



# Quality management in the cardiac catheterization laboratory

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**Abstract:** The development of quality assurance (QA) and quality improvement (QI) initiatives have paralleled the expansion and proliferation of cardiac catheterization laboratories. Quality cardiovascular care aims to deliver high standards for patient safety by developing processes and systems to optimize patient-team interactions. Quality can be assessed at the individual operator, team, program, facility or system level. Cardiovascular societies and organizations have developed national registries to help institutions benchmark their process and outcomes against national standards. Various quality measurement techniques are available to assess current performance and identify opportunities for improvement. Appropriate use criteria (AUC) for revascularization were implemented to serve as a QA measure to examine the use of medical procedures. In today's value-based payment systems-focused healthcare climate, quality metrics are followed closely by many payors. In this review, the framework for quality in the cardiac catheterization laboratory and tools to achieve continuous quality improvement (CQI) are discussed.

**Keywords:** Quality assurance (QA); quality improvement (QI); cardiac catheterization laboratory; continuous quality improvement (CQI); registry

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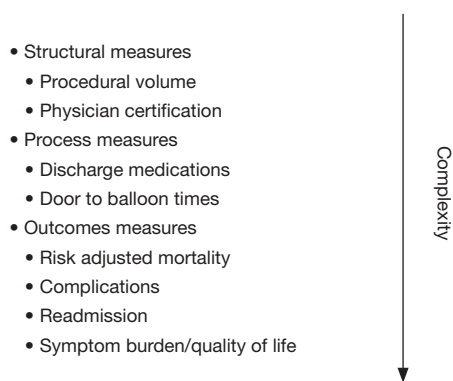
## Introduction

The development of quality assurance (QA) and quality improvement (QI) programs has paralleled the proliferation of cardiac catheterization laboratories (Cath labs), and the expansion of procedural indications including for complex coronary, peripheral endovascular, and structural heart procedures (1). While Cath lab procedures can reduce morbidity and/or mortality, there is a multitude of reasons for the emphasis on quality including the high volume and cost of procedures, the potential for serious complications, and variability in care. The Institute of Medicine has defined quality as “the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge” (2). In the Cath lab, quality is

often viewed as performing the right procedure, on the right patient, at the right time (3). This review will identify and describe QI frameworks; highlight quality registries; identify components of an effective Cath lab QI team, and list metrics to use when measuring QI within the Cath lab.

## Donabedian framework and quality measures

Evaluating the quality of care in the cardiac Cath lab can be approached using the Donabedian model, which encompasses a triad of measures: structure, process, and outcome (4). The structure is the context in which care is delivered such as the hospital or organization. This comprises the regulatory and compliance requirements which include peer review, credentialing criteria, continuing medical education requirements, registry participation



**Figure 1** Donabedian framework applied to the Cath lab.

and reporting (5). The physical structure of the Cath lab may vary among centers regarding a number of procedure rooms, location of cineangiographic equipment in relation to the control room, and other design variables (6). These physical variables, and other structural measures such as procedural volume, are relatively easy to measure but do not necessarily correlate with care quality (*Figure 1*). Process metrics are more complex and assess care through activities that occur at the level of the patients and providers. Numerous process metrics are relevant to the Cath lab such as: care algorithms for ST segment myocardial infarction (STEMI) and cardiac arrest. Process measures capture door-to-balloon time for STEMI, evidence-based discharge medication, and referral for cardiac rehabilitation when appropriate (5). The advantage of process measures is that they have clear definitions, the minimal incremental cost to collect, and accountability can be assigned. However, drawbacks include a ceiling effect, potentially excluded populations, and the possibility that they may not correlate with outcomes. Outcome measures focus on how the care delivered is reflected in the patient's health. Many of these complex measures must be risk-adjusted and include mortality, bleeding, and acute kidney injury (5,7-10). Other examples of outcomes metrics include patient experience, health status (functional status and quality of life), and cost. While outcome measures are the most meaningful, they must be interpreted with caution as misinterpretation may have unintended consequences such as shifting the accessibility of care or increasing risk aversion.

