

## **Position Statement**

# **Quality Assessment and Improvement in Interventional Cardiology: A Position Statement of the Society of Cardiovascular Angiography and Interventions, Part 1: Standards for Quality Assessment and Improvement in Interventional Cardiology**

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## **INTRODUCTION**

### **Assessing PCI Program Quality Is Critical for Quality Patient Care**

Percutaneous coronary intervention (PCI) improves quality of life and survival in certain clinical settings [1]. These benefits are counterbalanced by the procedural risks. To encourage quality patient care, each PCI program must evaluate its performance through a meaningful continuous quality improvement (CQI) process. The ACC/AHA/SCAI 2005 PCI guideline update, as well as the newly implemented SCAI/ACC catheterization laboratory accreditation program, Accreditation for Cardiovascular Excellence (ACE), requires a CQI program for every health care facility in which PCI is performed [2]. CQI is an iterative method to evaluate operational approaches and remedy deficiencies [3]. The primary emphasis in CQI is on evaluating the overall program structure, processes, and outcomes of care; however, specific operator performance assessed by peer review is highly desirable. The Federal Health Care Improvement Act of 1986 recognized the importance of these programs by protecting participants and their deliberations. The Society for Cardiovascular Angiography and Intervention (SCAI) has previously published guidelines to develop a framework for these activities in the catheterization laboratory [4,5]. This statement is

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intended to establish the standard by which interventional program quality should be measured.

Interventional cardiologists are best suited to perform the primary role in evaluating PCI quality and guiding a program focused on objective measures. The process must not be payor or hospital administration directed, as these stakeholders may have conflicting goals [6]. Nevertheless, quality will have important reimbursement ramifications in the future; this is particularly true if “pay for performance” is instituted, by which larger payments would be provided to institutions and cardiologists with higher quality measures [7–9]. The critical questions are “what is quality?” and “who decides?” Active physician participation in developing the tools to measure and report quality outcomes is essential; otherwise, control over the process will be lost to those who do not possess an in-depth comprehension of interventional practice [10].

## ESSENTIALS OF THE CQI PROCESS

### Determination of Quality

Quality measurement in the interventional laboratory goes beyond simply self-reporting excellent procedural outcomes. An optimal CQI process should include the input and concerns of physicians (including both those who perform the procedures and those who refer their patients for interventions), health care staff, hospital administration and patients in an attempt to continually improve processes and efficiencies as well as outcomes. Quality improvement methods evaluate (1) the structure of the system, (2) the processes (actions and policies) performed to further improve the results, and (3) the outcomes achieved [11]. Programmatic quality is comprehensive, evaluating quality over multiple patient subsets, so as to promote both individual physician and system-wide quality improvement.

The evaluation of individual operator quality is an integral part of the PCI CQI process. CQI must include an ongoing, peer review assessment of the clinical proficiency of each operator including random case review, realistic identification of programmatic and individual operator strengths and weaknesses, and comparison of individual and aggregate outcomes against national standards and benchmark databases. Although a high standard of performance may be the goal of each operator, an acceptable minimum level of quality level must also be defined that individual operators at all levels of competence must achieve for maintenance of privileges [12].

PCI quality is a complex entity, and it cannot be adequately characterized by any single clinical variable. Operator procedural volume is a weak and inconsistent measure of quality, and it should not be used alone as a

quality indicator. Institutional volume is a better programmatic predictor of outcomes, but does not supersede actual outcomes [2,13]. An appraisal of comorbidities, case risk, and appropriateness is critical when PCI volume is used as a process measure. A complete and accurate comprehension of clinical results requires benchmarking of risk-adjusted outcomes to account for differences in patient characteristics [14]. The optimal CQI program measures and evaluates all of the relevant variables, and seeks to improve PCI outcomes systematically.

SCAI urges that only validated methods be used to measure quality. Advertising and testimonials are not measures of quality. Hospital and practitioner ranking systems and self-proclaimed “centers of excellence” are not reliable quality indicators. Only an objective, physician-led process that includes appropriate evaluation and corrective action plans and is organized to assure a fair and impartial review of performance, provides a reasonable level of assurance that quality is being accurately assessed and promoted.

