The Effects of Prescription Drug Cost Sharing: A Review of the Evidence

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Objectives: To determine whether patients respond to increased cost sharing by substituting less expensive alternatives for medications with higher levels of copayments or coinsurance, and to examine the body of evidence on the relationships between cost sharing and use of essential or maintenance medications, health outcomes, process-of-care measures (such as medication adherence and discontinuation), and costs.

Study Design: Literature review.

Methods: Healthcare reference databases and key journals were searched to identify peer-reviewed empirical studies that examined the effects of variation in the amount of prescription drug copayments or coinsurance on healthcare utilization patterns. Thirty studies met our search criteria.

Results: Higher levels of prescription drug cost sharing generally produce intended effects, namely, decreasing the consumption of prescription drugs and steering patients away from nonpreferred to preferred brand-name drugs. However, patients do not always switch to generic drugs. Although not consistently reported, the most troublesome effects associated with higher levels of cost sharing are treatment disruptions (such as lower levels of treatment adherence, continuation, and initiation) for chronically ill patients. At times, higher levels of cost sharing can affect the use of essential medications and outcomes of care.

Conclusions: Cost sharing reduces the consumption of prescription drugs but may have unintended effects on the process and outcomes of therapy. Further research is warranted in this area. The central question for health plan managers and policy makers is whether we will continue to use cost sharing as is or make modifications to reduce unintended effects.

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Prescription drug expenditures are one of the fastest growing components of national health expenditures.[1] To control prescription drug costs, health plans and employers have increased prescription drug cost-sharing amounts for patients.[2] Copayments for enrollees in employer-sponsored plans have risen considerably. From 2001 to 2004, the mean copayments for generic drugs increased 42.9% (from $7 to $10), while copayments for preferred brand-name drugs rose 61.5% (from $13 to $21) and copayments for nonpreferred brand-name drugs increased 94.1% (from $17 to $33).[2]

In addition to increasing the cost-sharing amounts, health plans continue to move away from 1-tier plans that charge the same amount for all types of drugs and away from 2-tier plans that charge a lower cost-sharing amount for generic drugs and a higher cost-sharing amount for brand-name drugs.[2] As a result, 3-tier plans that assess a third, higher amount for nonpreferred brand-name drugs are now the dominant type of prescription drug benefit; 3-tier plans in 2004 applied to almost two thirds of workers.[2] Although less common (representing 3% of workers), some health plans are introducing plans that assign an even higher fourth tier to cover lifestyle or very expensive medications.[2-4]

In this review, we synthesize and summarize the state of knowledge about the effects of increased prescription drug cost sharing on use, expenditures, and outcomes. First, we address the following question: Do patients respond to increased cost sharing by substituting less expensive medications or delivery methods (eg, mail order) for medications with higher levels of copayments or coinsurance?

Second, concerns have been expressed about the adverse effects of cost sharing on health outcomes and the process of care.[5,6] In light of these concerns, we extend previous reviews of the literature and examine the growing body of evidence on the relationships between cost sharing and the use of essential or maintenance medications, health outcomes, process-of-care measures (such as medication adherence and discontinuation), and costs.

Previous reviews of the prescription drug cost-sharing literature summarized evidence related to the effects of changes in cost sharing on prescription drug use and expenditures, but the results of these studies are dated[7-9] or have a focus that is different from that of this review, such as the effect of cost sharing on seniors[10,11] or on vulnerable populations.[12,13] Other reviews evaluated the effects of cost sharing within the broader

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context of pharmacy benefit management tools[10,14] or are specific to multitiered formularies.[15] This review is not intended to replicate the results from prior reviews but rather to provide new insights, including an assessment of the effects of changes in prescription drug copayments and coinsurance on specific measures of use, outcomes, and expenditures.

SELECTING STUDIES FOR REVIEW

Studies were selected for this review on the basis of several MEDLINE searches, covering 1974 through April 2005. The first set of searches was based on the phrase *prescription drugs,* which was paired with *copayments* or *cost sharing* or *multitier formulary* or *multitiered formulary.* These terms were searched in various combinations with *direct costs, indirect costs, adherence, compliance, income, socioeconomic status,* and *Medicaid.* Studies were excluded that were not in English or were not based on study populations from the United States or Canada. The published studies that were identified were supplemented with studies from our files and with other studies that were identified in reference lists of selected publications. We selected empirical studies using claims-based data sources in which cross-sectional or longitudinal variation in the amount of copayments or coinsurance occurred, permitting an examination of the relationships between variation in these types of cost sharing and use patterns.