The National Quality Forum (NQF) is a non-profit organization that aims to improve the quality of care through performance measures and standards (11). NQF endorses national consensus standards that can be used for

measuring performance and public reporting. Due to the focus put on these metrics, they are selected based on validity, reliability, the ability for risk adjustment and that they are practical to measure. In addition, if variation exists, the measure should be modifiable with QI methods. Risk-adjusted in-hospital mortality in all percutaneous coronary intervention (PCI) patients is a commonly reported performance measure. Cardiovascular societies such as the American College of Cardiology (ACC) and Society for Cardiovascular Angiography and Interventions (SCAI) are committed to assisting physicians and hospitals in providing quality cardiovascular care. Quality competency statements written by physician experts and endorsed by medical societies and organizations serve to inform physicians, Cath lab leadership, and payors about quality related topics. Such statements have described the components of a quality curriculum for trainees, the development of risk-adjusted models for PCI outcomes, and updates on public reporting (12-14).

### Continuous quality improvement (CQI)

The CQI model is proactive and dynamic and focuses on data and statistics. In the Cath lab, the intent is to reduce variation and improve patient safety, quality, and efficiency through continuous assessment (15-17). Contrary to the traditional QA model that identified outliers and used standards for comparisons, CQI focuses on the improvement of performance using the framework of the structure, process, and outcome measures (1,18). CQI leadership teams that include physicians, Cath lab staff, and administrators must ensure the proper collection and validity of data (16,17). These data must be synthesized into a format that can be used to identify opportunities for improvement. Cath lab leadership teams then identify a problem that is measurable with valid quality indicators (*Tables 1-3*) (19). Within the institution, over time the indicator is tracked and compared to national benchmarks where available. Interventions are then developed to address the problem and follow up data collected to determine if there is a positive change in the indicator (19). This process is not intended to be punitive, but constructive. Attention to detail on systematic versus individual operator deficiencies is required. The aim is to strengthen the program to ensure patient safety (20).

An example of a CQI project is a process for radiation safety. Operators and all Cath lab team members should wear radiation dosimetry badges, properly placed, during

**Table 1** Examples of trackable quality indicators in the cardiac Cath lab

Quality indicators	Cardiac procedural adverse event	Systemic adverse event
Mortality: in-hospital and 30 days	No reflow from embolization	Neurologic event
Unplanned coronary artery bypass graft surgery	Coronary perforation	Acute kidney injury
Incidence of non-obstructive coronary artery disease	Cardiac tamponade	Radiation injury
Missed door-to-balloon time	Stent thrombosis	Bleeding
Wrong patient	Access site vascular injury	Infection

**Table 2** Examples of QI techniques used in the Cath lab

Technique	Cath lab QI
PDSA cycles	Radiation exposure
RCA	Medication errors
FMEA	Contrast induced nephropathy
TQM	Cross functional teams
Lean production	Vascular access
DMAIC	ST elevation myocardial infarction
DMADV	On-time patient arrival to Cath lab

QI, quality improvement; PDSA, plan-do-study-act; RCA, root cause analysis; FMEA, failure modes and effects analysis; TQM, total quality management; DMAIC, define, measure, analyze, improve, control; DMADV, define, measure, analyze, design, verify.

every case. The initial structure may include assuring proper testing of all lead gear to ensure safety compliance. This includes thyroid shields, lead aprons, eyewear, table suspended drapes, and shields (21). Regular assessment of the radiation dosimetry badges should be checked. Physicians who have higher than average radiation doses per month should be notified and reason for higher than average exposure, such as high case volume or poor radiation reduction practice, assessed. Once the issues are identified, adequate corrective processes can be put in place. This may include training the individual on radiation mitigation techniques such as optimal table and image intensifier height and shielding, use of less angulated views and lower magnification, lower frame rates, use of the fluoroscopy save rather than cineangiography, etc. Additional measures can be implemented including the use of radiation pads to reduce scatter, tubing extension and autoinjectors. After these processes are instituted the dosimetry badge should be rechecked after 1 month to monitor for outcome changes in radiation doses. This process should be modified as

**Table 3** ACE Cath lab standards

Cath lab standards
Facility
Equipment
Leadership structure
Physician extenders and cardiology fellows
Nurses
Technologists
Reporting of results
Procedure indications and consent
Procedure preparation and conduct
Patient outcomes
QA
Radiation safety

ACE, Accreditation for Cardiac Excellence; QA, quality assurance.

needed until an acceptable outcome is attained. The CQI methodology ensures a systematic approach to attaining the desired outcome.

