

ACC-CATHKIT

CathKIT: Improving Quality in the Cardiac Catheterization Laboratory

Gregory J. Dehmer, MD, FACC, FSCAI, John W. Hirshfeld, MD, FACC, FSCAI, William J. Oetgen, MD, MBA, FACC, Kristi Mitchell, MPH, April Wells Simon, RN, MSN, MaryAnne Elma, BA, Mirle A. Kellett, JR, MD, FACC, FSCAI, Ralph G. Brindis, MD, MPH, FACC, on behalf of the American College of Cardiology Foundation/Society for Cardiovascular Angiography and Interventions Task Force to Develop the Cardiac Catheterization Laboratory Continuous Quality Improvement Toolkit

CathKIT Task Force Members

Richard A. Chazal, MD, FACC, FSCAI (*Chair*), Gregory J. Dehmer, MD, FACC, FSCAI, (*Vice-Chair*), Ralph G. Brindis, MD, MPH, FACC, Charles E. Chambers, MD, FACC, FSCAI, Mary Heisler, RN, Frederick A. Heupler, JR, MD, FACC, John W. Hirshfeld, MD, FACC, Mirle A. Kellett, JR, MD, FACC, FSCAI, Thomas D. Lane, MBA, FAAMA, FACCA, William J. Oetgen, MD, MBA, FACC, Roger Siegfried, RCIS, FSICP, FSCAI, April Wells Simon, RN, MSN, C. Michael Valentine, MD, FACC, FSCAI

Over the past 50 years, the cardiac catheterization laboratory has evolved from an investigational facility that provided much of our current knowledge of cardiovascular pathophysiology to a mainstream clinical site for diagnostic and therapeutic procedures. Invasive cardiovascular procedures are now a cornerstone of the evaluation and management of many cardiovascular diseases. More than one million studies are performed annually in the U.S., and the number is growing with more invasive facilities being built (1).

Improvements in X-ray image quality, new potent antiplatelet agents, and coronary stent technology are only a few of the advancements that have resulted in higher success rates and a reduction in procedure mortality and adverse clinical events. Despite this, there is clear variation in patient outcomes among cardiac catheterization laboratories. Data from the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR™) show a wide variation in the risk-adjusted in-hospital mortality rate for percutaneous coronary intervention that cannot be explained completely by the clinical status of the patient (2,3). Such observations have focused attention on this variation and provoked debate on how to measure quality appropriately within the cardiac catheterization laboratory.

Currently, no national standards exist upon which to judge the quality of care in cardiac catheterization laboratories. Clinical practice guidelines and expert consensus documents published by the American College of Cardiology Foundation (ACCF), the American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) have been used to develop quality standards in some states. Although it was never the primary intent of these

documents to be used for such standards, they have become the *de facto* basis for licensure regulations imposed by some state health departments in an attempt to improve quality. Physician activity-level standards (the number of invasive procedures performed annually) derived from these documents have come to the forefront as the most controversial of these regulations. Although there are data suggesting a relationship between higher operator procedure volumes and improved outcome for percutaneous coronary intervention, similar data do not exist for diagnostic cardiac catheterization (4). Moreover, there are several flaws in using volume alone as a surrogate for quality in invasive cardiology (5). Simply put, completing 500 coronary interventions without a single complication does not equate to quality if 450 of the procedures were performed with poor indications or on lesions that would best be left alone.

Amid state regulations, consumer demand for quality, pressures from managed care and other payers to be cost-efficient, documented regional variation in the appropriate use of invasive procedures, and public reporting of mortality and morbidity rates, quality in the cardiac catheterization laboratory is being examined more closely than ever before. Therefore, it is crucial that invasive procedures, which consume considerable health care dollars and expose patients to small but important risks, adhere to the highest quality standards available. Similar to many areas of health care, there is within the cardiac catheterization laboratory a high potential for variation in structure and process as well as variability in operator training, skill, and judgment. Such variations can have either positive or negative impacts on patient outcomes. For this reason, health care professionals must continuously evaluate the practice of invasive cardiology and establish rigorous strategies for quality assessment, quality assurance, and quality improvement.