### Implementation of a CQI Program

Based upon the previously published SCAI guidelines for quality assessment and improvement in the cardiac catheterization laboratory, Table I provides an outline for the implementation of a CQI program for PCI [4,5]. The five elements in the SCAI “blueprint” for a CQI program include (1) identification of quality indicators, (2) systematic data collection using standard definitions, (3) analysis of the data with benchmarking to determine areas that require improvement, (4) development of an implementation plan to correct deficiencies, and (5) systematic repeat data collection to determine the effect of the corrective action. Programs must provide confidential and constructive feedback of performance and outcomes data to clinicians that promote changes in practice to improve performance [12]. These parameters, based on national guidelines and peer reviewed literature, should address the program’s specific outcomes and complications in addition to its overall quality metrics. An effective CQI process includes random case review, develops critical pathways, and accomplishes and documents positive changes in procedures and practice. Practical examples of successful implementation in PCI programs demonstrate improved outcomes and recognizing the barriers to improvement likely to be encountered [3,15].

### The CQI Committee

Assuring PCI quality depends on the active participation of physicians and the provision of adequate resources by the institution. An independent and dedicated committee which interacts with other divisional

**TABLE I. Implementation of the CQI Program**

- 
- CQI committee: suggested membership
  - Director: cath lab director or designate
  - Membership:
    - Voting members:
      - Representative interventional cardiologists
      - Administrative director of cath lab
      - Additional representative(s) as appropriate from:
        - Cath lab nursing staff
        - Cath lab technical staff
        - Noninterventional cardiologist(s)
        - Cardiac surgeon(s)
        - Emergency room physician(s)
        - Noncardiologist internist(s)
        - Other
    - Nonvoting members:
      - Representative from hospital CV administration
      - Representative from hospital QA Staff
  - Development of quality measures<sup>a</sup>
  - Structure (personnel, equipment, and organizational indicators)
  - Process (system performance indicators)
  - Outcomes (adverse events and individual performance indicators)
  - Systematic Data Collection
  - Appropriate, trained, support required
  - Database (national or large regional)
  - Random case review
  - Risk adjustment and benchmarking
  - Data analysis
  - Identification of areas for improvement
  - Intervention
  - Correct deficiencies and improve overall quality
  - Reassessment
  - Repeat data collection
  - Assess effect of remediation
- 

<sup>a</sup>Ref. [4].

and hospital quality CQI committees should be established (Table I). Although a consensus on organizational design does not exist, the committee structure should include both physicians and relevant health care personnel in a cooperative effort [3,4,16]. The composition of a PCI CQI committee may include noninvasive cardiologists, primary care physicians, catheterization laboratory nurses, and hospital administrators. In small PCI programs, all active interventionists may be included as members. In larger laboratories, a formal and equitable process for selecting and replacing members must be devised to assure fair representation. An expert in interventional cardiology who has attained the trust of multiple stake holders to conduct a fair and unbiased review of the sensitive issues discussed should chair this committee; the catheterization laboratory director or director of interventional cardiology is a reasonable choice. An oversight mechanism to evaluate the chair, as an operator, should be defined. Dedicated CQI staff trained to collect the data should be identified and participate in the data analysis under the direction of the committee.

The CQI Committee is responsible for all aspects of the CQI process (Table I). The monitoring of standard metrics, the identification of facility quality indicators, appropriate remediation, and follow-up are the critical responsibilities of the committee. Protecting patient safety is the central purpose of the CQI process. Programmatic deficiencies must be identified openly with the involvement of hospital risk management as appropriate. Attention to local political and interpersonal matters is essential. The CQI committee should meet at regular intervals, review each serious adverse outcome, and conduct random audits of all operators. A determination should be made regarding the impact of each event on the patient and the responsibility of the operator, with the committee chair charged to establish a consensus. When a disagreement as to the cause and/or significance of an event exists, a mechanism must be in place to reconcile or note these differences.

### Application of CQI and Peer Review

There are numerous challenges in applying PCI CQI and peer review processes in a constructive and impartial manner. A health care institution must assure that patients are selected appropriately and that procedures are performed safely. The hospital's "quality management" department, responsible for investigation of reported events and government-mandated quality indicators, should work with the physician-centered PCI CQI program. Its purpose should coincide with that of the CQI committee, namely, to document and improve "the quality of patient care." Use of this data for non-quality purposes, e.g. developing marketing strategies or improving operating margin, should be strongly discouraged.