## QA/QI tools

### Registries

The American College of Cardiology Foundation (ACCF) National Cardiovascular Data Registry (NCDR) is a group of data registries developed to assist hospitals and healthcare providers in measuring, benchmarking and improving cardiovascular care (22). Several of the registries are focused on care delivered in the Cath lab (*Figure 2*) and institutions performing these procedures should collect and submit data to these registries. The NCDR started in



**Figure 2** Timeline of launching of Cath lab based NCDR registries. NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons; ACC, American College of Cardiology; TVT, Transcatheter Valve Therapy; PVI, Peripheral Vascular Intervention; LAAO, Left Atrial Appendage Occlusion.

1997 and the CathPCI Registry was the first to be launched with over 17 million records collected by 2014 (17). SCAI collaborates with the ACCF on the registry effort (12,13). The CathPCI Registry captures patient demographics, baseline characteristics, treatments and outcomes following diagnostic Cath and/or PCI procedures. The NQF has endorsed elements of the CathPCI Registry such as composite discharge medications (i.e., dual antiplatelet therapy and statin), PCI risk-adjusted mortality, and hospital 30-day risk-standardized readmission rates (23). The CathPCI Registry offers a quarterly review of the facility's performance, based on the proceeding four quarters, compared to all other facilities and those with similar procedural volumes, for key metrics (23). As of 2014, 90% of PCI capable hospitals in the US used the registry with the majority submitting both diagnostic and interventional procedures (24). Individual operators practicing at registry sites, by using their unique national provider identifier (NPI) number, also have access to a physician dashboard. A physician specific report with select quality metrics is generated based on the procedures performed.

The Society of Thoracic Surgeons (STS)/ACC Transcatheter Valve Therapy (TVT) Registry was launched in 2012 with the initial approval of transcatheter aortic valve replacement (TAVR) in the US (25). The STS/ACC TVT Registry is a collaboration between the STS and ACC to provide quality metrics related to TAVR and transcatheter mitral valve repair (TMVR) in collaboration with the Federal Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), SCAI, and American Association for Thoracic Surgery (26). Important to hospital finances, participation in the TVT Registry meets the national coverage decision requirements for CMS. The Peripheral Vascular Intervention (PVI) Registry measures outcomes for patients undergoing percutaneous treatment for peripheral vascular disease and carotid interventions (carotid endarterectomy and stenting) (27). The PVI Registry provides quarterly benchmark reports

comparing an institution to its peer facilities. Cardiovascular procedures are also included in the Society for Vascular Surgery Vascular Quality Initiative (SVS-VQI) which collects in-hospital and 9–20 months follow-up (28). This registry includes biannual regional meetings to allow Cath lab members and quality officers to meet and share information about vascular care. The Left Atrial Appendage Occlusion (LAAO) Registry, launched in 2015 with FDA approval of the Watchman LAAO device, also meets registry requirements for CMS coverage and offers outcome and cost effectiveness data among national healthcare facilities (29).

In summary, the family of NCDR registries serves as a resource for Cath labs in the US. The repository of well-defined clinical data and risk-adjusted outcomes can be used to identify and close gaps in quality of care, reduce variation and disparities in care, improve efficiency and lower cost of care. Most Cath labs use NCDR Registries for CQI. The Registries have also contributed to device surveillance, outcomes research and clinical guideline development.

#### *Peer review*

Random cases from individual operators should be selected for peer-review on a regular basis. Individual and group outcomes should be compared with national benchmarks (15,17,19). Peer-reviewed cases as outlined by the Intersocietal Accreditation Commission on Standards and Guidelines for Cardiovascular Catheterization Accreditation must include a minimum of four cases per procedure type: adult diagnostic Cath, PCI, valve interventions, structural heart interventions, complex adult congenital heart disease, and pediatric cardiovascular Cath every 6 months (15). Discussions and findings in peer-reviewed activities are not liable to subpoena.

