Public reporting of mortality following percutaneous coronary intervention is now mandated in 3 US states (New York, Massachusetts, and Washington) and has been associated with improvement in outcomes. However, there is evidence of growing risk aversion among percutaneous coronary intervention operators in public reporting states, manifest as avoidance of treating those critically ill patients who might benefit the most from appropriate percutaneous coronary intervention. We propose 4 incremental changes to the reporting process that will preserve the benefits of public Reporting while mitigating the likelihood of high-risk case aversion, which may threaten access to life-saving care.

Public reporting of risk-adjusted in-hospital mortality rates after percutaneous coronary intervention (PCI) is intended to encourage adoption of best practices and to provide transparency for patients, payers, and public health officials. However, there is controversy regarding the ability of public reporting to improve patient outcomes while preserving access to care.

Though public reporting was originally expected to encourage educated consumerism, it has proven to have a more demonstrable effect on US physician behavior. Progressive risk aversion or “case selection creep”, the withholding of appropriate PCI from the highest risk patients who stand the most to gain from such treatment but have a poor overall prognosis, has become a potential public health concern.

Public reporting following PCI has been variously implemented on a state-by-state basis. Assessing the impact of such programs can be difficult, in part because public reporting in PCI is itself not a standardized concept. For example, the New Jersey Department of Public Health’s current public reporting process outlines institutional PCI case volumes and performance on door-to-balloon time in primary PCI, but does not currently report mortality outcomes. Alternatively, an independent state agency in Pennsylvania previously reported mortality outcomes following PCI but has suspended doing so since 2009. In 2012, Washington State began reporting on process measures and mortality outcomes following PCI through an independent state agency after many years of central adjudication without public reporting. However, our understanding of the impact of publicly reporting in PCI is largely driven by 2 states with arguably the most mature public reporting programs, New York and Massachusetts, both of whom report risk-adjusted mortality rates through their respective departments of public health. It is in these states that evidence of risk aversion has been most manifest.

In New York State, retrospective reports have demonstrated that the proportion of patients treated with PCI who were in cardiogenic shock was one eighth that of PCI-treated patients in Michigan. Separately, a prospective registry of patients presenting in cardiogenic shock demonstrated that the rate of treatment with PCI was less than half in New York as compared with the rest of the country and, importantly, that the overall mortality of patients presenting in cardiogenic shock in New York was significantly higher. Furthermore, in both studies, the decline in PCI frequency was not replaced by a compensatory increase in revascularization with coronary artery bypass grafting. In addition, an analysis of surgical revascularization in New York demonstrated significantly worsened racial disparity in the years immediately after the implementation of public reporting.

Similarly, data from Massachusetts suggest that the proportion of patients treated with PCI who presented in cardiogenic shock declined significantly during the first 5 years of PCI public reporting. Of course, secular trends, including process improvement efforts and patient education, may have affected the number of patients in cardiogenic shock who received PCI, perhaps by influencing earlier symptom recognition. However, national claims data has demonstrated that the states with public reporting of PCI outcomes in 2011 had significantly lower rates of treatment for patients with acute myocardial infarction than in surrounding states without public reporting. This analysis also showed that the rates of treatment for acute myocardial infarction in Massachusetts, while comparable with nonreporting states before the initiation of public reporting in 2003, fell to rates significantly below that of nonreporting states in the years since the implementation of public reporting. Finally, we have observed that centers identified as negative outliers through the PCI public reporting process demonstrate even greater declines in the predicted mortality of their patients in the years following the report, as compared with other institutions, indicating growing hospital level risk aversion following public identification as a statistical outlier.

Interestingly, among the 4 Massachusetts’ institutions identified as negative outliers since the inception of public...
reporting there in 2003, all have been tertiary care referral centers. It is important to consider that tertiary care centers may be fundamentally different than community PCI programs in that tertiary programs tend to have higher case volume (which is particularly important to reach statistical significance using hierarchical methods, as used in Massachusetts), have associated cardiothoracic surgery programs, which provide surgical backup and may also shunt uniquely high-risk referrals toward PCI, and typically do not transfer acutely ill patients to other centers after the initial PCI (thereby not benefitting from the censoring of patients who die following transfer to another institution).

Public reporting advocates have explained evidence of potential risk aversion as a possible reduction in performance of futile PCI procedures (ie, those patients no longer treated were judged unlikely to survive, even had they received successful PCI). Reducing PCI utilization rates where such technology has no clinical benefit, because the patient is either too sick or too well is clearly a beneficial outcome of public reporting. However, assessing PCI futility for critically ill patients is an extremely difficult task, frequently compounded by incomplete data, and often performed in emergent situations where time to treatment profoundly influences outcomes. In fact, the most critically ill patients are those who seem to derive the greatest benefit from PCI despite their overall poor prognosis. Yet, perversely, in the current public reporting system, PCI operators are incentivized to avoid exactly such critically ill patients so as to avoid identification of themselves or their programs as negative outliers; and they seem to have done so in New York and Massachusetts. Meanwhile, our healthiest, elective patients are both most likely to survive the PCI process and least likely to derive incremental mortality benefit. Although mortality benefit is not the sole rationale for PCI therapy, a fundamental disconnect exists between the potential clinical value of PCI and the overall mortality of those patients undergoing this procedure. Addressing this risk-treatment paradox is critically important to the iterative improvement of the public reporting process.

