Quality Measurement and Improvement in the Cardiac Catheterization Laboratory

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Case Presentation: A 46-year-old man with a past medical history significant for morbid obesity (body mass index of 66), hypertension, tobacco use, and dyslipidemia presented to an outside hospital with a non–ST-segment elevation myocardial infarction and was transferred for coronary angiography. Femoral arterial access was obtained for an uncomplicated percutaneous intervention (PCI) with the use of unfractionated heparin and a glycoprotein IIb/IIA inhibitor. After successful PCI of the right coronary artery with drug-eluting stent implantation, the femoral arteriotomy was closed without complication. Two hours after the completion of the procedure, the patient experienced ventricular fibrillation and respiratory arrest requiring prolonged resuscitation with a subsequent hematocrit level noted to be 12.5%. The patient was resuscitated with fluid and blood products. Emergent angiography showed no active iliofemoral contrast extravasation and a widely patent coronary stent. An abdominal CT scan without contrast confirmed the diagnosis of a retroperitoneal hemorrhage. Unfortunately, the patient experienced recurrent ventricular fibrillation, and he died despite additional resuscitative efforts.

Background
Cardiac catheterization is one of the most common invasive procedures performed in the United States. Although the benefits of cardiac catheterization remain great, the large number of procedures performed coupled with infrequent but potentially significant complications make the cardiac catheterization laboratory an important environment in which to constantly strive to improve quality. Although optimal patient outcomes remain paramount, state and national regulatory requirements, public reporting, and payers’ interests in both outcomes and cost raise the importance of quality measurement and improvement in the cardiac catheterization laboratory.

Minimal Requirements for Quality Monitoring and Societal Recommendations
Minimal requirements for quality monitoring in the cardiac catheterization laboratory vary with individual state regulatory practices. As an example, in Massachusetts, data elements are collected and reported as mandated by the Massachusetts Department of Public Health, The Joint Commission, Centers for Medicare & Medicaid Services, and mandated participation in the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR). The Table provides examples of the multiple data elements and organizations to which information is submitted by catheterization laboratories in Massachusetts.

Beyond the minimal requirements, organizations such as the American Heart Association (AHA), American College of Cardiology (ACC), and the Society of Cardiovascular Angiography and Interventions (SCAI) have made recommendations on quality monitoring. The ACC/AHA/SCAI 2005 PCI guidelines recommend that all institutions performing PCI should establish peer review of quality and outcomes at both the individual and institutional level, and those institutions should participate in PCI registries in an effort to benchmark outcomes against national statistics. Organizations such as The Leapfrog Group exist as an employer-driven voluntary reporting group to help payers of insurance compare quality across institutions. Recently, SCAI published a position statement on quality assessment for interventional cardiology. In addition, or-
organizations such as the Accreditation for Cardiovascular Excellence have been formed as a joint effort between ACC and SCAI to offer accreditation to facilities by way of external review based on adherence to established cardiac catheterization laboratory standards.\textsuperscript{5} 

\textbf{Introduction to the Continuous Quality Improvement Model}

Traditional models of quality assurance and quality monitoring in health care have focused on the measurement of performance and the subsequent comparison of performance with standards throughout the field.\textsuperscript{6} In contrast, the continuous quality improvement (CQI) model is a proactive approach designed to dynamically evaluate processes, procedural performance, and outcomes, and, most importantly, to implement programmatic changes to improve them. The nascent concepts of the CQI model can be traced largely to techniques and ideas developed by pioneers within industry.\textsuperscript{7,8} Concepts central to these fields focused on using data and statistics to reduce variation and focus, not merely on individuals, but also on processes.