#### *Morbidity and mortality (M&M) conference*

M&M is an opportunity to devote an allotted period of

time for all members of the care team to discuss cases with adverse outcomes. Cases should be presented with the intent to derive plans and solutions for future system improvement. These conferences should be formally structured to discuss the presentation of the deidentified physician-patient encounter, case-based review focusing on the pertinent labs, electrocardiogram (ECG), imaging findings, system processes, and the outcomes of the encounter. The Association of American Medical Colleges proposed M&M conference structure includes an introduction of the case; case narrative including pertinent findings from a chart review; a process map; explanation of system theories; QI teaching points; fishbone group interaction to identify factors that led to this outcome; a literature review of this procedure and/or outcome; a proposed action plan to mitigate future adverse outcomes; and a conclusion of the case (30). This is an opportunity for physicians and other Cath lab team members to identify medical errors when they occur, and other variables that can be optimized to improve future care. M&M should not be used as a platform for accusatory or punitive engagement (31). M&M conferences should promote a culture of patient safety and open communication among all physicians, caregivers and administrators. Adverse events in patient care usually result from a series of errors within the system (30).

### *Appropriate use criteria (AUC)*

AUC for revascularization were developed to serve as a QA measure for both under- and over-utilized procedures. Procedures are designated into 1 of 3 categories: appropriate, may be appropriate or rarely appropriate (15,32). In 2009, the ACC and other medical professional societies developed the AUC for coronary revascularization to examine selection criteria for PCI given concerns for overuse (32). The original reports revealed a large variation in nonacute PCI procedures across hospitals (33,34). The most recent PCI appropriateness guidelines were published in 2016 and 2017 for acute coronary syndrome and stable ischemic heart disease, respectively (32,35). In both revisions, clinical scenarios were drafted that mimic daily practice encounters including symptom status, risk of non-invasive findings, and coronary anatomy. Each of the clinical scenarios was independently ranked by a panel that scored them on a scale from 1 to 9. Scores from 7 to 9 suggest that revascularization is appropriate while scores from 1 to 3 suggest that revascularization is rarely appropriate; scores from 4 to 6 suggest that revascularization may be

appropriate for a given clinical scenario. The application of these criteria is utilized in the CathPCI Registry as a process metric. CMS has adopted AUC as a metric to evaluate care, facilities have utilized these criteria to establish protocols, and while not intended or recommended by those who drafted the AUC documents, some payors have used these for preauthorization of procedures, in some cases exacerbating disparities in care (e.g., in New York state Medicaid program). Although the intent of the AUC was not to dictate payment, some payors have established rules that if rarely appropriate procedures were performed that a physician would not be paid. Outliers may need to perform remediation at work, required to perform additional preauthorization for procedures, and receive a reduction in reimbursement.

### *QI techniques*

There are several well studied QI techniques that can be used to improve outcomes in the Cath lab including: plan-do-study-act cycles (PDSA cycles), root cause analysis (RCA), failure modes and effects analysis (FMEA), total quality management (TQM), lean production, and six sigma methodologies of define, measure, analyze, improve, control (DMAIC) and define, measure, analyze, design, verify (DMADV) (12). *Table 2* shows the application of QI techniques to Cath lab quality. PDSA cycles aim to use focus groups with stakeholders of the Cath lab team and brainstorm with flow charts about given problems. This technique can be used to evaluate process measures and if best practices are followed such as minimizing radiation exposure to patients and operators, appropriate dosing of procedural antithrombotic therapy, and efficiency in inter-procedural turnover time. RCA is a retrospective analysis quality tool to evaluate past problems via cause-and-effect diagrams in order to prevent future problems. This method is generally used to determine the cause of variations in the standard of care (i.e., medication error). FMEA is a prospective measure used to identify system problems that may negatively impact patient safety such as high contrast volume. This helps prevent process failure prior to implantation. TQM promotes quality measurement, leadership, customer orientation, and continuous improvement and generally requires the creation of multidisciplinary teams in the Cath lab. Lean production aims to reduce the cost of the production while ensuring that quality is uncompromised. This can be accomplished through standards for vascular access and closure, and post-procedure

recovery protocols. Six sigma DMAIC is used for existing projects and DMADV is used for new processes (12).