We identified 30 studies that met our criteria. More than one third (11/30) of the studies reviewed herein were not addressed in prior reviews. Most of the unreviewed studies postdated prior reviews or did not fit the criteria for more recent reviews.[10-12,15] Each study was assessed to determine whether the findings revealed that cost sharing had a significant (nonzero) effect, no effect, or mixed effects (some nonzero and some not significantly different from zero) on measures of prescription drug use.

A DEFINITION OF COST SHARING AND THE DEMAND FOR MEDICAL CARE

Cost Sharing

Cost sharing is defined as the direct charge to a patient at the time a prescription is filled. Cost sharing represents the price of the prescription drug to the insured patient, while insurance covers the remainder of the cost. This review addresses the effects of the 2 most common forms of prescription drug cost sharing, namely, copayments, a flat fee assessed per prescription (eg, $10), and coinsurance, a fixed fraction of each dollar of cost (eg, 20%).[2]

Economic Framework

Economic theory states that, when a patient is assessed the full price of a prescription drug and has enough information to assess the drug's benefits and adverse effects, he or she will consume an optimal amount of the drug, given his or her preferences and income constraints. The theory assumes that rational patients will weigh the costs and benefits of drugs vs other methods of producing health and will consume combinations of these that maximize their health, subject to their income constraints.

Having prescription drug insurance motivates patients to consume more drugs than they would normally consume, because the price to the patients is lower than the full price.[16,17] Raising the price of the drug via higher levels of cost sharing is expected to have the following economic effects, although this list is not exhaustive:

Changes in Consumption. Higher prices are expected to move patients up the demand curve and closer to the economically optimal amount, resulting in a reduction in consumption.

Substitution. Patients are likely to search for less expensive substitutes as the prices of prescription drugs rise. Therefore, if they discover a good substitute, patients are likely to consume smaller quantities of prescription drugs and larger quantities of the substitute.

Value. A price increase would decrease the likelihood that drugs of low value, for which the cost exceeds the benefit, would be used.[16,17] Conversely, patients would be price insensitive for high-value drugs, such as those that are life sustaining, and would be expected to continue to fill prescriptions. However, this assumes that consumers have adequate information to evaluate the benefits and costs of drugs, which has not been established.[18]

Previous studies[8,12,17,19] demonstrated the first effect, that higher levels of cost sharing result in reductions in prescription drug use. These studies found that, similar to most healthcare services, the demand for prescription drugs is insensitive to price changes. Most estimates of price elasticity suggest that a 10% increase in price, for example, would decrease use by less than that, ranging from 1% to 4%. However, the price elasticity of different medication classes can vary widely.[20,21]

We devote the next sections of this review to an analysis of several issues. First, we determine whether patients use larger quantities of drug substitutes as a result of cost sharing. Next, we evaluate whether patients distinguish between high- and low-value drugs by exam-

Table 1. Effects of Cost Sharing on Switching to Close Drug Substitutes

Substitution	Evidence of Effects	No Evidence of Effects
Nonpreferred to preferred brand-name	Fairman et al[22] 2003 Huskamp et al[23] 2003 Motheral and Fairman[24] 2001 Nair et al[25] 2003 Rector et al[26] 2003 Thomas et al[27] 2002	—
Brand-name to generic	Christian-Herman et al[30] 2004	Goldman et al[20] 2004 Joyce et al[28] 2002 Motheral and Henderson[29] 1999
Increased percentage of generic fills	Christian-Herman et al[30] 2004 Kamal-Bahl and Briesacher[31] 2004 Motheral and Henderson[29] 1999 Nair et al[25] 2003 Thomas et al[27] 2002	Leibowitz et al[19] 1985 Motheral and Fairman[24] 2001
Prescription to over-the-counter	Goldman et al[20] 2004	Leibowitz[33] 1989
Retail to mail-order pharmacy	Thomas et al[27] 2002	—

ining studies that relate to the use of various classifications of prescription drugs (eg, essential and nonessential medications). On a related note, we determine if patients are making well-informed decisions by assessing whether higher levels of cost sharing are associated with declines in patient health, patient care, and medical outcomes. Finally, we summarize the effects of higher levels of cost sharing on healthcare expenditures.