Conflicts of interest are common among competing physicians who may perceive a financial advantage to adjudicate adversely another physician's care. There are unsettling reports of the subversion of the CQI and peer review processes for political, financial, or other reasons [17]. Therefore, SCAI recommends that a formal method of oversight for perceived conflicts of interest within the CQI and Peer Review processes be developed by the hospital CQI process and/or medical staff bylaws. An independent facility accreditation process, when it becomes available, may be invaluable in this regard. The use of the CQI and peer review process for purposes that undermine its proper functions is not acceptable. Strong sanctions for such behavior should be formalized in the Medical Staff Bylaws and applied to any individual who violates the process.

Educational activities such as cardiac catheterization conferences and Morbidity and Mortality conferences should be held routinely, and an attendance threshold

for maintenance of privileges enforced. Presentation of clinical and technically challenging cases, including those with complications and unexpected developments during the conduct of a PCI, is rewarding to review and discuss in these conferences. Separation of peer review from such teaching activities is essential to the success of both in view of the legal issues involved, in particular, the possibility of potential discovery in non-protected conferences.

#### **Protection of Patients, Participants, and Process (P<sup>4</sup>): The Key to a Successful CQI Process**

The committee must behave equitably and transparently to ensure fairness to the operator, quality for the patient, and credibility for the committee. Federal and state regulations shield participants from litigation in peer review activities. Proceedings of peer review activities are protected against subpoena and are not discoverable in most situations. Admixing peer review proceedings in other settings should not occur.

Operator outcomes must be presented so that absolute confidentiality is maintained. Physicians whose activities are being investigated for issues related to quality of care also should be protected. Use of confidential information to target an individual physician should be considered a breach of the process [17]. Further, Committee members who may have conflicts of interests should remove themselves from deliberating in selected matters, as appropriate. The individual being investigated must always receive impartial consideration and “due process.”

#### **Methods of Remediation of a Process or Structure Within the Interventional Laboratory**

When the CQI process identifies a systemic problem that requires remediation, the CQI committee must investigate the cause and devise a solution. Illustrative examples may include an excessively high rate of access site complications, contrast-induced nephropathy, radiation dose, etc. Quality issues arising from catheterization laboratory structure or process indicators should result in a formalized plan and implementation strategy, including continued reassessment. Ongoing modification may be required to reach the target result. All policy and procedure changes must meet institutional approval requirements.

#### **Methods of Remediation of the Performance of an Individual Operator**

Concerns with operator performance may be due to problems either in professional behavior, including but not limited to attitude or ethical conduct, and/or defi-

ciencies in cognitive knowledge, judgment, procedural skills, mental impairment, addictive substance abuse, or a combination. Issues of professional behavior are frequently difficult to confront and require sensitivity to resolve [5]. To assure credibility, the CQI and Peer Review processes must be impartial. Criteria for review of cases for cause must be applied consistently and a mechanism for random review established.

Although each case is unique, recommendations should be based on a comprehensive knowledge of the issue and input from all appropriate stakeholders. An initial approach to influence physician behavior may be to charge a “neutral,” well-respected individual in the department to discuss the quality issue with the operator in question, comparing his/her performance in that regard with other operators based on objective benchmark data. This activity should be designated as a legally protected activity of the peer review process. Such quiet discussion may be all that is needed to improve performance.

When an alteration in technique or approach is considered necessary, a non-punitive action plan must be developed by the committee. Behavior modification requires appropriate feedback; this should always be constructive and, whenever possible, non-punitive. The corrective action plan should include metrics to determine effectiveness and should clearly state the expected outcome and targets. A random review is important to avoid “gaming” of the system. All corrective actions should be reassessed in an ongoing process to determine the effectiveness of the steps taken. If the goals are not met, further steps should be identified.

Referral to an outside agency and/or to the proper review body within the institution is reserved for circumstances in which internal resolution cannot be achieved and when the difficulty encountered has serious connotations. When requested, it is imperative that outside reviewers be expert and impartial, and that all parties agree that potential or real conflicts of interest do not exist. It would be optimal if the selection of the outside expert was made after consultation with all parties.

Penalties or sanctions, e.g., suspension of privileges, should be considered only after other methods of correction have failed. The seriousness of the sanction should fairly mirror the seriousness of the problem and the responsiveness of the operator [4,5]. If it is concluded that the operator has a deficiency in knowledge or skill, the CQI Committee or outside reviewer can recommend an appropriate educational approach or mentorship and consider limiting privileges until defined expectations have been met.

When all other appropriate measures to improve performance are unsuccessful, the committee may recommend revocation of an operator’s privileges. All

institutions have a policy covering this situation that should be used through their Medical Staff Bylaws, including reporting to required state regulatory bodies.