### **Cath lab accreditation**

The purpose of Cath lab accreditation is to ensure national quality standards among centers to optimize clinical and operational outcomes. These standards are established by promoting best practices, professional and national practice guidelines, and appropriateness. The essential components of Cath labs include: governance, quality, pre-procedure, peri-procedure, post-procedure, and clinical quality (36). There are currently two nationally recognized Cath lab accreditation programs: ACC CCL v1 and Accreditation for Cardiac Excellence (ACE). ACE provides accreditation based on the type of procedure being performed (i.e., diagnostic, PCI, EP, PVI) (37). The accreditation process includes an evaluation of written material submitted by the Cath lab by a panel of trained practitioners. Following the application process a panel of physicians determines whether to grant accreditation, provisional accreditation until updates are performed, or denial. Some facilities are required to have an on-site evaluation. These are usually outlier centers when compared to national outcome data. The frequency of reporting accreditation materials to the accreditation body will be determined by the accreditation body based upon past performance and areas of noncompliance. ACE has identified 12 areas of review (*Table 3*) (38).

### **Cath lab privileges**

A key role of the CQI process is to inform the clinician-privileging process (19). The Director of the Cath lab generally oversees the initial and maintenance privileging process at an institution. In addition to board certification, the QI tools discussed above, including peer review and M&M, ensure that individual operators receive an impartial assessment of procedures and their outcomes (16,17). As the types of procedures have expanded beyond PCI in the Cath lab, the qualifications of operators performing novel procedures have evolved. Lab directors must be current on the training and volume requirements to perform endovascular and structural procedures as well. Minimum annual case volume requirement standards (by type of procedure) and assessment of individual risk-adjusted and

other adverse outcomes are generally considered in the privilege renewal process (10,13,39).

### **Structured Cath lab reporting**

A health policy statement from the ACC on structured reporting in the Cath lab was published in 2014 (19). There are several tenants of structured reporting that reflect the quality of care delivered. The reported information must be relevant to clinical care and operational administration, the document clear, concise, organized and reproducible. Elements for determining AUC such as procedural indication and non-invasive testing results, should be included. In order for the document to be brief and thorough, the use of well-defined discrete data elements is required. The free text should be avoided wherever possible. There needs to be consistency among operators and institutions, which can be achieved by the use of vetted standard vocabulary such as defined in the NCDR data dictionary. Templated documents reduce omissions and errors. Cath labs should expect that reports will be used beyond clinical care for reimbursement and reporting.

### **Public reporting**

Public reporting of outcomes both at the institution and physician level is aimed at improving quality standards, procedure appropriateness, and reducing cost. This system works to provide transparency to process and outcome-related data to better inform stakeholders including: patients, employers, health plans, physicians, and policymakers with the intent to improve healthcare delivery (14). Currently, public reporting is well established for hospital systems but formats for provider reporting are still evolving. Public reporting initiatives include state initiatives, payor data, business consumer groups, and reports from independent organizations (16,40-52).

Public reporting mandates were created following the passage of the Affordable Care Act in 2010 which tasked the Agency for Healthcare Research and Quality and CMS with responsibility for oversight. Public reporting has resulted in risk-averse case selection for both CABG and PCI procedures (17,21,53,54). The NCDR CathPCI Registry has approved public reporting of the following quality indicators (*Table 4*) (39).