DRUG SUBSTITUTION

During the past 2 decades, health plans introduced different formularies that provided economic incentives, via higher patient cost-sharing amounts, for patients to use lower-cost prescription drugs or nondrug substitutes. Many studies addressed herein estimated the effects of incentive-based formularies on the use of substitutes, such as preferred brand-name drugs, generic drugs, and over-the-counter drugs. Several studies also estimated the effects of incentive-based formularies on the use of mail-order pharmacies, which are typically marketed as being less expensive than retail pharmacies.

We review the evidence in these areas to determine whether the use patterns of potential drug substitutes increased as cost sharing rose. We conclude that patients appear to be responding to some, but not all, financial cost-sharing incentives to switch to close drug substitutes (**Table 1**). To date, we found no studies that address the use of nonmedical substitutes, such as physical exercise, in response to higher levels of cost sharing.

Nonpreferred vs Preferred Brand-name Drugs

In accord with financial incentives, all of the studies[22-27] reviewed showed that adding a third tier for nonpreferred brand-name drugs resulted in a decrease in the use of these drugs and an increase in the use of preferred brand-name drugs, although the classifications of preferred and nonpreferred drugs differed among the studies. The extent of substitution varies by medication class[25] and can be significant. For example, in a study[26] of enrollees in independent practice health plans, the mean net increase in the use of preferred brand-name drugs for plans with differential copayments for preferred and nonpreferred brand-name drugs was 13.3% for angiotensin-converting enzyme (ACE) inhibitors, 8.9% for proton pump inhibitors, and 6% for statins.

Generic Substitution

In contrast, we found little evidence of generic substitution in plans introducing or increasing a generic vs brand cost-sharing differential. Few studies[20,28,29] reported an increase in the number of generic drugs dispensed as a result of higher generic vs brand price differentials. Conversely, in a recent study, Christian-Herman and colleagues[30] evaluated the effects of a switch to a generic-only benefit from a generic vs brand benefit in a Medicare health maintenance organization (HMO) and reported a 20% rise in generic prescriptions per person. However, the effect was attenuated considering the concurrent 13.7% rise in generic prescriptions in a comparison group of Medicare HMO enrollees who retained the generic vs brand coverage. Because health plans have long attempted to steer patients to less expensive gener-

ic drugs via differential cost sharing, these findings are somewhat surprising and bear further investigation.

Several studies reported the effects of higher levels of cost sharing on the generic fill rate, which is the percentage of drugs dispensed as generic. Two studies[19,24] reported no effect on the generic fill rate. Five studies[25,27,29-31] reported increases in the generic fills. Caution should be exercised when interpreting the findings of these studies. An increase in the generic fill rate is not a clear indication of generic substitution because the generic fill rate can be affected by a change in the number of generic drugs dispensed (in the numerator and the denominator), by a change in the number of brand-name drugs dispensed (in the denominator), or by a combination of both.

Two of the studies also assessed disaggregated generic vs brand use. The first, a study[29] of commercially insured adults in 2 health plans that raised 2-tier copayments and increased the generic vs brand differential, reported that the generic fill rate rose as a result of a decrease in brand-name use, although generic use remained unchanged. In the second study,[30] after introduction of a generic-only benefit in a Medicare HMO, the authors found evidence of a large increase (15%) in the generic percentage dispensed, although much of this resulted from a reduction in brand-name use. The exact size of the effect on the generic fill rate is unknown, as patients had little incentive to fill brand-name drugs within the plan and the authors were unable to track out-of-plan purchases of brand-name drugs.

It is possible that the copayment differential between generic and brand-name drugs has been too small, as larger generic vs brand differentials appear to motivate patients to consume more generic drugs.[27,30,31] Another possible reason for the observed lack of movement toward generic drugs may be that patients perceive differences between the quality of generic drugs and brand-name drugs that motivate them to avoid generic equivalents. These perceptions may be real. Lichtenberg[32] found that mortality rates, work loss days, and nondrug medication costs were significantly lower for patients taking newer drugs (which are more likely to be brand name) than older drugs (which are more likely to be generic).