## PCI QUALITY INDICATORS IN THE CQI PROCESS

### Identification of Quality Indicators

To evaluate the quality of a PCI program, a group of “quality indicators” must be identified and carefully followed. These should be established by the committee as suggested by guidelines, accreditation bodies, and local practice requirements. The frequency of internal evaluation is arbitrary, but monthly or quarterly are reasonable intervals, depending on institutional volumes. Many indicators can be evaluated both for the laboratory as a whole and for each operator. They should include processes and outcomes in which PCI is the central function but may include indicators outside the laboratory environment which impact on PCI quality. One example is the “door-to-balloon” time in acute myocardial infarction. Other examples include the following: appropriate administration of dual antiplatelet therapy, renal protection measures, lipid management and systems-based issues aimed at reducing bleeding complications and hospital readmission.

Components of an optimal CQI program require that several key outcome and process measures be routinely collected, analyzed, and constructively employed. As recommended previously [4,5], a dedicated database must be established with hospital support. The database should include quality indicators that reflect patient outcomes and processes of care. Data should be recorded using standard definitions and submitted to national or regional databases. Significant variation from these norms should prompt internal peer review of cases to evaluate the appropriateness of patient selection and risk-adjusted outcome. Sufficient resources must be available to the CQI committee to adequately measure baseline patient risk permitting valid risk-adjustment of outcomes and determining appropriateness of the intervention.

The CQI process may be best implemented by incorporating clinical practice guidelines and appropriateness criteria [2,18–20]. When guidelines are followed, clinical outcomes improve [21–24]. Of course, such guidelines usually apply only for those patients shown to lie within the boundaries covered by clinical trials and registries. In addition, guidelines are intended only as suggestions based on scientific studies; application to individual patients always requires clinical judgment. It cannot be over-emphasized that quality measurement tools must be applied properly, and uniformly, and to the correct patient subsets, to achieve an accurate evaluation and true quality improvement.

**TABLE II. Major Adverse Events**

<ul style="list-style-type: none"> <li>● Mortality<sup>a</sup> <ul style="list-style-type: none"> <li>○ In-hospital</li> <li>○ 30 day</li> </ul> </li> <li>● Unplanned CABG<sup>a</sup> <ul style="list-style-type: none"> <li>○ Same day</li> <li>○ Same stay: urgent vs. elective</li> </ul> </li> <li>● Stroke, TIA or other neurological event<sup>a</sup></li> <li>● Myocardial infarction or ischemia           <ul style="list-style-type: none"> <li>○ ECG evident: New Q waves in two or more leads, ST elevation or depressions<sup>a</sup></li> <li>○ Prolonged peri- or postprocedural chest pain requiring evaluation and/or therapy, or prolonged peri- or postprocedural chest pain requiring therapy and &gt;5 times elevation in biomarker</li> <li>○ Evidence of new wall motion abnormality</li> <li>○ Myonecrosis (cardiac enzyme elevation only, asymptomatic)</li> <li>○ Universal Definition of Myocardial Infarction should be employed</li> </ul> </li> <li>● Dysrhythmias requiring treatment</li> <li>● Cardiac arrest in laboratory<sup>a</sup></li> <li>● Hemodynamic instability requiring therapy<sup>b</sup></li> <li>● Major contrast reaction (anaphylactoid reaction)</li> </ul>
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<sup>a</sup>Denotes core measure.

<sup>b</sup>It is recommended this measure conform to a standard definition.

Specific quality measures to constructively improve patient selection for PCI, operator performance, team proficiency, and overall care systems should be selected carefully by the CQI committee. Outcomes of direct importance to the individual patient are the most clinically meaningful measures. Given wide variation in baseline patient risk, outcomes closely linked to PCI are perhaps the most useful quality assurance measures. A proposed list of core and optional measures may be found in Tables II-IV.