Abbreviations and Acronyms

ACCF	= American College of Cardiology Foundation
ACC-NCDR™	= American College of Cardiology-National Cardiovascular Data Registry
AHA	= American Heart Association
CQI	= continuous quality improvement
GAP	= Guidelines Applied in Practice
GWTG	= Get With The Guidelines SM
JCAHO	= Joint Commission on Accreditation of Healthcare Organizations
SCAI	= Society for Cardiovascular Angiography and Interventions

National efforts to promote quality care began over 10 years ago. In 1992, the Centers for Medicaid and Medicare Services (formerly known as the Health Care Financing Administration) announced a shift in direction to assure that high-quality medical care was provided to Medicare recipients (6). Previously, the emphasis was on *quality assurance*, a process based largely on the retrospective review of selected outcomes to determine the presence of discrepancies between actual practice and recommended standards of care (7). The quality assurance process focuses on correcting problems that affect patient outcomes at the individual level and sometimes engenders a level of defensiveness among physicians (8). Building upon traditional quality assurance methods while emphasizing a broader perspective of health care delivery, the new approach borrowed from industry was to analyze patterns of care and identify opportunities for improvement by evaluating the process, structure, and outcomes of medical care (9). This approach, known as *continuous quality improvement (CQI)*, has now become a vital and expected component of a quality cardiovascular program.

Three lessons were learned as the health care industry began to adopt the CQI process. First, the application of CQI techniques to the process, structure, and outcomes of medical care was frequently a difficult, time-intensive, and expensive endeavor (10). Second, many examples were discovered where there was underutilization of therapies that had documented benefits to patients (11). Finally, a CQI approach could successfully improve the use of proven treatments across the continuum of care during a patient's encounter with the health care system (12).

In addition to the federal government's mandate to adopt the CQI process, other accreditation and governmental bodies began to require CQI as partial fulfillment of their regulatory standards. For example, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) established standards requiring CQI programs for both inpatient care and disease-specific areas of oversight (13,14). Moreover, individual states, as part of their licensing and regulation capacities, are requiring documentation of ongo-

ing CQI projects in high-risk areas such as the cardiac catheterization laboratory rather than relying on strict institutional or physician procedure volume requirements or on-site cardiac surgical support to ensure quality of care (15).

Simultaneously, individual practitioners are beginning to recognize the benefits of this methodology, and professional organizations have encouraged CQI in efforts to promote quality care. To that end, several guidelines and expert consensus documents jointly produced by the ACCF, AHA, and SCAI specifically recommend CQI programs for the upgrading of cardiovascular care (16,17). In addition, both the ACCF's "GAP" (Guidelines Applied in PracticeSM) and the AHA's "GWTG" (Get With the Guidelines) programs, which embrace this quality improvement philosophy, have shown measurable success in improving care ever since their inception (18,19).

Although the importance of CQI in the cardiac catheterization laboratory is now very clear, it is also apparent that many institutions do not completely understand this process or how to fully implement CQI into laboratory operations. It is also apparent that many College members who are also leaders of cardiac catheterization laboratories poorly understand the CQI process. In response to these needs, the ACCF and SCAI with representation from the AHA, the Alliance of Cardiovascular Professionals, the American College of Cardiovascular Administrators, and the Society of Invasive Cardiovascular Professionals developed a cardiac catheterization laboratory CQI toolkit (known as CathKIT). The goal of CathKIT is to provide cardiac catheterization laboratories with the tools necessary to develop and implement CQI that results in improved quality of care. Accordingly, it is fitting that the "KIT" in CathKIT stands for *knowledge, improvement, and tools*.

BACKGROUND LEADING TO THE DEVELOPMENT OF CATHKIT

Consistent with the mission to foster optimal quality in cardiovascular care, the leadership of the ACCF concluded that there was a critical need to develop a scientifically rigorous and appropriate process that would assure optimal quality in invasive cardiovascular procedures. Because the ACCF had already established the ACC-NCDR™, which could serve as the data repository for laboratory quality assessment, it seemed logical that any additional initiative should complement the ACC-NCDR™. To that end, a Task Force, lead by John Hirshfeld, MD, FACC, was organized to evaluate the prevailing status of cardiac catheterization laboratory quality monitoring. The Task Force identified two important, interrelated quality issues. First, there is no generally accepted, effective, and systematic process for quality assessment and assurance in cardiac catheterization laboratories. Second, considerable heterogeneity exists among laboratories in operations, practices, and

reporting. The Task Force considered three potential action plans to address this situation:

1. Do nothing, accepting the status quo.
2. Develop an ACCF-sponsored cardiac catheterization laboratory accreditation procedure.
3. Develop a product to assist laboratories in CQI.