Over-the-counter Drugs

We found 2 studies that addressed substitution of over-the-counter drugs for prescription drugs, with mixed results, but the findings were inconclusive. In the RAND Health Insurance Experiment, in which cost-sharing tiers were randomly assigned to families, the number of over-the-counter drugs purchased rose as the level of cost sharing decreased, suggesting that over-the-counter drug purchases are a complement to other medical care services.[33] However, this study was based on purchases of over-the-counter drugs, which are often bought and stockpiled for later use. Conversely, Goldman and colleagues[20] estimated that, if cost sharing was doubled, the decrease in the use of medications for chronic conditions was more than twice as large (32%) when a close over-the-counter substitute was available than when an over-the-counter substitute was not available (15%), but no data were available to verify that patients consumed more over-the-counter drugs.

Mail-order Pharmacy

Finally, we discovered evidence from a study[27] that patients with higher levels of retail pharmacy cost sharing are more likely to use mail-order pharmacies. Additional evidence in this area is warranted.

VALUE OF PRESCRIPTION DRUGS

In the next sections, we first summarize the effects of higher levels of cost sharing on the use of essential or maintenance medications and assess whether patients reduce the consumption of low-value prescription drugs instead of those that may affect health, outcomes, or the process of care. We then summarize the effects of higher levels of cost sharing on medical costs. Detailed information on these studies in an appendix is available from the author or at http://www.medstat.com/1research/gibson2.mht.

Essential Medications

"More essential" medications are generally considered to be necessary to maintain or improve health. These drugs include maintenance medications that are taken regularly over a long period (eg, antihypertensive medications) and medications that are taken sporadically (eg, bronchodilators). As the medical need for medication rises, we would expect that higher levels of cost sharing are likely to have a smaller effect on the use of medications that are essential to health and well-being. To examine the evidence, we focused on studies that examined the relationship between cost sharing and the use levels of essential medications. We summarize the evidence in **Table 2.**

Although the definitions of essential drugs differed, most studies[20,21,23,24,30,31,34-38] found that higher levels of prescription drug cost sharing were associated with a reduction in the consumption of essential medications. Two exceptions examined the effects of the 1996 introduction of a 25% coinsurance policy with an income-based cap in Quebec (with a small change in cost sharing because of the cap). One study[39] focused on the

use of 4 classes of medications in older patients, and the other study[40] focused on cardiac medication use among older patients discharged after acute myocardial infarction (MI). Both studies relied on a pre-post design without a comparison group to assess changes in use, with the authors identifying the effects of the cost-sharing increase by comparing changes in prepolicy and postpolicy use. Because prescription use has been rising rapidly over time, a comparison with contemporaneous trends instead of historical trends may have produced different results. In addition, Pilote et al[40] investigated the utilization of services for patients recently hospitalized for acute MI, who may have been reluctant to reduce cardiac drug use even after an increase in cost sharing.

Most of the studies[20,23,35,37] that found a significant association between cost sharing and a reduction in the use of essential medications focused on a broad population of acutely and chronically ill beneficiaries. Other studies[21,24,30,31,34,36,39] found smaller reductions in use for chronically ill patients or active users of essential medications, who are less likely to be price sensitive. One exception to this finding was the study of regular users of essential medications among older and welfare recipients in Quebec who were subject to the 1996 coinsurance increase. In this study, Tamblyn and colleagues[38] reported reductions in the use of essential medications. Unlike most of the other studies, which examined the effects on the use within individual classes of medications, this study examined a large number of medications grouped into a single class, which may have had cumulative results.

Less Essential and More Essential Medications

When the price of a drug rises, patients who are armed with full information about the benefits and risks of medications would be expected to decrease the consumption of less essential medications to a greater extent than more essential medications. We examined the results of studies that included less essential and more essential medication classes. In the studies[21,35,39] examining the relationships between cost sharing and the use of individual therapeutic classes of medications, there were no clear trends for less essential compared with more essential medications. However, larger reductions in the use of less essential medications were reported in 3 studies[29,36,38] in which individual therapeutic classes were not examined and medications were aggregated into the 2 classes of more essential and less essential medications. Patients perhaps make substitutions across individual classes of essential medications, although further investigation into the effects of higher levels of cost sharing on essential medications is warranted.

