

Eliminating Copayments for Patients After Myocardial Infarction Improves Adherence and Some Outcomes

Choudhry N, Avorn J, Glynn R, et al. Full coverage for preventive medicines after myocardial infarction. *N Engl J Med* 2011;365:2088–97.

Study Overview

Objective. To determine whether providing full coverage for statins, beta blockers, angiotensin-converting enzyme (ACE) inhibitors, or angiotensin receptor blockers (ARBs) post-myocardial infarction (MI) decreased recurrent cardiovascular events.

Design. Group randomized trial where patients were assigned to receive full prescription coverage (no copayment, coinsurance, no deductible applied) for the study medications or usual prescription coverage (copayment, coinsurance, deductible paid as already arranged at baseline). Randomization was at the level of the insurance sponsor (ie, employer, union, government). At the time of enrollment in the study post-MI, all subjects were contacted and reminded of the importance to take their prescribed medications. Those assigned to the full coverage arm were informed about the change in their benefits: they would receive the study medications without any costs to them.

Setting and participants. 1494 plan sponsors and 2845 patients in the full coverage arm and 1486 plan sponsors

and 2010 patients in the usual coverage arm. Patients were eligible if they received medical and prescription drug coverage through Aetna insurance company, were hospitalized with a diagnosis code consistent with an MI, and had a length of stay of 3 to 180 days. Exclusions were for patients who had a health savings account (already had full coverage for the study medications) and those who were over 65 years of age because they had primary coverage through Medicare. Subjects were tracked post-MI for at least 3 months (median of 394 days with interquartile range of 201 to 663).

Main outcome measures. Primary—first readmission for a major vascular event (fatal or nonfatal acute MI, unstable angina, stroke, or congestive heart failure) or revascularization (coronary bypass, stenting, or angioplasty). Secondary—rates of medication adherence, total major vascular events or revascularization, first major vascular event, and health expenditures.

Main results. Of all eligible individuals, 13.5% (913) did not enroll because their plan sponsors declined to

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participate in the study. Among participants, mean age was 53.6 and 53.7 years in the full prescription and usual coverage arms, respectively. Most of the subjects were male (75.6% and 74.7%). More than half of participants were on ACE inhibitors/ARBs, beta blockers, statins, and clopidogrel prior to their index hospitalization for MI. Almost all participants had a procedure during their index hospitalization with two-thirds having percutaneous coronary interventions and 17.9% and 18.1% having coronary artery bypass grafting. Because assignments to a study arm were made based on insurance claims, for which there is a lag in processing post-hospitalization, the median duration post-hospitalization discharge until randomization was 49 days. Subjects on all 3 study medications who filled prescriptions pre-randomization (but post-hospital discharge) paid approximately \$50 per month in copayments. There was no difference between arms for the primary outcome of first major vascular event or revascularization (17.6 events per 100 person-years in full coverage arm vs. 18.8 in the usual coverage arm; hazard ratio, 0.93; 95% confidence interval [CI], 0.82–1.04; $P = 0.21$). Subjects in the full coverage arm did have a lower rate of total major vascular events or revascularization (21.5 vs. 23.3; hazard ratio, 0.89; 95% CI, 0.90–0.99; $P = 0.03$) as well as a lower rate of first major vascular event (11.0 vs. 12.8; hazard ratio, 0.86; 95% CI, 0.74–0.99; $P = 0.03$). Medication adherence was improved in the full coverage arm as well. Adherence ranged from 35.9% to 49.0% of days for the 3 study medications in the usual care arm and was 4.4% to 6.2% higher in the full coverage arm ($P < 0.001$); full adherence (defined as possession of medication for at least 80% of days) was 25.2% to 31.6% in the usual coverage arm and was 4.8% to 7% higher in the full coverage arm ($P < 0.001$). Adherence to medications that were not subject to payment alterations was not different between the 2 arms. Overall spending was not significantly different between groups though patient costs for drugs and other services were lower in the full coverage arm (relative spending, 0.74, 95% CI, 0.68–0.80; $P < 0.001$).

Conclusion. Eliminating copayments for ACE inhibitors/ARBs, beta blockers, and statins post-MI improved adherence and improved some outcomes (though not the primary outcome).

Commentary

Medication adherence for prescription drugs is poor, even for critical medications such as those used after MIs to reduce the risk of future events. In one study of low-income Medicare beneficiaries in 2003, 46.4% were fully adherent to their prescribed statin, beta blocker, and ACE inhibitor/ARB in the year post-hospitalization after an MI [1]. Out-of-pocket costs for medications, even for those patients who are insured, are commonly cited as a reason for nonadherence. One study of Medicare beneficiaries found that nearly one-third did not fill a prescription or reduced the dose of their medication because of costs [2].

Several studies have previously documented a modest increase in medication adherence with lowering or eliminating copayments [3,4]. This study by Choudhry and colleagues carries this evaluation a step further by not only examining the effects of the elimination of copayments on adherence but also examining the impact on clinical outcomes. With the elimination of copayments (full coverage) on ACE inhibitors/ARBs, beta blockers, and statins for post-MI patients, they found an increase in adherence, a reduction in total major vascular events or revascularization, and a lower rate of a first major vascular event. The primary outcome, first major vascular event or revascularization, was lower in the full coverage arm than in the usual coverage arm, but this difference was not significant.

The study was well-conducted with a large sample size and a large number of events, allowing for the detection of a difference between arms. Most of the plan sponsors (employers, unions, etc) permitted their beneficiaries to enroll in the study, with only 13.5% of eligible patients not included in the study because their plan sponsors declined to participate. Conducting this study within a large national insurance company also gave credibility to the intervention, improving the likelihood that a similar benefit change could be implemented widely across insurance companies and large employers. The study had a few limitations however. Because the study was conducted entirely within an insurance company, subject eligibility depended solely on insurance claims, as did the determination of outcomes. Insurance claims are often quite accurate, and they provide easier access to summary information about a large number of patients, connected to costs, than medical records. However, claims data lack the precision of medical records, espe-

cially for the establishment of diagnoses, such as whether someone had a documented vascular event. The study authors did not review medical records as part of this study, and thus the identification of outcomes was not verified. Yet there is no reason to believe that errors of ascertainment of outcomes would have been different between the intervention and control arms. The use of insurance claims to identify subjects also created a long lag—more than 1 month—between hospital discharge and study assignment. Patients already would have filled their first prescriptions post-hospitalization prior to study enrollment, and this could have changed the impact of the intervention.

This is the first study to find health outcome differences from altered insurance coverage for medications. Even without showing a difference in the primary outcome, the improvement in adherence from full coverage along with some improvements in outcomes, is suggestive that full coverage could provide an improvement in care. The lack of evidence for additional cost to the insurance company could convince other companies to incorporate this innovation. Of course, full adherence was still quite low in the full coverage group, 27.7% to 38.6% for the 3 study medications, an absolute improvement of 4.8% to 7% over usual coverage. We still have a long way to go to ensure that post-MI patients receive the medications they need to

prevent recurrent events. Full coverage could be an important step in the process.

Applications for Clinical Practice

Eliminating medication co-payments for post-MI patients improves adherence and some health outcomes. Physicians should advocate for improved coverage for medications to compel more patients to adhere. However, physicians also should be aware of how few of their patients actually comply with prescribed regimens, even after the elimination of copayments, and work closely with their patients to encourage adherence.

—Review by Jason P. Block, MD, MPH

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