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Caution is Needed in Designing Pharmacy Coverage

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Pharmaceuticals are a critical component of modern medical care and have contributed substantially to health and quality of life. They are also expensive, accounting for ≈10% of US health care costs.[1] By the end of this year, Medicare beneficiaries are expected to spend $343 billion on medications, and drug spending is projected to grow faster than both the inpatient and outpatient care categories.[2] Commercial and public payers use a range of mechanisms to constrain these costs, including formularies, tiered copayments, and preauthorization. These coverage policies may have potent impacts on medication usage, and their effects deserve close scrutiny. In the current issue of the journal, Li et al examine the impact of the Medicare prescription drug program on the use of statin medications.[3] The researchers exploit the unusual design of the Medicare program to assess how changing copayments impact both therapeutic substitution and medication discontinuation.

At its inception, the Medicare program was designed to provide catastrophic coverage to hospitalized elderly Americans. As beneficiary survival increased over time, the emphasis shifted toward management of chronic disease.[4] Yet, for its first 38 years, the program included no prescription drug benefit. The Medicare Modernization Act of 2003 established the Medicare prescription drug program (known as Medicare Part D), and coverage began in 2006.[5] The drug program added a major new entitlement for Medicare beneficiaries, the cost of which was shared between beneficiaries and taxpayers. Even so, the plan struggled to balance the desire for comprehensive coverage with the need for cost containment.[6] As a compromise, comprehensive coverage was established for indigent patients, while most beneficiaries faced significant coverage gaps. After meeting the $250 deductible, participating nonindigent patients were responsible for 25% of drug costs up to $2250, but then were responsible for all costs until they reached the "catastrophic" limit of $5100 (Table 1). This coverage gap between $2250 and $5100 became colloquially known as the "donut hole." Although many seniors benefited financially from the program, its unusual design imposed predictable financial shocks for patients with multiple chronic conditions.

Using a 5% random sample of administrative claims drawn from the Medicare Chronic Condition Warehouse in 2006, the researchers identify patients taking branded Lipitor (atorvastatin) and Crestor (rosuvastatin) at the beginning of 2006 and assess whether they converted to a generic alternative or discontinued treatment. In a difference-in-differences model, their analysis compares patients who were subject to generic-only gap coverage (study group) to propensity-matched, low-income subsidy patients (LIS; control group). They find that study patients decreased branded statin use by 12%, and that these declines were only partially offset by new generic statin prescriptions. Relative to controls, the coverage gap was associated with reductions in mean monthly 30-day fills of any statin (−0.18; CI, −0.23, 0.13) and any lipid-lowering drug (−0.17; CI, −0.22, −0.12). The researchers conclude that increased copayments caused some patients to switch from branded to generic statins, whereas others discontinued them altogether.

The study has a number of limitations. First, to be included in the analysis, all patients spent more than $2250 on medications in 2006, suggesting that they were sicker than

Table 1. Medicare Part D 2006 Program Design for Patients With Incomes Greater Than 135% of the Federal Poverty Line

Drug Expenditure ($)	Patient (%)	Medicare (%)
0 to 250	100	0
251 to 2250	25	75
2251 to 5100	100	0
Over 5100	5	95

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excluded patients. Patients may respond differently to copayments depending on their health status. Second, the researchers appropriately used difference-in-differences methods for the study, but they use propensity scores to match patients who were subject to the coverage gap with LIS patients who were not. Although they incorporate area-level median household income as a matching criteria, by definition, LIS patients (less than $12 123 for individuals and $16 362 for a couple) have incomes well below their area median household income ($30 387).[6] The study and control groups are highly likely to respond differently to copayment changes.[7] As a sensitivity analysis, the researchers also compare the study group to non-LIS patients who were not subject to the coverage gap and find similar results. However, non-LIS (wealthier) patients who were not subject to the coverage gap voluntarily enrolled in the most costly plans and may have also responded differently to copayment changes. Finally, patients subject to the coverage gap may have elected to purchase branded statins internationally, but were unable by statute to use Medicare prescription drug coverage to pay for them. Administrative claims only document prescriptions for which a bill was paid, and the impact of international purchasing is unknown.