HEALTH OUTCOMES

If patients are fully informed about the benefits and risks of medications, we would expect that higher levels of cost sharing, and any associated reduction in prescription drug use, would not have an effect on health outcomes. Patients would reduce consumption at the margin, with little to no effect on quality and health outcomes. In this section, we review studies that examine the effects of an increase in cost sharing on indicators of health outcomes in the categories of (1) healthcare service utilization and (2) health status and mortality.

Healthcare Service Utilization

Although healthcare service utilization is not a direct measure of quality of care or health status, an increase

Table 2. Effects of Cost Sharing on the Use of More Essential and Less Essential Medications

Category	Evidence of Effects	Mixed Evidence of Effects	No Evidence of Effects
Reduction in the use of essential medications	Foxman et al[35] 1987 Goldman et al[20] 2004 Huskamp et al[23] 2003 Huskamp et al[37] 2005 Tamblyn et al[38] 2001	Blais et al[34] 2003 Christian-Herman et al[30] 2004 Johnson et al[21] 1997 Kamal-Bahl and Briesacher[31] 2004 Harris et al[36] 1990 Motheral and Fairman[24] 2001	Blais et al[39] 2001 Pilote et al[40] 2002
Reduction in the use of more essential medications < reduction in the use of less essential medications	Harris et al[36] 1990 Motheral and Henderson[29] 1999 Tamblyn et al[38] 2001	—	Blais et al[39] 2001 Johnson et al[21] 1997 Foxman et al[35] 1987

in the utilization of services (outpatient medical visits, emergency department visits, inpatient admissions, or hospital readmissions) coincident with higher levels of cost sharing may indicate poor outcomes or the occurrence of adverse events (**Table 3**).

Table 3. Effects of Cost Sharing on Health Outcomes

Outcome	Mixed Evidence of Effects	No Evidence of Effects
Outpatient medical services	—	Fairman et al[22] 2003 Motheral and Fairman[24] 2001 Johnson et al[41] 1997 Pilote et al[40] 2002
Healthcare services utilization, namely, emergency department visits, inpatient admissions, and long-term care admissions	Christian-Herman et al[30] 2004 Tamblyn et al[38] 2001	Fairman et al[22] 2003 Johnson et al[41] 1997 Motheral and Fairman[24] 2001 Pilote et al[40] 2002
Health status	Johnson et al[21] 1997	—
Mortality	—	Pilote et al[40] 2002

In most cases, higher levels of cost sharing were not associated with changes in the utilization of low-intensity outpatient medical services, such as physician office visits,[22,24,41] outpatient visits,[40] and home health visits.[41] However, these studies assessed small changes in prescription drug cost sharing. As cost sharing continues to rise, it is plausible that the utilization of outpatient visits may change as patients seek physician advice for medication management and other services.

Two studies reported an increase in high-intensity health services, such as inpatient visits, as cost sharing rose. In the first study, Christian-Herman and colleagues[30] found that inpatient visits rose after a generic-only drug plan, comprising a large change in cost sharing, was initiated among Medicare HMO enrollees. However, the findings were not adjusted for differences in the composition of the treatment and comparison groups because the authors did not have access to detailed demographic data. In addition, an increase in admissions was not detected across all of the diagnostic groups that were studied. Patients with congestive heart failure or coronary artery disease did not have a significant change in admission rates, but patients with diabetes mellitus had significantly more admissions. In the second study, which measured the effects of the implementation of the 25% coinsurance charge up to an income-based cap, a minimal change in cost sharing) among older persons and welfare recipients in Quebec, Tamblyn and colleagues[38] found that patients who decreased the consumption of essential drugs had more adverse events (including first acute hospitalization, long-term care admissions, and death). Patients reducing the consumption of less essential medications did not have a significant change in adverse events.

Four studies reported no association between higher levels of cost-sharing and utilization rates for higher-intensity services, such as inpatient admissions,[22,24,41] emergency department visits,[22,24,40,41] and readmissions among older patients hospitalized with complications after acute myocardial infarction.[40] The lack of association with higher levels of cost sharing may be explained by the patient populations, in which (for many of the privately insured[22,24] and older[41] enrollees who were studied) prescription drug costs may represent small percentages of incomes. Furthermore, in the study by Pilote et al,[40] the utilization of services was investigated among patients recently hospitalized for acute myocardial infarction, whose demand for prescription drugs and other medical services may have been price inelastic.

