
| Institutional volume: sharing of techniques, more experience in high-risk cases |
| Operator volume: annual, lifetime   |
| Appropriateness criteria and indication level                                   |
| High-risk case selection may be related to higher case volume                   |
| Location of hospital: rural/suburban, community, academic teaching              |
| Board certification: cognitive learning, evidence-based practice                |

maintain competency after formal training and to obtain board certification. Several third parties [35] incorporate a minimum annual volume as a criterion for being named a preferred provider. The supporting data, PCI Guidelines [25], and the ACC Competence Statement [36] suggest a weak and inconsistent relationship of volume with outcomes. They also suggest that PCI annual volume not be used as a surrogate for quality or risk-adjusted outcomes.

In the stent era (Table II), no relationship between operator volume and in-hospital mortality exists. Further, there is only a weak relationship with unplanned CABG [38–44], which is likely due to the many clinical variables that impact outcomes (Table III). In the Northern New England Registry [26] there was no relationship between operator volume and clinical success, MI as a complication, mortality (low or high-risk patients) or in-hospital CABG. Among Medicare beneficiaries [27], only a 0.6% difference in CABG and no difference in 30-day mortality or MACE were found at high versus low volume programs. In over 38,000 PCIs in Canadian hospitals, there was no relationship between operator volume and outcomes [32]. Although the Michigan database [30] showed a 0.63% difference in unplanned CABG (just one additional unplanned CABG per 157 PCIs) when comparing the lowest two quintiles (1–33 and 34–89 PCI/year) vs. the highest quintile (>206 PCI/year), no relationship between low operator volume and death, MI, or stroke at any quintile, or mortality or all MACE at 75 cases/year was

demonstrated. In the New York State Registry [29], there was no relationship between mortality, unplanned CABG and operator volume. Only the subgroup of lowest operator volumes at the lowest volume centers had any relationship with increased CABG and perhaps mortality, a finding the editorialists [45] suggested should be accepted only with caution due to the very small sample size in that subgroup.

Yet another consideration is whether the 75 case/year standard is practical. If there are 9,000 active interventionists in the country, and 600,000 PCIs per year [46], then the average interventionist performs 67 PCIs/year. Moreover, there is a skew in the distribution of cases such that few interventionists do >150 cases and many more are less active. SCAI recognizes that mandating 75 cases per year as a measure of competence may be unrealistic.

It is probably true that certain high-risk cases are better performed by operators most experienced with the specific clinical situation or technical problem. Any relationship between outcome and operator volume is probably minimized through careful case selection by operators themselves: the low volume, more risk averse, or limited skilled and experienced operators, likely and appropriately avoid high-risk elective cases. Supporting this point, there are excellent data that annual operator volume is highly predictive of outcomes in primary PCI for STEMI [47,48]. No studies have examined the impact of lifetime operator experience as a predictor of outcomes.

Institutional volume may be a better quality indicator, but it does not supersede validated clinical outcomes [29,33,37,38,49]. A team with more experience in high-risk cases, increased sharing techniques, greater collaboration with surgical colleagues, and broader access to newer technologies are possible explanations for better outcomes at large-volume institutions. It should be pointed out, however, that the absolute benefit of high volume centers is about 0.1% lower for unplanned CABG or death, or 1 in 1,000 cases [29]. Additionally, it must be recognized that geographic, social, or cultural isolation usually are the reasons why

small volume programs remain active; furthermore, local perceived quality and insurance matters increasingly are important considerations. Where patients choose to go for their health care depends on more complex reasons than measured quality. Hence, it is impractical to advocate closing laboratories simply because they do not perform 400 cases, especially if their outcomes are reasonably good.

Public reporting of operator and institutional volumes and unadjusted complication rates penalizes adverse outcomes, regardless of patient risk, and rewards high procedural volume, regardless of appropriateness [50]. This approach creates incentives for operators and hospitals to perform large volumes of low-risk cases regardless of appropriateness. The consequence is increased healthcare costs without measurable benefit [51].