Maximizing quality is important from a financial premise

**Table 4** NCDR CathPCI registry quality indicators

CathPCI public reporting
Aspirin at discharge
Thienopyridine at discharge
Statins at discharge
Composite discharge medications (aspirin, P2Y12 inhibitor and statin)
PCI in-hospital risk-adjusted mortality
30-day all-cause risk-adjusted mortality (ST elevation myocardial infarction or cardiogenic shock)
30-day all-cause risk-adjusted mortality (without ST elevation myocardial infarction or cardiogenic shock)
30-day risk-adjusted readmission rates for PCI

NCDR, National Cardiovascular Data Registry; PCI, percutaneous coronary intervention.

given its correlation with positive operating margins. Due to the decline in reimbursement, unfavorable payor mix, patient defaults as a result of large patient deductibles, and uninsured patients, facilities must now transition from a fee-for-service to value-based payment systems (5). The pressure for healthcare operations to reduce costs must not compromise procedure quality and safety. Third-party payors are beginning to select preferred providers and organizations that have demonstrated the consistent higher quality of care metrics compared to their peers (5). For example, these payment contracts may be awarded to facilities that have excellent patient satisfaction scores and outcomes. The converse could result in a loss or de-selection by payors (50). Facilities should use benchmarking via one of the multitudes of registries to identify areas of improvement compared to national standards.

### Quality committees

The QI oversight committee is responsible for training medical staff, assessment of patient and cardiac Cath lab quality metrics, adherence to National Patient Safety Goals, organizing QI activities, and developing corrective action plans (15). A complete QA/QI committee includes: chair, staff coordinator, and database manager. The QA/QI committee develops methods for data collection and may focus on areas including: continued education,

patient care, system processes, medical guidelines, cost-related items (1,7,20,55,56), review of complications that were not discussed in M&M conferences, lapses in universal protocol, equipment issues, and door-to-balloon time (19). The chair of the QI committee identifies and reviews concerns regarding the performance of individual operators with respect to professional behavior, judgement, clinical knowledge, complication rates and procedural appropriateness. Quality concerns should be addressed with the operator in confidence with a structured plan and implementation strategy for improvement followed by reassessment (20). The Joint Commission developed the Ongoing Professional Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) processes to make physician privilege decisions more objective (57). The OPPE is a screening tool to identify physicians with privileges that have low-quality performance metrics (57). The FPPE is the follow-up process for physicians that were identified during the OPPE process (57). The corrective action plan should be constructive, not be punitive, and should clearly state expected outcomes and targets (19). Outside CQI committees or impartial reviewers can be enlisted to offer additional advice, when appropriate. Penalties resulting in the suspension of privileges should only be considered following the failure of the operator to comply with the action plan.

The QI committee may also focus on the patient experience. Cath lab design quality can be assessed by using an “end-user experience framework” (6). For example, with a patient user-centered goal the comfort of the procedure and transportation are variables. These patient-centered goals can be measured by patient satisfaction scores. Depending on the results, the team can incorporate different tactics to respond to these results by reducing transportation distance, increased frequency of sedation and pain management checks, etc. A physician centered-goal may include visibility of the monitor, room lighting, tableside ergonomics and set-up, and radiation protection. These can be measured by using surveys, observational studies, and radiation badges.

### Summary

Cath lab QA can focus on a multitude of factors that directly and indirectly impact patient care. Quality is viewed as performing the right procedure, on the right patient, at

the right time (3). The Donabedian model is an effective framework to use those measures: structure, process, and outcome (4). Multiple professional organizations (i.e., NQF, NCDR, ACE, etc.) are involved in measuring, reporting, and developing national standards for physicians, Cath lab facilities, and payors to use to measure their improvement. Cath lab quality indicators are tracked and compared to national benchmarks. The CQI model aims to optimize processes and outcomes through a rigorous process at all levels of patient and team interactions. Multiple QI frameworks have been discussed to analyze and develop solutions for optimizing quality outcomes (i.e., PDSA and RCA). This QI and assurance initiatives are expected by healthcare stakeholders when assessing the safety, efficacy, and appropriateness of Cath labs which affect reimbursement, accreditation, and public perception. Cath lab public reporting metrics are used to improve quality standards, procedure appropriateness, and reduce cost. The importance of QI is to ensure patient safety and enhance cardiac procedure-related outcomes that will lead to further practice refinements. As we gather more knowledge from clinical research outcomes, we will be better prepared to adjust our quality metrics to benefit our patients. In the value-based payment model, physicians and healthcare systems will be rewarded on how they steward their resources to achieve similar clinical outcomes. Cath labs will be rewarded based on their ability to demonstrate high-quality care through the use of collaborative processes focused on quality outcomes.

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