Health Status and Mortality

We found no studies measuring the effects of cost sharing on direct measures of health status, such as self-reported health status and empirical measures of clinical health status (eg, laboratory readings). However, Johnson and colleagues[21] reported a significantly large decline in a claims-based score of health status (based on the Chronic Disease Score and the Diagnostic Cost Group) for a Medicare HMO with copayment increases from $1 to $3 to $5 but not in a Medicare HMO with a copayment increase from 50% with a $25 maximum to 70% with a $30 maximum.

Finally, the study[40] focusing on the introduction of the 25% coinsurance charge in Quebec reported that higher levels of cost sharing had no effect on mortality rates among patients discharged after acute MI. Future studies that add to the evidence of the effects on health status and mortality are warranted.

MAINTENANCE MEDICATIONS AND PROCESS OF CARE

Many health conditions require adherence to a regular regimen of maintenance prescription drugs to slow

the progression of disease, to maintain health, or to improve health.

While an increase in adverse health outcomes may be indicative of inadequate treatment, changes in the process of care may similarly be indicative of treatment disruptions. We herein review the evidence of the links between higher levels of cost sharing and process-of-care measures for maintenance medications, including adoption of therapy, drug discontinuation, and adherence.

Adoption of Therapy

Because many chronic conditions are managed with prescription drug therapy, initiation of appropriate drug treatment can be essential to manage the progression of disease. Two cross-sectional studies revealed that higher levels of cost sharing may lessen the rate of adoption of expensive, newer therapies, such as disease-modifying drugs for multiple sclerosis[42] and cyclooxygenase-2 inhibitors.[43] For patients taking a large number of concurrent medications, we found no studies that addressed the relationship between cost sharing and cost-related trade-offs between medications. Future studies evaluating whether higher levels of cost sharing delay initiation of therapy will aid in treatment and benefit design for patients with chronic and other serious illnesses.

Drug Discontinuation

Drug discontinuation is perhaps the most extreme response to a prescription drug price increase. Drug discontinuation is typically identified by an absence of refills within the same or a similar medication class (after allowing for switching to related medications). We found evidence in the literature that patients do, at times, discontinue medications when cost sharing rises, but the results varied across studies and medication classes (**Table 4**).

Ellis and colleagues[44] reported that, compared with patients with copayments less than $10, discontinuation rates of statins for new and incident statin patients were more than 4 times higher for patients with a copayment of $20 or more and 1.4 times higher for patients with a copayment between $10 and $20. In this study, discontinuation was defined as a 7-day gap in treatment, so patients who stretched out refills may have been classified as discontinuers. Because this may occur more frequently in groups with higher copayments, this could have inflated the discontinuation rate; however, it raises the issue of whether short gaps are acceptable treatment patterns.

In a study[23] of enrollees from 2 employers that moved to a 3-tier pharmacy benefit, the employer moving from a 1-tier plan to a 3-tier plan and increasing copayments in all tiers had significantly higher rates of drug discontinuation (no refills in the 6 months after the copayment increase) than a comparison group for the 3 classes of medications that were analyzed (ACE inhibitors, proton pump inhibitors, and statins). The second employer instituted less extreme cost-sharing changes, moving from a 2-tier to a 3-tier plan and increasing copayments in the third tier only; here the discontinuation rates for proton pump inhibitors and statins were no different from those in the comparison group. Somewhat surprisingly, enrollees of this employer's health plan had significantly lower rates of discontinuation for ACE inhibitors than the comparison group.

Conversely, Huskamp and colleagues[37] discovered that discontinuation rates for children taking attention-deficit/hyperactivity disorder medications for an employer moving from a 1-tier to a 3-tier plan were not significantly higher after the copayment change. This finding may be a result of the necessity of these medications for the well-being of children, resulting in price insensitivity; also, parents may be acting as good economic agents for their children.

Two related studies, by Motheral and Fairman[24] and by Fairman et al,[22] evaluated drug continuation rates for preferred provider organization enrollees who were

Table 4. Effects of Cost Sharing on the Process of Care

Measure	Evidence of Effects	Mixed Evidence of Effects	No Evidence of Effects
Adoption of therapy	Briesacher et al[43] 2004 Ozminkowski et al[42] 2004	—	—
Drug discontinuation	Ellis et al[44] 2004	Fairman et al[22] 2003 Huskamp et al[23] 2003 Motheral and Fairman[24] 2001	Huskamp et al[37] 2005
Adherence	Ellis et al[44] 2004 Dor and Encinosa[53] 2004	Christian-Herman et al[30] 2004	Pilote et al[40] 2002

current users of medications in 4 drug classes. After a 3-tier plan was introduced, there was a decline in 6-month (in both studies) and 11-month (in the first study) continuation rates for estrogens. No difference in continuation rates were noted for the other classes of medications (oral contraceptives, antihypertensive medications, and antihyperlipidemic drugs).