In summary, the unadjusted incidence of adverse events is a potentially misleading indicator of PCI quality and cannot be satisfactorily interpreted. Unless case selection is adequately addressed, the reporting and comparison of observed outcomes may lead to incorrect conclusions regarding relative quality. SCAI supports the use of operator and institutional volumes as a quality metric only in the context of an adequate description and case mix analysis. Furthermore, a means of assessing the clinical appropriateness of PCI procedures must be developed; good outcomes alone do not constitute high quality. Although SCAI agrees with the current guidelines advocating a minimum caseload, that agreement is contingent on the understanding of its inherent flaws, which are well documented in this statement as well as in other guidelines. Ultimately, perhaps in the near future, the Society supports moving away from the flawed volume standard and embraces risk adjustment as inherently the most accurate method. Recognizing that risk adjustment is a science which is in constant change and that there continue to be problems with it as well, as will be discussed below, nevertheless it is this standard which needs to be adopted over the next several years. The ACE process moving toward accreditation of interventional programs also has this society's firm support as another measure of cath lab quality.

## RISK ADJUSTMENT

### Basic Principles of Risk Adjustment Models

Risk adjustment to account for case selection is necessary to be able to compare results between institutions and operators. Patient risk is the single most important factor in determining short-term outcomes after PCI [52]; thus, case selection will significantly impact outcomes. A uniformly collected, contemporaneously

collected and analyzed measure, adjusted for patient risk, provides the clearest measure of performance.

Risk adjustment methods have limitations [53]. Older models are mathematically complex, requiring simplification for physician acceptance. The use of self-reported patient risk data without independent audits raises concerns about accuracy, regardless of the case mix. There is still a need for risk models of health status and quality of life, which represent great value to patients [54]. These models do not assess the risk-benefit ratio, and cannot be used to evaluate the appropriateness of the intervention; hence, models cannot be the sole determining factor in decision-making.

### Quantitative Mortality Models

Risk adjustment models, developed from diverse patient populations, are strongly predictive of outcomes [39,40]. As this endpoint represents the primary measure of clinical outcome and appropriateness, the cardiology community must ensure the accuracy of the databases and registries from which these models are derived. External validation is the critical step in determining the value of any model [39–42].

Four recently published risk prediction models derived from contemporary datasets are detailed in Table IV [43,44,55–57]. Older models are depicted in Table V [52,58–65]. Most current models predict in-hospital mortality only; two [55,57] predict all MACE.

The newer models incorporate integer-based risk scores to quantify risk; this simplifies their use by patients and health care providers. The most important clinical risk factors associated with in-hospital mortality are reviewed in Table VI [66–71].

### Benchmarking Applications

The NCDR, through the CathPCI Registry, provides benchmarks in quarterly reports to each participating institution. The executive summary illustrates the ranking of each institution within 95% confidence intervals in 23 quality metrics, including risk-adjusted mortality and composite MACE over a rolling four-quarter period [72]. New York State provides a 3-year summary of each PCI program and each operator that includes: the total number of cases, deaths, observed and expected risk-adjusted mortality rates for all cases and for emergency cases [8]. Outliers are demarcated with two asterisks. Massachusetts publishes annual risk-adjusted mortality rates for all hospitals, stratified by cardiogenic shock or STEMI vs. all others, with statistical assessment of outlier status based on a 3-year rolling average [7,73].

NCDR has advocated the use of an observed:expected (O:E) mortality ratio of 2.25 as the cut-point of

**TABLE IV. Comparison of Recent Risk Models Predicting In-Hospital Complications Following Percutaneous Coronary Interventions**

|   | ACC-NCDR (43)       | New York State (44) | Mayo clinic (55, 56)    | Texas heart institute risk score (57) |
|---|---------------------|---------------------|-------------------------|---------------------------------------|
| Outcome(s) studied                            | Mortality           | Mortality           | Mortality and MACE      | MACE                                  |
| Study time period                             | Jan 2004–March 2006 | 2002                | January 2000–April 2005 | January 1996–December 2002            |
| Sample size (model development)               | 302,958             | 46,090              | 7,640                   | 9,494                                 |
| Event rate (%)                                | 1.23                | 0.7                 | 1.8                     | 2.8                                   |
| Area under ROC (derivation data set)          | 0.926               | 0.886               | 0.90                    | 0.701                                 |
| Area under ROC (Internal validation data set) | $c = 0.925$         | $c = 0.905$         | $c = 0.90$              | $c = 0.671$                           |
| Area under ROC (External validation data set) | NA                  | NA                  | NCDR, $c = 0.884$       | NA                                    |
| Simplified scoring tool                       | Yes                 | Yes                 | Yes                     | Yes                                   |
| Long-term mortality assessment                | No                  | No                  | No                      | No                                    |
| Operator volume included in the risk score    | No                  | No                  | No                      | No                                    |
| Institutional volume                          | No                  | No                  | No                      | No                                    |