In 1989, Dr Donald Berwick encouraged the transition to the CQI model, likening previous quality assessment models to a Theory of Bad Apples, wherein physician outliers were identified and penalized, which he contrasted with CQI concepts focused on improvement of quality within the entire organizational structure.\textsuperscript{8}

At the heart of the CQI model, as applied to cardiac catheterization laboratories, are several basic principles. First, a multidisciplinary healthcare team identifies a problem and a valid quality indicator of this problem that can be tracked, as well. Second, quality indicators are tracked systematically within the institution such that they can be evaluated within the institution over time and compared with regional and national benchmarks. Third, interventions are made within the complex process of delivery of

<table>
<thead>
<tr>
<th>Data Element Group</th>
<th>Data Requirement Examples</th>
<th>Organization Reporting\textsuperscript{*}</th>
<th>Definition</th>
<th>Challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Process</td>
<td>Door-to-balloon time</td>
<td>DPH, CMS, JC, NCDR</td>
<td>ST-segment elevation or new LBBB hospital arrival to primary PCI &lt; 90 min</td>
<td>Accurate recording of hospital arrival time</td>
</tr>
<tr>
<td>AMI, aspirin at arrival</td>
<td>DPH, CMS, JC, NCDR</td>
<td>Patients with AMI without aspirin contraindications receive aspirin within 24 h before or after hospital arrival; for NCDR, aspirin within 24 h before or during PCI</td>
<td>Variation may occur in the assignment of ICD-9 codes; accurate medical documentation of aspirin administration or contraindication</td>
<td></td>
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<tr>
<td>Length of stay post-PCI</td>
<td>NCDR, Leapfrog</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outcomes</td>
<td>Inpatient mortality</td>
<td>DPH, NCDR, Leapfrog</td>
<td>30-day all-cause risk-standardized mortality rates after AMI admission</td>
<td>Accuracy and adequacy of risk adjustment methods used</td>
</tr>
<tr>
<td>30-day mortality</td>
<td></td>
<td>CMS, JC</td>
<td>30-day all-cause risk-standardized mortality rates after AMI admission</td>
<td></td>
</tr>
<tr>
<td>Vascular complications</td>
<td>DPH, NCDR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Appropriateness</td>
<td>Indication</td>
<td>DPH, NCDR</td>
<td></td>
<td>Given complexity of patient care, no one metric defines “appropriateness”—thus, multiple data elements are required to be entered correctly before determination of appropriateness</td>
</tr>
<tr>
<td>Angina class</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Risk assessment on noninvasive testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary findings</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of “normal” angiograms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Volume</td>
<td>No. of diagnostic cases</td>
<td>DPH, NCDR, Leapfrog</td>
<td>For DPH and NCDR operator-specific volume reports, by type of procedure available</td>
<td></td>
</tr>
<tr>
<td>No. of PCI cases</td>
<td></td>
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</tbody>
</table>

\textsuperscript{*}In addition to internal organizational review.

DPH indicates Department of Public Health; CMS, Centers for Medicaid & Medicaid Services; JC, The Joint Commission; NCDR, National Cardiovascular Data Registry; LBBB, left bundle-branch block; AMI, acute myocardial infarction; PCI, percutaneous coronary intervention; and ICD-9, International Classification of Diseases, Ninth Revision.
care to address this problem. Last, follow-up data are collected to understand the impact of an intervention, and the process begins anew.\textsuperscript{4,9,10}

Since the Institute of Medicine’s landmark publication “Crossing the Quality Chasm: A New Health System for the 21st Century,”\textsuperscript{11} there has been increasing awareness that quality in health care in the United States could be significantly improved through structured processes and initiatives.\textsuperscript{9,12} Data suggest, though largely observational, that adherence to many of the core principles of the CQI model can lead to improvements at the community-based hospital, tertiary referral center, and health systems levels.\textsuperscript{13–15}

**Core Elements and Categorized Recommendations for a Cardiac Catheterization CQI Model**

Because individual practitioners and institutions vary, no one model is appropriate for all. However, beyond the acquisition of minimal standards required by regulatory agencies, each institution should use CQI models in an effort to continually improve the quality and process of care delivered. The CQI effort is most effective when the team includes individuals offering differing perspectives on the delivery of care, such as cardiologists, nursing leadership, and technical staff. Although fitting together the numerous complex pieces that might fall under the umbrella of quality may seem like a puzzle, 4 core elements deserve particular attention: (1) clinical outcomes, (2) process measurement, (3) clinician privileges, and (4) appropriateness (Figure 1).