Although patients and professionals may differ in their perception of necessity, the drugs that were discontinued in most of these studies were considered to be clinically essential medications, for which discontinuation was generally not recommended. Until long-term studies are undertaken, the ultimate effects of discontinuation on the outcomes of care will remain unknown. Also, all of the studies were performed among privately insured patients, for whom copayments were typically a small percentage of income. Similar studies of discontinuation behavior need to be performed on more vulnerable population groups in which cost may be a larger issue and discontinuation behavior may differ from that of the privately insured.

Adherence

In response to higher prices, patients may exhibit behaviors that reduce the amount of prescription drugs taken, such as skipping doses and stretching out refills.[45,46] This is a concern because adherence to a regimen of maintenance medication has been, for the most part, associated with better outcomes.[47-49] While we found no empirical studies that linked cost sharing to adherence and outcomes (although surveys have linked cost-related underuse to negative outcomes[50-52]), several studies that addressed the relationship between cost sharing and adherence are addressed herein.

Although no commonly accepted standard definition for adherence exists, in this review adherence may also be considered as compliance or persistence and typically refers to refill compliance (the timing of refills) or adequacy of medication coverage (the percentage of days with usable medication on hand). The study by Pilote et al[40] found no relationship between the introduction of the 25% coinsurance charge (up to a cap) in Quebec and adherence to cardiac medications after discharge from the hospital following acute MI. As stated previously, patients surviving an acute MI are more likely to be price insensitive and, consequently, adherent to cardiac medications when facing a price increase.

Three other studies found a relationship between cost sharing and adherence. The first study[44] analyzed adherence among adult patients in a midwestern US managed care organization who were prescribed statin therapy. Patients with higher copayments were less likely to adhere (based on the percentage of days without adequate prescription drug coverage) than patients with lower copayments. In a second study[53] of adults in 9 firms taking oral antidiabetic medications, higher levels of coinsurance or copayment were associated with lower levels of refill compliance (based on refilling within 90 days after an initial prescription ran out). The third study,[30] which analyzed the effects of the institution of the generic-only benefit among Medicare HMO enrollees, found that adherence (based on the mean number of months with an available prescription supply) was significantly reduced in 4 of 5 disease or medication categories (congestive heart failure [ACE inhibitors or angiotensin II receptor blockers], coronary artery disease [statins], diabetes mellitus [any diabetic agent, ACE inhibitors or angiotensin II receptor blockers, and statins], and antidepressant use). Adherence in the fifth category, the use of epileptic agents, declined but not significantly; however, the sample size for epilepsy was small, which may have reduced the statistical power.

DIRECT AND INDIRECT COSTS

Expenditures are a composite of the rate of use and the cost per prescription (defined as quantity-×-cost per prescription) (**Table 5**). The demand for prescription drugs is inelastic, and higher levels of cost sharing are expected to result in small declines in the quantity of prescription drugs. The costs of drugs also affect the expenditures. We examined 3 types of expenditures, namely, total expenditures (quantity-×-total amount paid for a prescription), health plan expenditures (quantity-×-health plan payment), and patient expenditures (quantity-×–cost-sharing amount).

We would expect to see a small decline in total expenditures associated with a decline in the drug quantity consumed unless patients switched to more costly drugs. Consistent with this expectation, studies[19,24,27-29,36,54] that estimated the effects of an increase in cost sharing on direct prescription drug costs found that higher levels of prescription drug cost sharing were associated with a reduction in total prescription drug expenditures.

