Continuous Quality Improvement in the Cardiac Catheterization Laboratory

Are the Benefits Worth the Cost and Effort?

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Continuous quality improvement (CQI) has been described as a methodology to continually improve the processes associated with providing a product or service to meet or exceed customer expectations. In reality, the CQI process is a collection of techniques borrowed from the fields of systems theory, statistics, engineering, psychology, and others and is based on the work of pioneers in industrial management such as Deming and Juran. As a management philosophy, CQI is an organized, scientific process for evaluating, planning, improving, and controlling quality. Simply stated, the goal of CQI is to reduce variation and improve overall performance. Positive experiences in other industries lead to the application of CQI methods in healthcare in the hope that reduced variation and better performance would improve patient outcomes and result in cost savings. This is fundamentally different than the earlier quality assurance (QA) process used in healthcare, which was geared to identify and eliminate “low-end performers or outliers,” leaving only the acceptable performers. The CQI approach in healthcare has been promoted by individuals such as Donabedian, Berwick et al., and Jencks and Wilensky. It builds on traditional QA methods to develop programs that will reduce variation and improve overall performance.

CQI efforts in cardiovascular care have shown benefits such as attaining a high level of adherence to evidence-based performance and process measures in the management of acute coronary syndromes. More importantly, CQI, through an improvement in patient care processes, has an association with better clinical outcomes with emerging data demonstrating decreased mortality. However, large confirmatory randomized clinical trials are still lacking. An important question is whether large-scale randomized trials are really necessary in this circumstance. Is it necessary to have direct evidence that you have saved lives, or is it enough to show that you have improved processes that have a strong link with outcomes? That will be a very important question in the future as there is a greater emphasis on improving the quality of medical care.

The core of most CQI programs includes the following: (1) the collection of data containing clinically relevant patient variables that allow assessment of clinical processes, performance, and outcomes; (2) feedback of this performance and outcomes data to the clinicians, ideally with risk adjustment and benchmarking of the data; and (3) implementation of appropriate interventions to promote reduction in wasteful and inefficient variation in care while simultaneously improving performance. These interventions might include the development of evidenced-based clinical guidelines and then dissemination of this information through grand rounds, “pocket guides” of critical pathways, and other reminder tools such as preprinted order sheets. The actual “key ingredients” from the smorgasbord of potential tools to best ensure successful CQI programs are still not fully understood. We also have much to learn regarding the context of how these “key ingredients” are applied. We do know that there are several known predictors of success for CQI programs, invariably focusing on the presence or absence of local physician champions in conjunction with an administrative and financial commitment from the parent organization.

In this issue, Moscucci and colleagues describe a substantial effort to implement a statewide CQI initiative in Michigan, specifically devised for the cardiac catheterization laboratory. Their program, designed to examine and reduce outcome variation in the performance of percutaneous coronary intervention (PCI), documents the positive effects of a CQI program. This topic is both relevant and important as ~1 million PCI procedures are now performed annually in the United States. The potential for improvements in PCI outcomes attained through a CQI program could have a major impact, as measured by lives saved and a decrease in hospital costs through a reduction in prolonged hospitalizations that are associated with procedural complications, such as contrast nephropathy, vascular injury, bleeding, stroke, and myocardial infarction. The authors, recognized leaders in the cardiovascular outcomes and quality community, are to be congratulated for their vision and effort in developing this program and, more importantly, in evaluating the impact of this CQI program. Through this documentation, the quality and outcomes community can better understand the importance of CQI implementation in the cardiac catheterization laboratory and its potential for improving care.

The Michigan PCI CQI program used a wide range of concurrent and reinforcing strategies directed throughout the

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system of care. A key element was the quarterly feedback to clinicians on their adherence to process and performance measures along with crude and risk-adjusted outcomes. Grand rounds presentations, site visits, work group meetings, and newsletters were also used to provide information to clinicians. Various bedside clinical tools to assess the risk of in-hospital mortality after PCI and aids for the prediction and prevention of contrast nephropathy requiring dialysis and reduced blood transfusions were distributed. Other examples of interventions instituted in participating hospitals included uniform preprocedure order sets to ensure the administration of critical medications, standard nursing protocols for assessing preprocedure medications, delay of cases if necessary medications were neglected, routine preprocedure hydration plus efforts to limit contrast administration in high-risk patients with renal insufficiency, and modification and standardization of emergency department protocols for patients with acute coronary syndromes.

