

EDITORIAL COMMENT

Strengths and Limitations of Using Cost Evaluations to Inform Cardiovascular Care*



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Consideration of the cost of medical care in the context of health policy or insurance coverage has been a decidedly unpopular exercise in the United States. Rather than addressing the \$3.2 trillion elephant in the room, U.S. political leaders prefer to focus on access to benefits and choice of physicians when discussing health reform. They ignore the threats of high and rising health care costs to our ability as a nation to continue providing health care services at their current levels, or the fact that we make tradeoffs—both implicitly and explicitly—between the health care services we receive and other goods that we value. The U.S. is exceptionally unique in its health technological capacity but these attitudes toward costs are in stark contrast with the approach that other developed countries have taken to explicitly incorporate cost and value assessments into their health policy decision making, including Britain (National Institute for Health and Clinical Excellence), Germany (Institute for Quality and Efficiency in Healthcare), Australia (Pharmaceutical Benefits Advisory Committee), and Canada (Canadian Agency for Drugs and Technologies in Health) (1). Peter Neumann, director of the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center, has written a book about misadventures in efforts to explicitly incorporate cost considerations in U.S. health policy, and the drivers of this tension (2). Recent examples of this problem's persistence include the Patient-Centered Outcomes

Research Institute, which is forbidden by law from using cost-effectiveness thresholds, and the U.S. Preventive Services Task Force, which explicitly refrains from considering cost or cost effectiveness in developing its recommendations.

The Affordable Care Act—whose future is highly uncertain given the election of Donald Trump as president with a Republican-controlled Congress—includes provisions for Accountable Care Organizations and bundled payment reforms that are some of the most aggressive attempts to restrain U.S. health care costs in recent history. These payment-targeted reforms force physicians, hospitals, and other health care providers to incorporate cost and value considerations in their decision making. Some believe that, if successful, these programs could prompt private insurers to adopt similar care design and payment models, potentially ushering in system-wide transformation toward more efficient care delivery in the United States. Their promotion of greater integration and coordination among health care stakeholders working under the constraint of a bundled payment for an episode of care immediately aligns financial incentives. For example, although continuity between inpatient and outpatient providers has been historically poor in the United States, bundled payments for surgeries should increase both outpatient and inpatient interest in promoting smoking cessation before and after the perioperative period, because smokers face substantially greater risks for wound infections, respiratory failure, and admission to an intensive care unit compared with nonsmokers (3). They are much more costly. Financial incentives from bundled payments should also increase hospitals' interest in providing intensive therapies in the most efficient way possible while maintaining quality. Percutaneous coronary intervention (PCI) is a prime example of the type of procedure that should be

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sensitive to policy changes that affect costs. It is performed an estimated 954,000 times in the United States annually and leads national expenditures for cardiovascular procedures, with several billion dollars in direct expenditures (4). Hence, the publication by Amin et al. (5) in this issue of *JACC: Cardiovascular Interventions* is of particularly high relevance.

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In this study, the authors compare the hospital costs for PCI of transradial versus transfemoral arterial access and same-day discharge versus discharge on a subsequent day. Using data from 279,987 patients in the National Cardiovascular Data Registry CathPCI Registry and their associated Medicare claims, the authors use propensity score and inverse probability weighting methods to compare hospital costs. They report low rates of transradial interventions (9.0%) and same-day discharge (5.3%). In their cost comparisons that were adjusted with propensity scores, they find that transradial interventions (vs. transfemoral interventions) were associated with less bleeding, fewer complications, a shorter duration of stay, and lower costs (\$916). Similarly, same-day discharge was also associated with cost savings (\$3,502) compared with non-same-day discharge. In addition, patients who received both transradial interventions and same-day discharge were \$3,689 less costly than patients receiving transfemoral interventions and non-same-day discharge. A budget impact analysis found that cost savings of \$332 million annually could be achieved in the United States through modest shifts toward transradial interventions and same-day discharge as the standard of care. If valid, these findings clearly have important implications for care practices among the hundreds of thousands of patients in the United States undergoing PCI. To judge validity, we must closely examine the study's methods.

The primary objective of propensity score methods is to balance groups using observed characteristics, but the method cannot ensure balance across unobserved characteristics that could confound results. The magnitude of this problem can hardly be understated. In one of the earliest demonstrations of the risk of bias with observational data analyses in cardiovascular disease, McClellan et al. (6) examined the effect of invasive cardiac catheterization and revascularization on mortality in elderly patients with acute myocardial infarction (MI) from 1987 through 1991. Using standard statistical methods for adjusting for observable

differences (the multivariate regression model), the estimated absolute effect of invasive catheterization on mortality among these patients at 4 years post-MI was 28 percentage points. However, noting that selection bias in observational data could lead patients with a higher likelihood of survival a priori to be selectively admitted to hospitals with catheterization capabilities compared with patients with a lower likelihood of survival, they used patients' differential distances to hospitals with catheterization to construct an instrumental variable—an independent predictor of how intensively a patient with acute MI would be treated. This analysis demonstrated that the impact on mortality at 4 years after acute MI of the incremental use of invasive procedures in Medicare patients was at most 5 percentage points, which is more in line with randomized trial findings.

Is there reason to be concerned about selection bias in the analysis by Amin et al. (5)? Yes. Patients most likely to undergo a transradial procedure and same-day discharge are the least complicated, lowest risk patients. Indeed, some patients in the non-same-day discharge group would almost certainly have been discharged on the same day if they had not experienced a complication that prolonged their hospital stay. The authors' propensity score methods attempt to account for these differences, but it is virtually impossible to attenuate fully the risk of bias without randomization. Indeed, the group with the most favorable outcomes—transradial and same-day discharge—represented only 1.2% of the population, further underscoring the risks of selection and bias.

What are the implications of these potential issues with selection for how we interpret their findings? To answer this, we must apply our understanding and judgment of the clinical context and the strengths and limitations of propensity score methods (7). On the basis of the information provided by the authors, there seems to be good balance in the observed characteristics after the propensity score method is applied. This is encouraging, but even balance across observable characteristics does not guarantee an unbiased result. Although the true (unbiased) cost differences in this National Cardiovascular Data Registry cohort are unknowable, this author's opinion is that the cost differences estimated by the authors experience only a moderate amount of bias and that the findings are significant, although perhaps smaller in magnitude than those estimated by the authors. Others may reach different conclusions. To the extent that accountable care organizations and bundled payment reforms increase cost awareness among

physicians and hospitals, studies like Amin et al.'s (5) are critical to informing professional society guidelines and helping physicians, hospitals, and health systems provide high-quality care while constraining growth in health care costs (8). And if the results from Amin et al. (5) bear out, studies like this will even help us to reduce health care costs.

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