optimal utility as a benchmark [74]. This value was identified by an evaluation of the frequency distribution curve of NCDR among participants [75], and corresponds to the 3% of programs with the worst outcomes. Lower O:E ratio thresholds would identify a larger number of possibly problematic programs.

A statistical model based on a corporate quality control method (cumulative funnel plots) has been proposed [76,77]. The model plots a specific risk-outcome cross point and compares that value to two and three sigma limits using cumulative results over 3 years. This method allows specific plots to be created for high-risk, acute MI or shock cases.

### Limitations of Risk Adjustment

Benchmarking and public reporting are credible only if safeguards insure that outcomes and the clinical variables employed for risk-adjustment are reported accurately. Part of the reluctance to acknowledge adverse events relates to the fear that all such occurrences will be considered causally related to the procedure, when it is evident that some are not. Physicians and hospitals that are lax about reporting complications may appear to have good quality, while vigilant operators and facilities will be penalized. Over-coding of risk factors will lead to false perceptions of better quality after risk adjustment, while adherence to published definitions will be interpreted as poor quality.

A thoughtful approach to evaluating O:E adverse event ratios is required. The best operators and institutions are those with a relatively high-risk case mix yet who produce acceptable observed results, e.g., an O:E ratio of less than 1.0, but not necessarily near 0, which suggests low-risk case selection. An evaluation of the expected rate of adverse events along with the O:E ratio is required. A program or operator's expected risk should reflect the distribution of risk in the cases they typically perform.

### Recommendations

- The SCAI endorses previously described standards for public reporting [3,4].
- Risk-adjusted complication rates using validated risk models for mortality and major complications are recommended to gauge operator and institutional proficiency.
- A mechanism that accurately determines 30-day mortality should be developed. Future risk-adjusted models should conform to this standard.
- The SCAI strongly opposes the use of claims data and supports the use of audited, validated clinical data as the optimal means of evaluating quality.
- Operator and institutional volume should not be used as primary quality indicators.
- Validated risk-adjusted models should be the primary method to assess clinical outcomes.
- A means of assessing the clinical appropriateness of PCI procedures must be developed; good outcomes alone do not constitute high quality.
- The SCAI strongly supports the development of accurate national and regional databases and registries
- The use of validated risk-adjustment models as the standard of quality is the goal which the SCAI endorses
- Risk-adjusted models that include all major complications, not just mortality, should be developed and used as the primary means to assess PCI programmatic quality.
- Benchmarking programmatic results against a national standard is the next crucial step in the evolution of PCI quality assessment.

### Summary

In this two-part Position Statement, SCAI supports the fundamental position that interventional cardiologists must actively participate and help establish the standards of quality in PCI delivery. Practitioners of interventional cardiology should lead in the definition