### Benchmarking

Benchmarking against national standards is a valuable means to understand high variances in low incidence adverse events. Comparing observed programmatic and individual operator outcomes to expected results is critical to avoid the criticisms related to self-reported data. Such analyses and collection of many of these variables are captured in ACC-NCDR CathPCI Registry version 4 [25,26], as well as in other recognized regional registries. Not only has registry data been shown to be effective in predicting outcomes, but also they provide quarterly reports with benchmarking and risk-adjusted outcomes [27]. The registries use standardized definitions to collect patient demographics, clinical variables, and outcomes on each procedure. These evidence-based data elements are combined with process and performance measures that are linked to current ACC/AHA/SCAI clinical practice guidelines [12]. Quarterly reports are sent to each participating facility benchmarking its results, including

**TABLE III. Adverse Procedural Events—Coronary**

- Abrupt closure requiring specific therapy i.e., spasm, dissection
- Distal embolization/no reflow
- Perforation<sup>a</sup>
- Cardiac tamponade<sup>a</sup>
- Stent thrombosis<sup>a</sup>
- Loss of stent – intracoronary
- Other equipment mishaps – e.g., retained foreign body<sup>a</sup>, guidewire fracture
- Wrong patient<sup>a</sup>, wrong/wrongful procedure<sup>a</sup>

## Process measures

- Door-to-balloon time in STEMI

<sup>a</sup>Denotes core measure.

risk-adjusted mortality, against national and peer groups [27]. Collaboration with Centers for Medicare and Medicaid Services (CMS) is ongoing in a variety of projects to measure and assess quality. There are limitations, however, in the registries: (1) there is no long-term follow-up, (2) the data are self-reported without mandated periodic auditing, (3) the existing models risk-adjust only mortality, not other outcomes, and (4) participation is voluntary so that the data may not be representative.

### Data Collection of Site-Specific Quality Measures

The desire to gather all adverse events must be balanced against the available resources and personnel required to collect, manage, and analyze extensive amounts of data. Although the core elements should be present in every program, which optional elements to include will depend on the problems and concerns at each site.

Since accurate data collection is a pivotal component of this process, data verification is essential. Adequate staff with knowledge of interventional procedures is required. An accurate tool to collect the data is indispensable; Table V provides an example. Random audits from competent, objective reviewers should be conducted to assure data correctness. Decreasing the number of times a given data set has to be entered decreases staff time and potential for error. A well-integrated information system is extremely helpful to this process. Data access to the CQI database must be restricted to those directly involved in the CQI process, for both patient privacy and potential medical-legal concerns.

The optimal internal quality assurance program employs patient-specific risk prediction tools to supplement clinical judgment and intuition in nonemergency PCI cases [28,29]. For example, validated prediction tools for contrast-induced nephropathy and bleeding risk should routinely prompt activation of risk mitiga-

**TABLE IV. Adverse Procedural Events—Systemic and Peripheral**

- Contrast induced nephropathy
  - “Mild”: >0.25 mg% but <0.5 mg% increase in serum creatinine
  - Rise in serum creatinine > 0.5 mg/dl
  - New requirement for dialysis<sup>a</sup>
- Loss of stent – peripheral
- Fluoroscopy time/dose: “excess” radiation dose
- Intracranial hemorrhage<sup>a</sup>
- Fall in hemoglobin > 3.0 g/l or requirement for blood transfusion<sup>a</sup>
- Major bleeding<sup>b</sup>
- Access site vascular injury<sup>c</sup>
- Retroperitoneal hemorrhage<sup>a</sup>
- Femoral arterial occlusion<sup>a</sup> (or arterial access vessel) or dissection
- Access site infection<sup>a</sup>
- DVT/pulmonary embolism

<sup>a</sup>Denotes core measure.

<sup>b</sup>It is recommended this measure conform to a standard definition.

<sup>c</sup>Includes need for surgical or interventional repair, hematoma or pseudoaneurysm requiring treatment, vessel thrombosis or embolization producing a clinical event.

tion strategies and intensified care and surveillance for early detection and appropriate treatment of adverse outcomes [30–33].

Future integration of health information systems may facilitate tracking of longer-term (i.e.,  $\geq 30$  day) outcomes and provide further insights for optimizing PCI Verification that appropriate short-term follow-up has been arranged prior to discharge should be mandatory. Thirty-day outcomes are increasingly required by both government and private payers and acquisition of these data should be supported by hospital resources, as it will affect their reimbursement. For example, 30-day readmission has been suggested by NQF and CMS as an important metric, although not necessarily attributable to PCI directly. These longer term measures are critical to assess whether treatment choices and long-term care have optimized patient outcomes in a complex medical environment.