The Task Force rejected the “do nothing” option because of the issue’s importance. Developing a cardiac catheterization laboratory accreditation procedure also was debated and rejected. Accreditation procedures for certain types of clinical facilities have been developed, but the Task Force concluded that a comprehensive accreditation process for cardiac catheterization laboratories would require substantial on-site assessments. When multiplied by the number of facilities, this would require resources well beyond the ACCF’s capabilities. In addition, such a process would move the ACCF away from its fundamental purpose of education and standard setting to an organization with regulatory activity. This would be inconsistent with the ACCF’s mission and relationship to its members. Consequently, the Task Force envisioned that a CQI product could:

- Present and teach the CQI process in a manner both relevant and accessible to cardiac catheterization laboratories.
- Provide a compendium of best practices covering all aspects of cardiac catheterization laboratory operation.
- Compile quality standards for cardiac catheterization laboratory outcomes.
- Provide a forum for cardiac catheterization laboratory leadership to share ideas and experience and further develop the process.

In March 2001, the Task Force recommended to the ACCF Board of Trustees that they proceed with the development of a cardiac catheterization laboratory CQI product. The Board approved this recommendation and funding was authorized. A new Task Force, chaired by Richard A. Chazal, MD, FACC, FSCAI, and Gregory J. Dehmer, MD, FACC, FSCAI, began the development process in late 2001.

WHAT IS CATHKIT?

A large body of information exists related to the management of a cardiac catheterization laboratory. This includes not only benchmark data on complication rates and other outcome variables, but also credentialing standards for physicians, training standards for other professional personnel, data on maintaining optimal image quality, regulations related to radiation safety and infection control, and directives for administration of a catheterization facility. Furthermore, there is an additional body of information containing regulatory requirements from JCAHO and from federal and state governments. Unfortunately, this substantial amount

of information is found scattered among many different resource documents and publications. CathKIT brings this information into one comprehensive resource. Some material concerns traditional measures of quality, whereas other materials involve management issues such as scheduling efficiency and patient flow. However, CathKIT is more than simply a reference source. The primary purpose of CathKIT is to assist cardiac catheterization laboratories with the development and implementation of CQI programs. For laboratories just beginning a CQI program, an initial tutorial is provided; laboratories with established CQI programs will have the online capability to evaluate their existing efforts, network with colleagues, and share ideas for problem solving and process improvement. CathKIT is intended to be a self-contained resource with features for every member of the cardiac catheterization team. By using an Internet-based platform, CathKIT enables the user to interact with colleagues and the ACCF with regard to quality issues. Ongoing updates to existing materials are an integral part of the design.

CathKIT goes beyond traditional quality assurance measures and thus complements but does not replace the ACC-NCDR™. CathKIT shows users how to apply data obtained from the ACC-NCDR™ and other national databases to their individual laboratory to continuously improve their entire service, both clinically and operationally. Used appropriately, with both medical and administrative leadership, CathKIT can be the cornerstone for a very successful CQI program.

MAJOR SECTIONS OF THE CATHKIT

The content of CathKIT ranges from didactic CQI information to templates and resources for users to download and modify for their individual facility. CathKIT is organized into six core content areas that are navigated from an interactive table of contents (Table 1).

Home. The *Home* section provides the background and rationale for the development of CathKIT as well as basic instructions for use and navigation of the product. This section also includes a cross-referenced glossary of CQI terms, clinical definitions, and abbreviations consistent with ACC/AHA clinical guidelines, ACCF expert consensus documents, and the ACC-NCDR™. Upon first accessing CathKIT, the user is provided with suggested roadmaps for the order in which sections of the CathKIT should be accessed based on the individual’s role within the cardiac catheterization laboratory. This non-linear approach to CathKIT, facilitated by the Internet-based structure, maximizes the benefit of its interactive capabilities.

Learn About CQI. The *Learn About CQI* section provides both basic and in-depth content of CQI principles and methods appropriate for all members of the cardiac catheterization team (Table 1). Future enhancements to CathKIT will offer continuous medical education and continuous education units for individuals completing the tutorials.

