Setting the Stage for Evidence-Based Medicine

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In 2015, the federal government allocated $30 billion toward groundbreaking new health research through the National Institutes of Health, with the biomedical industry, foundations, and others contributing substantially as well. Although these investments in biomedical innovation hold tremendous promise to improve the health, quality of life, and survival of Americans, we often fail to make best use of the therapies that we already have within our grasp. Optimal use of cardiovascular medications is critical to improving outcomes for the 15.5 million Americans with coronary artery disease. Nearly, half of the reduction in coronary heart disease mortality in the United States between 1980 and 2000 has been attributed to well-established evidence-based medications. Extensive evidence suggests that patients with chronic conditions adhere to only 50% to 60% of prescribed medications, even where these drugs have been shown to improve survival and quality of life. Poor medication adherence also leads to increased healthcare costs, with estimates ranging from $100 to 300 billion annually.

The Post-Myocardial Infarction Free Rx Event and Economic Evaluation (MI FREEE) trial was a cluster-randomized controlled policy study, which examined the effect of eliminating copayments for guideline concordant medications after myocardial infarction (MI) on adherence and outcomes of care. All patients in the trial (n=5855) were enrolled in Aetna medical and prescription drug benefits and were randomized at the level of the plan sponsor. Participating plans were randomly assigned to full coverage or usual pharmacy benefits. Covered medications included any brand name or generic statin, β-blocker, angiotensin-converting enzyme inhibitor, or angiotensin-receptor blocker for every prescription after randomization. The elimination of copayments for drugs prescribed after MI did not significantly reduce rates of the primary composite clinical outcome (first readmission for a major vascular event or coronary revascularization). However, elimination of copayments did improve medication adherence and rates of first major vascular events. Moreover, patient spending was decreased without increasing overall health costs.

In the current issue of the journal, Ito et al extended the MI-FREEE study over a longer time-horizon using a Markov model of hypothetical commercially insured patients. The authors drew model inputs from numerous sources, including MI FREEE, pooled data from the Framingham Heart Study, Atherosclerosis Risk in the Community Study, Cardiovascular Heart Study of the National Heart, Lung, and Blood Institute, and the Arterial Revascularization Therapies Study. They found that, compared with usual coverage, elimination of copays would increase survival by 0.14 quality-adjusted life-years and decrease overall per-patient costs by $4011. If applied nationally, they estimated that free provision of these medications after MI would save society $2 billion each year. Their model predicted that full coverage would be cost-saving compared with usual coverage in 56% of simulations and would be cost-effective at a conventional willingness-to-pay threshold of $100,000 per quality-adjusted life-year gained in 86% of simulations.

By necessity, Ito et al constructed their hypothetical model by making assumptions that extrapolated from existing evidence. Most importantly, although the MI FREEE study had a median duration of follow-up of 394 days, they extended the full effects of the intervention for 5 years and then tapered the effect of the intervention in a linear fashion during the subsequent 5 years. Whether this critical assumption was realistic is unknown. Their model also allowed for branded medications and did not consider the effects of including clopidogrel, prasugrel, or ticagrelor. The authors performed an extensive sensitivity analysis, and their findings were robust across a wide range of input parameters for age of the cohort, rates, mortality, utilities, cost of post MI events, and the discount rate.

These findings add to a growing literature surrounding value-based insurance design (VBID), a health insurance approach wherein a patient’s copayment tracks with value of the clinical service. A simple VBID example is when patients pay a higher copayment for a brand name drug than for a clinically equivalent generic drug. More complex examples include reducing or eliminating copayments for recommended services, such as annual eye examinations for diabetic patients, or increasing copayments for services lacking evidence-based support, such as nuclear stress testing when an exercise treadmill test would suffice. As our healthcare system increasingly seeks to improve value, VBID uses evidence to better engage patients in their own decision making. Patients retain their decision-making autonomy, but their choice architecture is constructed to support high-value decisions. Well-designed VBID programs can guide patients toward more healthful decisions, as this study has shown with medications post MI, and away from costly and ineffective decisions.
The Affordable Care Act added substantial heft to this concept by requiring insurers to provide first dollar coverage for selected preventive services, yet challenges remain. Ito et al identify that the issue of churn, where individuals frequently change insurance providers, reduces the incentive for insurers to focus on prevention when the benefits may not be accrued until after an individual may have changed to a different insurer. As of 2015, the Affordable Care Act has extended insurance coverage to an estimated 16.4 million new patients. However, many of these patients are eligible for assistance based on income and eligibility may fluctuate over time, potentially increasing insurance churn. Although requirements for all insurers to provide similar coverage for evidence-based services would effectively minimize the churn problem, persistent opposition to the Affordable Care Act and uncertainty about its implementation remain impediments. Thus, the overall effect of insurance exchanges on insurance purchasing behavior remains unknown.

Moreover, recent years have seen a significant growth in high-deductible health plans where the individual bears the burden of most initial healthcare costs and may choose to forgo primary or secondary preventive measures, reserving insurance for more substantial healthcare needs. Almost a third of US employers say that a high-deductible plan will be their only insurance offering in 2015, and 85% of individuals obtaining insurance through the public health insurance exchanges have selected plans with ≤30% to 40% cost sharing. Such high-deductible plans represent a real threat to patients obtaining necessary preventive and chronic disease management services. Implementation of VBID for high-value services could ameliorate some of these negative consequences, and the MI FREEE follow-up data present an excellent place for insurers to start.

VBID is by no means a cure-all, and a broader approach is necessary to improve adherence with high-value medical services. Adherence with medications is a highly complex behavior and may be undermined by either unintentional or intentional factors. Unintentional factors include nonadherence without the patient making a conscious decision. Factors driving unintentional nonadherence include issues, such as forgetfulness, lack of understanding, and physical problems. Conversely, Løventhal’s Common-Sense Model of Self-Regulation emphasizes factors that contribute to intentional nonadherence, such as illness beliefs; the perceived risks, benefits, and necessity of potential treatments; the patient–practitioner relationship; intercurrent physical and mental illness; pharmaceutical/pharmacological issues; and financial constraints. Hence, with the multifactorial drivers of nonadherence, it is not surprising that the provision of free medications in the MI FREEE study only increased adherence by 4% to 6%. In fact, improving adherence is challenging as demonstrated by a Cochrane review that showed no simple interventions, and only some complex ones, effectively improved adherence and health outcomes.

Placing the findings from Ito et al into the current healthcare landscape, the timing could not be better. The rapid growth in high-deductible insurance plans creates an urgency to identify areas where low or no cost-sharing makes sense, even for high-deductible plans. If all insurers implement proven interventions like those provided in MI FREEE, then the potential VBID limitation of churn melts away, and payers and patients are the beneficiaries. Although challenges to VBID certainly exist, the MI FREEE and follow-up study show that providing free medications post MI is smart, plain, and simple. The medical community should continue to look for situations where removing financial barriers to evidence-based care is effective in improving healthcare value, and then work to remove those barriers.

**Disclosures**

None.

**References**


**Key Words:** Editorials ■ coronary artery disease ■ healthcare costs
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Circ Cardiovasc Qual Outcomes. 2015;8:223-225; originally published online May 5, 2015;
doi: 10.1161/CIRCOUTCOMES.115.001891
Circulation: Cardiovascular Quality and Outcomes is published by the American Heart Association, 7272
Greenville Avenue, Dallas, TX 75231
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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/8/3/223

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