### Appropriateness

The optimal internal quality improvement program would employ ACC/AHA/SCAI guidelines, the most recent peer reviewed scientific literature and quantitative tools to assess the appropriateness of institutional PCI case selection [18]. Although it is important that each institution address the appropriateness of each procedure, this is logistically challenging. Random case reviews should be performed and include a review of the report for appropriate indication and procedure documentation as well as cine review to address technique. Operators who do predominantly low risk cases that should be treated medically might appear to be competent PCI operators utilizing the

TABLE V. Data Quality Event Review Form

**Patient Data**

Patient Name: \_\_\_\_\_ Age: \_\_\_\_\_ ID#: \_\_\_\_\_  
 Procedure: \_\_\_\_\_ Physician: \_\_\_\_\_ Date: \_\_\_\_\_

**Reason for Review:**

Potential for Patient Safety: \_\_\_\_\_; Sentinel Event: \_\_\_\_\_  
 Mortality: In Lab \_\_\_\_\_; In Hospital \_\_\_\_\_ 30 Day \_\_\_\_\_  
 Morbidity: Neuro: \_\_\_\_\_; Vascular: \_\_\_\_\_; Coronary: \_\_\_\_\_;  
 Arrhythmia: \_\_\_\_\_; Renal: \_\_\_\_\_; Radiation: \_\_\_\_\_  
 Other: \_\_\_\_\_

**Case Summary:**

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

<b>Risk Group:</b>	Average/Low	High	Salvage
<i>Clinical</i>	_____	_____	_____
<i>Angiographic</i>	_____	_____	_____

**Process Review:**

	Appropriate	Uncertain	Inappropriate
<i>Indication :</i>	_____	_____	_____
<i>Technique :</i>	_____	_____	_____
<i>Management :</i>	_____	_____	_____

*Related to:* Disease: \_\_\_\_\_; Provider: \_\_\_\_\_; System: \_\_\_\_\_;  
*Preventable:* \_\_\_\_\_; Not Preventable: \_\_\_\_\_; Comments: \_\_\_\_\_

**Recommendation by Reviewer:** \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_  
 Reviewer: \_\_\_\_\_

**Recommendation by Committee:** \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_

*Patient Safety/Risk Management Review:* Y N; *Hospital/Department Review:* Y N;  
*Corrective Action:* Y N; Education \_\_\_\_\_; Proctor \_\_\_\_\_; Other: \_\_\_\_\_  
 Date: \_\_\_\_\_ Signature: \_\_\_\_\_

risk-adjusted models and volume criteria which currently exist but not be providing optimal patient care [34,35]. The preprocedure evaluation for ischemia either by noninvasive or in-lab functional testing (e.g. FFR) further contributes to an assessment of appropri-

ate patient selection. More sophisticated patient-specific outcome prediction under various management strategies may become feasible as tools continue to be developed, validated, and more efficiently implemented, such as SYNTAX Score, Euroscore, and

Global Risk Score [36–42]. Transition from anatomic-based decisions is crucial in the correct evaluation of appropriateness as a quality measure [43]. More contemporary appropriateness use criteria are currently being developed that embrace and promulgate the importance of combining functional assessments and individualized outcome prediction along with traditional anatomic characterizations for optimal patient management.

## SUMMARY AND RECOMMENDATIONS

1. Each institution in which PCI is performed must have a specific Cardiac Catheterization Laboratory CQI Committee devoted to PCI quality performance with adequate resources provided by the hospital to support this activity. Interventional operator participation and direction are essential.
2. The PCI CQI program must be focused on quality of care with careful attention to the quality indicators: structure, process, and outcomes. All proceedings should be confidential and conducted equitably and impartially.
3. Development of a written protocol for PCI review, including the use of standard definitions of adverse events, is necessary to minimize arbitrariness in process and maximize physician and staff acceptance.
4. Quality measures should be compared to benchmarks from the medical literature. National or regional database participation is strongly recommended.
5. The PCI quality review process should include evaluation of the individual operators' performance (peer review), including random case reviews. This process must be nonpunitive with the primary purpose to improve process within the spectrum of care.
6. Specific methods of remediation with defined follow-up and goals should be established by the CQI Committee.
7. Referral to outside agencies and to the proper review body within the institution is reserved for circumstances in which external resolution is deemed necessary by the CQI committee. When outside review is requested to determine issues related to quality of care, a professional, objective and independent organization or individual should be selected. All potential conflicts of interest must be clarified prior to any external review.
8. Breaching of the confidentiality of the PCI review process is unacceptable. Each institution should provide clear guidelines and sanctions for such behavior.
9. The concept of "due process" should be followed in evaluating operator performance to protect the operator and the process.

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