Although risk aversion seems to be growing, public reporting seems to have also had a positive impact on many aspects of the PCI care process, including a cultural shift toward complete and thorough data collection and process transparency—a principal recommendation of the recently released American College of Cardiology/American Heart Association joint report on performance measures for PCI—and greater institutional and leadership investment in performance improvement. However, to mitigate the potential of reduced access to care for high-risk patients while continuing to endorse quality improvement efforts, process improvements in public reporting are required to increase trust with all stakeholders, including the interventional cardiology providers themselves. Massachusetts has begun such a process through the implementation of compassionate use and exceptional risk designations, which allow for improved risk classification for certain PCI cases that meet specific criteria following adjudication by an independent review board. New York state now excludes (ie, censors) any patients with procedural shock or who ultimately succumb from hypoxic brain death from their analyses altogether. Adding such exclusion criteria has helped to address issues of incomplete risk adjustment among unusual cases with risk profiles that are both significantly elevated and difficult to fully capture using currently available data elements.

Nevertheless, we think the current strategies for reducing risk aversion are not uniform across public reporting states and may well be insufficient in scope. Given the need to balance the significant benefits of public reporting of PCI outcomes with the impact of risk aversion, we endorse the following 4 changes to the PCI quality reporting process for all public reporting states:

1. States should continue to collect, adjudicate, and interpret PCI clinical outcomes data for all PCI cases. However, the public PCI quality report should censor those patients at uniquely high risk and report the risk-adjusted outcomes of the remaining representative patients. This recommendation is based on the insufficient granularity of the existing data available, the consequent inability to accurately predict the expected mortality of certain patients, the potential for markedly uneven distribution of such cases across hospitals, and the disproportionate influence even a small number of such cases can have on a center’s aggregate data. Specifically, patients who satisfy any of the following conditions should be adjudicated, and if verified, excluded from the analysis for the purposes of the public report:
   a. All patients with out of hospital cardiac arrest with impaired neurological status on presentation, consistent with the 2013 American Heart Association scientific statement which recommended that “out of hospital cardiac arrest (OHCA) cases should be tracked but not publicly reported.”
   b. All patients presenting to the emergency department in cardiogenic shock with ongoing hemodynamic instability. This measure is not meant to include fluid-responsive hypotension or other readily reversible scenarios but rather patients with verifiable hemodynamic collapse preprocedure. This was one of the changes in the New York state, which began excluding such patients as of 2006. Furthermore, the establishment of a uniform, rigorous definition of cardiogenic shock that can be readily substantiated within the medical record on adjudication is essential to the success of such a criteria and to diminish the risk of gaming the reporting process. The criteria currently accepted in New York include acute hypotension with a systolic blood pressure <80 mm Hg or a cardiac index <2.0 L·min⁻¹·m⁻² despite pharmacological or mechanical support.
   c. Patients in whom the alternative of cardiac surgery was deemed prohibitively high risk after review and documentation by qualified cardiac surgeons or Heart Team. This group is meant to capture those very high-risk PCI cases for whom cardiac surgery could not be offered because of extremely high surgical risk or urgency of treatment (but not because of patient preference). Such a designation has been associated with significantly increased mortality rates following elective PCI despite comprehensive risk adjustment using existing data elements. Furthermore, such an exclusion is an established indication for high-risk transcatheter valve treatment for aortic stenosis.

2. Any publicly released report regarding PCI clinical quality should provide an interpretation of the results from an overall quality review perspective and not be restricted to a statistical comparison of risk-adjusted outcomes. Before the release of a PCI public report, and after the exclusion of the cases noted above, any negative outlier should be thoroughly reviewed by independent quality reviewers (eg, the American Medical Foundation, the Society for Cardiovascular Angiography and Intervention; SCAI Accreditation for Cardiovascular Excellence program [http://www.cvexcellence.org], or others), with the context of their findings regarding the presence or
absence of an underlying clinical quality issue included in the public report. It is important to contextualize the statistical findings of the public report to mitigate the risk of changes in physician behavior regarding case selection and the deleterious impact on access to care for very high-risk patients. Such a strategy would also strengthen the value of the report to the public and offer evidence that statistically poorly performing hospitals were further reviewed and provided actionable plans for improvement or absolved of systematic performance-related issues.