**TABLE VI. Variables Commonly Included in Risk Stratification Models (adapted from Ref. 68)**

| Odds ratios from logistic regression models |                         |                                |                            |                   |                        |                       |                  |                          |
|---|-------------------------|--------------------------------|----------------------------|-------------------|------------------------|-----------------------|------------------|--------------------------|
| Event Study                                 | Mortality ACC-NCDR (52) | Complications NY State (58,59) | NNE model (60)             | Michigan (61)     | Beaumont hospital (62) | Cleveland clinic (63) | Mayo Clinic (64) | Brigham and Women's (65) |
| Age   | by decade logarithm     |                                | 1.83                       |                   |                        |                       | 24.9             | 1.37                     |
|   | 75 y                    |                                |                            |                   |                        | 1.95                  |                  | 1.35                     |
|   | >65 y                   |                                |                            |                   |                        |                       |                  |                          |
|   | 50-59 y                 | 2.61                           |                            | 0.93              | 1.00                   |                       |                  |                          |
|   | 60-69 y                 | 3.75                           |                            | 1.63              | 1.00                   |                       |                  |                          |
|   | 70-79 y                 | 6.44                           |                            | 3.32              | 2.24                   |                       |                  |                          |
|   | 80 y                    | 11.3                           |                            | 3.72              | 2.65                   |                       |                  |                          |
| LV Function                                 | 50-59% (EF)             | 1.00                           | 1.00                       | 2.53              | 1.00                   |                       |                  |                          |
|   | 40-49%                  | 0.87                           | 1.00                       | 3.32              | 1.66                   |                       |                  |                          |
|   | 30-39%                  | 0.99                           | 1.49                       | 5.16              | 1.66                   |                       |                  |                          |
|   | 20-29%                  | 2.04                           | 1.49                       | 5.16              | 1.66                   |                       |                  |                          |
|   | 10-19%                  | 3.43                           | 3.68                       | 5.16              | 1.66                   |                       |                  |                          |
|   | <10%                    | 3.93                           | 3.68                       | 5.16              | 1.66                   |                       |                  |                          |
| Acuity of Presentation                      | CHF                     |                                | 2.38                       | 3.01              |                        |                       |                  | 2.11 (NYHAIII)           |
|   | Urgent PCI              | 1.78                           |                            | 2.19              |                        |                       |                  | 2.13                     |
|   | Emergent PCI            | 5.75                           |                            | 7.71              |                        |                       |                  | 2.13                     |
|   | AMI 1-7d                |                                | 2.10                       | 1.85              |                        | 2.14                  |                  | 1.44                     |
|   | AMI 6-23h               | 1.31                           | 3.67                       | (primary therapy) | 2.80                   | (<14d)                | 4.75             | 3.15                     |
|   | AMI <6h                 | 1.31                           | 5.22                       |                   | 2.80                   |                       | 4.75             | 3.15                     |
|   | Cardiogenic shock       | 8.49                           | 18.3                       | 6.10              | 11.5                   |                       | 12.7             | 3.47                     |
| High-risk angiographic features             | IABP use                | 1.68                           | 2.39                       | 3.91              |                        |                       |                  |                          |
|   | 2-VD                    |                                | 1.82                       |                   | 1.54                   | 2.20                  | 1.32             | 1.86                     |
|   | 3-VD                    |                                | (Multivessel intervention) |                   | 2.37                   | 2.20                  | 1.74             | 1.86                     |
|   | LM disease              | 2.04                           |                            |                   | 1.67                   |                       | 4.34             | 2.40 (LM treated)        |
|   | Thrombus                |                                |                            |                   |                        |                       | 1.90             |                          |
|   | ACC/AHA B2              |                                |                            |                   |                        |                       | 1.63             | 2.58                     |
|   | ACC/AHA C               |                                |                            | 1.94              |                        |                       | 2.66             | 2.58                     |
|   | SCAI II                 | 1.64                           |                            |                   |                        |                       |                  |                          |
|   | SCAI III                | 1.87                           |                            |                   |                        |                       |                  |                          |
|   | SCAI IV                 | 2.11                           |                            |                   |                        |                       |                  |                          |
| Other high-risk clinical features           | Renal failure           | 3.04                           | 3.51                       | 2.32              | 5.5                    | 2.06                  |                  | 2.41                     |
|   | PVD                     |                                | 1.78                       | 2.12              | 1.57                   | 3.21                  |                  | 1.54                     |
|   | Diabetes mellitus       | 1.41                           | 1.41                       | 1.54              | 1.82                   | 1.54                  |                  |                          |
|   | Female gender           |                                | 1.31                       | 3.57              |                        | 3.57                  |                  |                          |

of quality, in collaboration with other stakeholders. Furthermore, the principles outlined in this Statement should be employed both within each institution performing interventional procedures as well as by outside agencies, which we believe are the best means of assessing quality and evaluating the structure, processes, and outcomes of PCI care.

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