**Clinical Outcomes**

Examples of clinical outcomes to be tracked include postprocedural mortality, stroke, and vascular complications.\textsuperscript{4} Participation with regional or national registries such as the ACC-NCDR CathPCI Registry helps ensure standardized data definitions.\textsuperscript{7} Risk adjustment models that incorporate complexity of case mix are essential for comparison to account for the significant differences in expected event rates between relatively healthy individuals and those who are profoundly ill. Advancing efforts to track clinical outcomes beyond discharge to 30 days postprocedure should remain a top priority, because it can provide significant insights into the effectiveness of current treatments, and important issues regarding follow-up care and patient satisfaction with the care provided, as well.

**Process Measurement**

Examples of elements collected to track processes include door-to-balloon time, use of renal protective measures for chronic kidney disease, tobacco cessation counseling, and adherence to appropriate pharmacotherapy for patients with acute coronary syndrome. The development of critical care pathways, collaborative efforts among emergency medical services, emergency department, and cardiology personnel, and safety checklists and utilization of electronic patient records, as well, are examples of interventions that can be customized locally to profoundly impact patient care and process.\textsuperscript{16,17}

**Clinician Privileges**

A fundamental role of the CQI process is to provide peer review of practitioners and to inform the clinician-privileging process. Beyond certification examinations,\textsuperscript{18} impartial assessment and review of cases are important to ensure that clinicians are prepared to be privileged to perform procedures. The quickly expanding role of percutaneous approaches to address vascular disorders outside the coronary bed, and novel approaches to treat structural abnormalities, as well, require strategies to ensure a meaningful clinician-privileging process. It is clear that training for coronary intervention does not qualify a clinician to perform all catheter-based treatments. Minimum annual case volume requirement standards (by type of procedure) and assessment of individual risk-adjusted adverse outcomes are important components of the privileging and recredentialing process. Further work is needed to ensure that clinicians performing complex procedures are adequately trained to do so.\textsuperscript{19}

**Appropriateness**

Complex clinical case presentations and unique patient characteristics make the assessment of appropriateness of invasive catheterization techniques challenging. Regional variations in practice patterns also exist.\textsuperscript{20} Despite this, appropriate use criteria for coronary revascularization have been developed by professional organizations,\textsuperscript{21} and adherence to these criteria should remain a focus area for the demonstration of quality in the catheterization laboratory. Transparent, collaborative, and standardized review of case examples helps ensure that procedures are performed in patients most likely to derive benefit. Data elements reflecting
appropriate use criteria are included in the most recent NCDR CathPCI Registry collection forms, and findings from this dataset suggest that there is room for improvement, because there is substantial variation across hospitals and a significant number of procedures classified as inappropriate.\textsuperscript{22}

**Brigham and Women's Hospital CQI Process and Case Presentation**

At our institution, comprehensive data are prospectively collected for each patient, including information regarding medical history and clinical presentation, procedural details, and clinical follow-up in accordance with standardized data elements and definitions used by the NCDR CathPCI Registry. Monthly morbidity and mortality conferences are held to review all PCI-related mortalities, bleeding, strokes, and additional events of interest, and these conferences often serve as the inspiration for quarterly quality improvement initiatives. Federal legislation, such as the Health Care Quality Improvement Act of 1986, and individual state legislation serve, in part, to provide physicians with legal protection while they are participating in the peer review process.\textsuperscript{21,24}

**Review of the Presented Case**

This case led to a quality improvement project to identify patients at particularly high risk for adverse vascular outcomes, such as the fatal post-PCI retroperitoneal bleed experienced by this patient. Although several patient characteristics increase the risk of vascular complication, extreme obesity places patients at additional risk.\textsuperscript{25} More frequent and routine use of radial access is important to maintain both provider and staff comfort and expertise in this technique. Recognizing this presented an opportunity to implement a protocol emphasizing a “radial first” preference for at-risk patients, in particular, those with body mass indexes $>35$. Each member of the healthcare team, from nursing staff to physicians, is charged to help identify the patients who are most vulnerable. This initiative has resulted in a significant increase in radial access for those most at risk of complication (Figure 2).

**Disclosures**

None.

**References**


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