3. Departments of public health and public reporting agencies should prospectively monitor the rates of treatment for patients presenting with cardiac arrest and cardiogenic shock by treating center and within geographic regions over time as an additional quality indicator of access to care. Although an incomplete measure of access to care, this particular metric allows for ongoing evaluation of the public reporting process itself.

4. Reporting agencies should strive to form a consortium across states to encourage the exchange of ideas and insights and the rapid dissemination of best practices in process and procedures related to public reporting of PCI outcomes. Although states may differ on how they wish to enact public reporting of PCI, such a consortium may help limit initiation of suboptimal public reporting practices, particularly as the study of public reporting processes grow. We think such a consortium would be particularly important to states newly initiating reporting programs and may help states wishing to initiate public reporting programs do so effectively.

Adoption of the policies suggested above will require both human and resource capital, particularly for public reporting states that have not otherwise routinely adjudicated submitted cases. However, we think that these policies can strengthen the perceived integrity of the public reporting process while addressing concerns regarding access to care. We also think that such policy changes would lead to the exclusion of only a small fraction of patients from the public reporting process. Using Massachusetts’ data from 2011, we estimate the number of patients excluded from the public report would be $\approx 3\%$ of the total cases performed (Table in the Data Supplement), thus leaving 97% of all cases available for compilation of the public report.

The goals of public reporting, including fostering quality improvement among all participating centers while building transparency for consumers, payers, and public health officials, are broadly supported by the cardiology community. However, there is increasing evidence to suggest that public reporting of PCI risk-adjusted outcomes continue to limit access to care for the highest risk patients and may not be able to accurately identify evidence of fundamentally poor performance (if such exists). In fact, after 20 years of working under the auspices of public reporting of PCI and cardiothoracic surgery outcomes, $>50\%$ of surveyed New York state cardiologists still perceive “risk-adjustment methods [as] inadequate to compare surgeons”. Although the veracity of this opinion is certainly debatable, building trust with the cardiovascular community is paramount to furthering the community’s investment in quality improvement programs.

Public reporting of PCI quality will continue to play an important role in ensuring adherence to practices best suited to the public health; however, the current risk-treatment paradox and its manifestation as risk aversion threaten to undermine the value of these efforts. Eventually, we hope that overall PCI quality will come to be defined in a more comprehensive framework, which would include other important risk-adjusted clinical outcomes (not just mortality), access to care (such as minimization of risk avoidance), appropriateness of clinical decision making, and process measures (door-to-balloon time, adherence to guidelines for medications before and after procedures, etc), while also incorporating patient-centered decision making (Figure). A more ambitious program would even include a protocolled peer-to-peer review process in an effort to move beyond purely abstracted data and engage regional stakeholders. In the interim, however, we think that states and other regulators have a responsibility to preserve access to appropriate care for all patients and in particular those patients with the most to gain from emergent coronary revascularization.

We would encourage the American Heart Association, American College of Cardiology, and Society for Coronary Angiography and Intervention to consider and endorse these strategic recommendations in the next iteration of their PCI reporting and quality guidelines.

Disclosures
Dr Resnic has been a long-time advisor to the Massachusetts’ Department of Public Health and their public reporting agency (MassDAC). Dr James McCabe is on the management committee of the Washington State public reporting committee (COAP) and chair of the COAP PCI Reporting and Analytics Subcommittee. There are no financial conflicts to disclose.

References
6. Resnic FS, Normand SL, Piemonte TC, Shubrooks SJ, Zelevinsky K, Lovett A, Ho KK. Improvement in mortality risk prediction after percutaneous coronary intervention through the addition of a “compassionate use” variable to the National Cardiovascular Data Registry CathPCI.


Key Words: health care quality, access and evaluation ▪ percutaneous coronary intervention ▪ quality indicators, health care
Strengthening Public Reporting and Maintaining Access to Care
James M. McCabe and Frederic S. Resnic

Circ Cardiovasc Qual Outcomes. published online September 2, 2014;
Circulation: Cardiovascular Quality and Outcomes is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2014 American Heart Association, Inc. All rights reserved.
Print ISSN: 1941-7705. Online ISSN: 1941-7713

The online version of this article, along with updated information and services, is located on the World Wide Web at:
http://circoutcomes.ahajournals.org/content/early/2014/09/02/CIRCOUTCOMES.114.001211.citation

Permissions: Requests for permissions to reproduce figures, tables, or portions of articles originally published in Circulation: Cardiovascular Quality and Outcomes can be obtained via RightsLink, a service of the Copyright Clearance Center, not the Editorial Office. Once the online version of the published article for which permission is being requested is located, click Request Permissions in the middle column of the Web page under Services. Further information about this process is available in the Permissions and Rights Question and Answer document.

Reprints: Information about reprints can be found online at:
http://www.lww.com/reprints

Subscriptions: Information about subscribing to Circulation: Cardiovascular Quality and Outcomes is online at:
http://circoutcomes.ahajournals.org//subscriptions/