This study adds to a body of literature that finds that patients respond to financial incentives.[1] Prescription drug insurance coverage generally increases use of prescription drugs and decreases cost-related nonadherence.[8,9] Conversely, cost-sharing policies may decrease pharmaceutical expenditures, but may have unintended consequences on the use of other health services and on care outcomes.[10] It is precisely the unintended consequence of a payment policy decreasing adherence of a proven beneficial treatment that Li et al have studied with statin prescriptions. The benefits of statins in preventing cardiovascular events are convincingly demonstrated in multiple, large, randomized, controlled trials[11] and supported epidemiologically by observational decreases in cardiovascular events concordant with decreases in population cholesterol.[12] Moreover, the abrupt discontinuation of statins after myocardial infarction may have detrimental effects beyond simply the absence of statins.[13] Li et al have linked a policy feature, namely, the increase in copayments for branded statins, to an overall decrease in statin prescriptions even when a generic alternative was available.

Although Li et al effectively use a natural experiment to show that payment policy can adversely impact evidence-based medication adherence, a number of subsequent developments have decreased the impact of the Medicare Part D design. First, coverage revisions have substantially decreased financial shocks within the donut hole (see Table 2).[14] Second, drug cost transparency is much greater today for both patients and providers. Ambulatory electronic health record adoption has increased from around 25% in 2006 to greater than 75% in 2014,[15] and many systems display insurance copayment tier levels at the point of prescribing. Patients and their providers are now better able to make informed and shared decisions in the exam room about medications that fit the patient's medical and financial needs.

Table 2. Medicare Part D 2017 Program Design for Patients With Incomes Greater Than 135% of the Federal Poverty Line[14]

Drug Expenditure ($)	Patient (%)	Medicare (%)	Discount (%)
0 to 400	100	0	0
401 to 3700	25	75	0
3701 to 4950	40	10	50
Over 5100	5	95	0

Drugs make an increasingly important contribution to health care outcomes, and drug coverage policies aim to contain costs while improving value. Ideally, coverage decisions should discourage low-value drug prescribing, encourage selection of low-cost drug options where they exist, and encourage evidence-based prescribing. However, policies are written to apply to all patients, and individual patient circumstances may vary. Although conversion of branded to generic formulations of the same drug makes sense in nearly all circumstances, the therapeutic substitution to another drug in the same class, as promoted by tiered copayments, is more problematic. In particular, statin drugs vary substantially in potency, a factor explicitly recognized in current treatment guidelines.[16] They are also metabolized differently, have different half-lives, and vary in chemical characteristics, such as lipophilia. These drug reimbursement policies may increase drug-drug interactions and prompt safety concerns.[17] Statin side effects are also unfortunately common and may be idiosyncratically specific to individual drugs.[18]

Although tiered pharmacy pricing coverage is commonplace, the design of the original Part D program placed the greatest financial burden on the sickest patients, and in the face of sharp copayment increases, some patients choose to forgo statins altogether. Notably, a recent economic simulation based on the MI-FREE study suggests that the opposite approach may actually be cost saving.[19] The study found that following a myocardial infarction, provision of free evidence-based medications, including statins, would increase survival by 0.14 quality-adjusted life years and decrease overall per-patient costs by $4011. They project that the policy would save $2 billion annually if nationally implemented.

Given the very legitimate variations in the needs of individual patients and the fact that many patients will ultimately defer to their clinicians' judgment, policies directed to the prescriber may be more appropriate. Prescribers are

better positioned to make informed trade-offs between costs and outcomes than many patients are. Immediate and effortless availability of patient-specific drug formulary options and pricing is an important step toward achieving greater value. Efforts to hold prescribers accountable for generic prescribing rates, overall pharmacy costs, and patient outcomes at the population level also have merit. Population-level accountability avoids the administrative inefficiencies of preauthorization programs and allows prescribing flexibility for individual patients. This approach is increasingly prominent in emerging payment reforms, including the landmark Medicare Access and Children's Health Insurance Program (CHIP) Reauthorization Act legislation.[20]

The growth of US health care spending is unsustainable, and effective solutions are needed to improve value. Drug spending is increasingly contributing to the cost of care, and policies are needed to manage pharmacy utilization. Whereas large patient pharmacy copayments almost certainly impact drug utilization, they may be counterproductive if they decrease use of evidence-based therapies. Policy makers should pay careful attention to program designs to avoid unintended consequences like those demonstrated in the study by Li et al.

Disclosures

None.

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