Table 1. Major Sections and Subsections of CathKIT

Home	Reporting and Outcomes
Background	Introduction
What Is CathKIT?	Self-Evaluation Summary
Why Use CathKIT?	Quality Score Card
Reward and Recognition Program	PCI Questions and Measures
How to Use CathKIT	PCI Scorecard Report
Profiles	Institutional Competencies and Capabilities
How to Get Help	Process Management
Feedback	Clinical Outcomes
Glossary	Patient Satisfaction and Quality of Life
Acronyms and Abbreviations	Financial Indicators
Contributors	Diagnostic Catheterization Questions and Measures
Learn About CQI	Institutional Competencies and Capabilities
Introduction	Process Management
CME	Clinical Outcomes
Principles of CQI	Patient Satisfaction and Quality of Life
Tools for Successful Teamwork	Financial Indicators
Analytical Tools for CQI	Diagnostic Scorecard Report
Measuring and Improving Outcomes	Implement CQI
Using Benchmark and Comparative Data	Introduction
Organizing for CQI	CME
Putting the CQI Process in Motion	CQI Readiness Assessment
Managing Workplace Change	Step 1: Find a Process to Improve
Change Management for Physicians	Step 2: Organize a Team
Peer Review in the Cardiac Catheterization Laboratory	Step 3: Clarify Current Process
Political and Legal Aspects of CQI	Step 4: Understand Process Variation
References	Step 5: Select the Improvement
Meets Standards	Step 6: Plan the Improvement
Introduction	Step 7: Do Implement the Plan
Facilities and Environment	Step 8: Study to See if Improvement Made a Difference
Self-Evaluation Checklist	Step 9: Act to Hold All Gains Realized and Continuously Improve
Evolution of the Modern Cardiac Catheterization Laboratory	Resources
Space Requirements	Introduction
Relationship to Other Services	Stakeholder Relations
Equipment	State-by-State Requirements
Additional Equipment	State Regulatory Contact Information
References	Tools and Templates
Management Considerations	Care Plans
Self-Evaluation Checklist	CQI Tools
Budgeting and Financial Management	Flowcharts
Human Resources Management	Forms
Supply, Procurement, and Inventory	Reports
Essential Information Needs	Policies and Procedures
Environmental Issues	Standing Orders
References	Case Studies
Personnel	'How We Do It' Strategies
Self-Evaluation Checklist	Contributing Your Ideas
Leadership Responsibilities and Qualifications	Discussion Board
Credentialing Process Overview	Catheterization Laboratory Network
Responsibilities, Qualifications, and Credentialing for Laboratory Physicians and Staff	Library
References	Bibliography
Patient Care	Recommended Reading
Self-Evaluation Checklist	
General Management	
Preprocedural Management	
Procedural Management	
Postprocedural Management	
References	

CME = continuing medical education; CQI = continuous quality improvement; PCI = percutaneous coronary intervention.

Meets Standards. In one of the most extensive areas within CathKIT, the *Meets Standards* section focuses on the space and equipment requirements for a contemporary

laboratory and the important interrelationships existing between the laboratory and physicians or other hospital services (Table 1). Each major subsection has a comprehen-

sive checklist to help sites assess the overall status of the laboratory. Each question directs the user to the specific section within CathKIT that supports the answer or is linked to an appropriate reference. In addition, specific JCAHO standards are demarcated for rapid identification and to increase ease of use.

Reporting and Outcomes. The *Reporting and Outcomes* section provides facilities with summary reports of their self-evaluation checklists from the Meets Standards section and supplies a Quality Scorecard. The Checklist Report pulls all of the answers from the individual checklists into an organized and printable format that can be used for quality assurance and improvement purposes. The Quality Scorecard enables the facility to identify additional opportunities for improvement in several areas including institutional competencies and capabilities, process management, clinical outcomes, patient satisfaction or quality of life, and financial indicators. Threshold scores in each area enable the individual laboratory to benchmark itself against a gold standard, thereby identifying areas for improvement. CathKIT directs each facility to complete the scorecard upon first accessing CathKIT so as to provide an initial internal benchmark. Documenting the baseline is considered the first step of the CQI process. Both the Checklist Report and the Quality Scorecard have printable versions that include the demographic information of the facility for internal documentation needs.

Implement CQI. The main purpose of CathKIT is to enable catheterization laboratory teams to apply the FOCUS Plan-Do-Study-Act method to quality improvement within the laboratory (20). This method, similar to the "Deming" cycle, is a nine-part method for discovering and correcting assignable causes to improve the quality of processes. To facilitate this, the *Implement CQI* section is an outcomes-oriented, do-it-yourself training guide for conducting cardiac catheterization-specific CQI projects. Each of the steps in the cycle is described, with application to the cardiac catheterization laboratory (Table 1). Included are downloadable worksheets for facilities to complete based on individual quality improvement projects.

CathKIT also guides the user in the application of this knowledge to actual practice. Once an appropriate CQI initiative is identified, the implementation plan walks users step-by-step through the process from organization of the CQI team through maintaining the gains made during the improvement process. The CQI tools are also available to assure appropriate communication within the CQI team, analysis of the information, and brainstorming for solutions.