As a result of these interventions, there was a demonstrable decrease in bleeding, transfusion requirements, vascular complications, and contrast utilization and a trend for the reduction in the occurrence of contrast nephropathy. Increased adherence to these process measures further translated into temporal improvements in major clinical outcomes. Compared with the period before the CQI program, there were lower crude and risk-adjusted rates of in-hospital death, emergency coronary artery bypass graft surgery, contrast nephropathy requiring dialysis, myocardial infarction, and stroke. With the exception of contrast nephropathy, many of these other improvements could be ascribed to temporal advances in PCI care that occurred between 1998 and 2002. However, their study results support the benefits of CQI implementation, even when these temporal trends are considered. The differences in catheterization laboratory performance measures and associated clinical outcomes documented in their control versus intervention cohort studies from 2002 further support the value of a PCI CQI program. When comparing 2002 data from the PCI CQI intervention hospitals with data from the control hospitals, the authors described statistically significant better clinical outcomes defined by a quadruple end point of death/emergency coronary artery bypass graft surgery/stroke/repeated PCI. Of interest, the control hospitals reported a trend toward a lower rate of periprocedural myocardial infarction than the CQI-utilizing hospitals. This observation most likely reflects an incorrect assessment of the frequency of periprocedural myocardial infarction than the CQI-utilizing hospitals. The observation most likely reflects an incorrect assessment of the frequency of periprocedural myocardial infarction, a finding typical in PCI registries, where it is related to the lack of a consistent measurement of cardiac biomarkers after the procedure compared with studies in which the measurement of cardiac biomarkers is mandatory after the procedure.

Unfortunately, this was not a randomized study, a major weakness that undermines support for the hypothesis that a CQI program is beneficial. Therefore, it is not possible to definitively determine whether it was the CQI program that caused the improved outcomes or whether these improvements would have occurred in any case for reasons related to temporal changes in PCI practice. Moreover, although these data were risk adjusted, there were important variations in the clinical characteristics of the patients treated between the intervention and control arms. The authors freely acknowledge this shortcoming in their discussion and analysis. Temporal practice patterns, such as higher use of glycoprotein IIb/IIa inhibitors, increased use of PCI <48 hours after a myocardial infarction, better stent technology, and the increased use of stents in PCI all contribute to improved PCI outcomes. However, the markedly increased in-hospital mortality associated with contrast nephropathy requiring dialysis is well known. This study’s unequivocal demonstration that achieving a decrease in contrast use led to a decreased incidence of contrast nephropathy, as well as a trend in decreased contrast nephropathy requiring dialysis when postintervention hospitals are compared with both themselves temporally and with the control hospitals in 2002, validates the use of these CQI initiatives. Indeed, the Michigan CQI program of Moscucci et al most likely contributed substantially to the positive changes in performance observed, although the strength of this evidence is not as strong as it might be with a randomized controlled trial. Particularly commendable was their building into their project an evaluation component that should serve as a model for future programs. Such an effort can also help us to determine whether such programs might paradoxically reduce quality or have an adverse, unintended, and unexpected effect.

Barriers to CQI Program Implementation

The article of Moscucci et al also notes the most important and frequent challenge to the implementation of a catheterization laboratory CQI initiative. Of the 9 hospitals originally agreeing to participate in the CQI initiative, only 5 were able to offer uninterrupted participation and data collection over the study period. Four hospitals were unable to successfully implement this CQI program. Lack of hospital administrative and financial support for the project and the required internal data collection was the main reason cited for the dropout of 2 institutions; lack of both physician leadership and administration support occurred at 1 hospital, and a loss of physician leadership was the reason in the remaining hospital. This is a very sobering statistic, especially when the potential benefits to patients and institutions from the implementation of a CQI process are considered. The presence of a highly committed physician champion with full administrative and financial support is a prerequisite for any successful CQI initiative. It is hoped that further research like that shown in this study will validate the clinical value of CQI efforts in the cardiac catheterization laboratory and lead to an increased acceptance by clinicians. Furthermore, hospital administrators need to look beyond the immediate bottom line and appreciate that the added costs have the potential for substantial financial savings through a reduction of costly PCI complications. In the end, however, there is still a fundamental conflict in that everyone wants a quality product, but few are willing to pay the extra cost for that product.

External Driving Forces in CQI

Many nonhealthcare industries have successfully incorporated CQI into their corporate culture. Healthcare stakeholders such as JCAHO, Leapfrog, and third party payers under-
stand the value of outcomes assessment and the role of CQI in attaining quality outcomes and are actively promoting hospitals to develop these types of programs at the local level. Unfortunately, the healthcare industry remains in its awkward adolescence regarding the implementation of proven-quality initiatives as encouraged by the Institute of Medicine, the Institute of Healthcare Improvement, and others. In the cardiovascular area, quality programs have been promoted by the American College of Cardiology (ACC), the Society for Cardiovascular Angiography and Interventions (SCAI), and the American Heart Association (AHA). The core of these programs invariably centers on an “infrastructure engine” for data collection and outcomes assessment. The ACC–National Cardiovascular Data Registry (ACC-NCDR) for cardiac catheterization and PCI data now has >700 US hospital participants, representing close to a 40% market penetration.\textsuperscript{11–14} The ACC-NCDR uses a standardized format and data definitions created through the AHA/ACC Data Standards Committee, with data quality monitored by an on-site auditing program. Approximately 4 million patient records have been entered in the ACC-NCDR since its inception in 1998. The participating institutions receive quarterly reports detailing their cardiac catheterization laboratory and PCI performance, with national and regional benchmarking of patient demographics, clinical variables, and outcomes, including risk-adjusted mortality data. As demonstrated in the article by Moscucci et al., “closing the loop” of the quality cycle requires not only the collection and feedback of accurate benchmarked data to identify opportunities for improvement but also the creation of tools to aid clinicians and cardiac catheterization laboratory directors in developing CQI programs designed to reduce variation and improve outcomes.

Working together, the ACC and SCAI have created a cardiac catheterization laboratory quality improvement tool called ACC-CathKIT. ACC-CathKIT is an up-to-date Web-based cardiac catheterization and PCI tool kit to aid clinicians and hospitals in developing their own CQI initiatives in the cardiac catheterization laboratory.\textsuperscript{16} Included in CathKIT are lessons in CQI methodology, examples of relevant CQI projects, such as management and avoidance of groin complications, and downloadable templates for catheterization laboratory protocols and PCI pathways. Individual NCDR hospital presentations given at ACC-NCDR user group meetings have confirmed the effectiveness of adopting CathKIT CQI projects with the demonstration of positive changes in aspects of cardiac catheterization care along with cost savings to their institution.

**Pay for Performance and CQI**

There are new drivers for change on the horizon in the area of cardiovascular quality. These recent developments are due in part to the recognition by external healthcare stakeholders that active participation in quality initiatives has been sluggish. After the initial recruitment of an independent wave of highly motivated hospitals, ACC-NCDR participation has grown substantially, following new mandates by state regulatory agencies, third party payers, or health plans. To motivate hospitals and clinicians to embrace and implement quality improvement programs and with appreciation of the cost and time commitment required for CQI program implementation, payers are developing “Pay for Performance (P4P)” initiatives. The concept of differential payment for the delivery of high-quality care is increasingly penetrating the healthcare landscape and the cardiac catheterization laboratory. The encouraging outcomes and quality research shown in the study of Moscucci et al provide further credence for healthcare payers to pursue this avenue. However, this must be done with great caution, and significant challenges exist for these P4P programs, including the following:

- Actually defining what constitutes cardiac catheterization laboratory and PCI quality. This must be based on well-established evidenced-based and proven performance measures.
- Providing adequate incentives for investments in structure, best practices, and tools that can lead to improvement and high-quality PCI care.
- Ensuring that a P4P environment is not punitive but instead is supportive. This will likely be a zero-sum game in that the rewards for high performance will be derived from lower reimbursements to those judged to have lower performance. Therefore, it is mandatory that the methods used for assessing performance be objective and without ambiguity.
- Assigning attributions of credit for performance to physicians in ways that are credible and encourage collaboration.
- Rewarding hospitals and clinicians for participating in the process of outcome assessment and improvement through the use of CQI programs, as well as the actual demonstration of high quality.

Perhaps through direct financial support by the payers, hospitals and clinicians will be more motivated to embrace the quality initiatives already demonstrated to be of significant value in the management of acute coronary syndromes and now being highlighted in the cardiac catheterization laboratory.

**Disclosures**

None.

**References**


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