Resources. CathKIT provides access to a network of cardiac catheterization facilities and external resources. The *Resources* section includes a searchable database of state regulations that will be updated periodically. This section also contains a virtual library of reference materials, including tools and templates developed in other laboratories (Table 1). These tools cover aspects of daily operations, budgetary guidelines, inventory control, staffing, peer-

review process, credentialing, and various outcomes measures. These tools can be utilized to elicit ideas during brainstorming sessions while developing plans for improvement, and they can be downloaded and modified as necessary by a laboratory to fit their local situation. Individual laboratories using CathKIT may submit ideas and projects that they have used successfully at their facility. As a dynamic section with frequently changing content, the Resources section takes full advantage of its Internet-based platform to offer up-to-date information and cross-referenced content.

REWARD AND RECOGNITION PROGRAM

CathKIT has a three-tiered Reward and Recognition Program to document participation of individual cardiac catheterization laboratories in quality improvement initiatives. External recognition will encourage internal CQI initiatives at user facilities, foster support from administration, physicians, and staff, and provide an incentive to improve and sustain performance. Furthermore, recognized achievement may fulfill some of the requirements being imposed by state regulators, hospital accrediting bodies, or third-party payers. The principles of the Reward and Recognition Program are:

- Achievements at the three reward levels would have significance with the various stakeholders and be viewed favorably as an alternative to external regulatory and accrediting initiatives.
- Active use of CathKIT with its attendant recognition would serve as a marker of continued self-improvement.

With these principles in mind, three progressive levels of recognition were created. The first level is designed primarily to encourage participation and indicate adoption of the CathKIT methodology. It will be achievable for a large number of facilities within the first year of use and will define meaningful user participation. The goal for this level is to create a CQI infrastructure within the cardiac catheterization laboratory and to begin using it for improvement projects. The second level builds on the first and requires participation in an external benchmark database and documentation of CQI efforts. The third level is set to be a competitive award based on outstanding quality improvement initiatives submitted for review. Such projects could be highlighted at the annual ACCF meeting and eventually published in an appropriate peer-reviewed journal. Therefore, the CathKIT Reward and Recognition Program is designed to meet the simultaneous goals of improving quality in the cardiac catheterization laboratory and documenting improvement for external stakeholders.

THE FUTURE OF CATHKIT

Through CathKIT, the ACCF has created an Internet-based quality tool to aid hospitals, cardiac catheterization laboratories, and cardiologists in the implementation of CQI. Active input and feedback from the users of CathKIT

and other stakeholders will allow ongoing improvements in the product and enhancements to upgrade the value of this product for its participants. The Internet-based format enhances the ease with which participant-created CQI projects and future assessment methodologies can be quickly incorporated into CathKIT.

There is already substantial enthusiasm for CathKIT coming from hospitals, third-party payers, and government regulators, demonstrating both the need for such products and the potential value of this effort to the cardiovascular community at large. For example, in addition to the requirement for each cardiac catheterization laboratory to participate in the ACC-NCDR™, Massachusetts has already embraced and encouraged laboratories to use CathKIT when it becomes available. Most believe this proactive approach, directed toward improvement in cardiovascular care, is preferable to a retrospective punitive approach directed at quality outliers. Some payers are beginning to explore the possibility of differential reimbursement schemes based on quality indicators. CathKIT should assist laboratories and individual providers in their response to such initiatives.

The ACCF, based on its underlying mission to promote quality cardiovascular care, is committed to other opportunities for future "Quality Guides." The ACCF, in partnership with the AHA and other national organizations continues to create and update clinical guidelines, performance measures, and data standards in cardiovascular disease. These activities plus the ACC-NCDR™ for outcomes assessment and CathKIT for CQI development, complete the "cycle of quality improvement" for the cardiac catheterization laboratory (21). As data standards are defined for electrophysiology and peripheral vascular disease, opportunities will then exist for expansion of the ACC-NCDR™ to include outcomes assessment modules in these areas along with the creation of the corresponding quality products. Also being considered is a CQI toolkit for the echocardiography laboratory (EchoKIT).

In summary, CathKIT is a direct result of the commitment of the ACCF to respond to the needs of its membership and simultaneously improve the quality of cardiovascular care. Participation in CathKIT should enhance the ability of a cardiac catheterization laboratory to fully utilize quality assessment data and move CQI to a higher level in their facility.

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Address for correspondence: Ms. MaryAnne Elma, American College of Cardiology Foundation, 9111 Old Georgetown Road, Bethesda, Maryland 20814.

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