Three studies[22,55,56] that reported no effects or inconsistent effects of higher cost sharing were based on the experience of privately insured individuals, who tend to have higher incomes and may be less price responsive. In a study[55] of 212 employer groups in preferred provider organization and managed indemnity plans, patients with higher levels of cost sharing appeared to use fewer but more expensive medications. In a study[56] of managed care enrollees in employer-based plans, higher copayments were associated with a reduction in

Table 5. Effects of Cost Sharing on Prescription Drug and Healthcare Services Costs

Category	Evidence of Effects	Mixed Evidence of Effects	No Evidence of Effects
Total expenditures	Harris et al[36] 1990 Joyce et al[28] 2002 Leibowitz et al[19] 1985 Motheral and Henderson[29] 1999 Motheral and Fairman[24] 2001 Nelson et al[54] 1984 Thomas et al[27] 2002	Hillman et al[55] 1999	Fairman et al[22] 2003 Smith[56] 1993
Health plan expenditures	Christian-Herman et al[30] 2004 Fairman et al[22] 2003 Johnson et al[41] 1997 Joyce et al[28] 2002 Motheral and Henderson[29] 1999 Meissner et al[57] 2004 Motheral and Fairman[24] 2001 Nair et al[25] 2003 Smith[56] 1993 Thomas et al[27] 2002	—	—
Patient expenditures	Christian-Herman et al[30] 2004 Johnson et al[41] 1997 Joyce et al[28] 2002 Meissner et al[57] 2004 Motheral and Henderson[29] 1999 Motheral and Fairman[24] 2001 Nair et al[25] 2003 Smith[56] 1993 Thomas et al[27] 2002	—	—
Healthcare services expenditures	—	—	Johnson et al[41] 1997

expenditures for enrollees in independent practice association plans but not network-based plans. The findings may be attributed to physician prescribing incentives to eliminate less essential prescriptions. These incentives have had more of an effect on prescribing than patient copayments. In another study[22] of the effects of a 3-tier copayment in a preferred provider organization, the absence of cost savings in the intervention group should be interpreted with caution because the cost estimates were based on average wholesale price and not actual cost.

We would also expect that an increase in cost sharing results in pharmaceutical cost savings to a health plan as its cost per prescription is reduced by the increase in patient cost sharing. This was consistently reported in the literature.[22,24,25,27-30,41,56,57] Not surprisingly, another consistent finding was cost shifting to patients via an increase in out-of-pocket payments.[24,25,27-30,41,56,57]

It is striking to discover how little we know about the cost effects of an increase in cost sharing, beyond the effects on prescription drug costs. Johnson et al[41] studied the effects of higher prescription drug cost sharing in 2 Medicare risk-based HMOs from 1987 to 1991 and found that changes in cost sharing did not have a significant effect on medical expenditures.

Further research needs to emphasize whether an increase in cost sharing is cost saving or results in long-term or short-term spending. The indirect and direct effects of cost sharing are important areas of future study and would move current knowledge beyond a compartmentalized focus on prescription drugs and into a broader view of the effects on health and healthcare.

DISCUSSION

Cost sharing was originally intended to curb insurance-related overuse, and research confirms that higher levels of prescription drug cost sharing generally produce some of the intended effects of decreasing the con-

sumption of prescription drugs and steering patients away from nonpreferred brand-name drugs to preferred brand-name drugs. However, patients do not consistently appear to be switching to generic substitutes, which are considerably less expensive than brand-name drugs.

It is also becoming clear that cost sharing is not always a benign instrument, and at times it may come at a price. Although not consistently reported in the literature, the most troublesome effects associated with higher levels of cost sharing are reports of treatment disruption for chronically ill patients who depend on a regular regimen of prescription drugs. In addition, higher levels of cost sharing can have significant effects on the use of essential or maintenance medications, the outcomes of care, and the process of care.

Overuse and Underuse

Prescription drug cost sharing is expected to continue to increase in the near future. In the 2004 Kaiser Family Foundation and the Health Research and Education Trust[58] survey of employer-sponsored benefits, 38% of small firms and 53% of large firms stated that they were likely to increase the amount that employees pay for prescription drugs in the next year. Whether cost sharing will continue to proliferate depends on the extent of overuse vs underuse of prescription drugs. If overuse is the primary problem, then cost sharing could be an acceptable cure when patients and providers have adequate information about the risks and benefits of medications. However, actual patient behavior does not reinforce the notion that patients can always discern between overuse, underuse, and appropriate use.

Equity and Fairness

One of the clearest conclusions noted in the literature is that higher levels of cost sharing transfer a larger financial burden to the patient. As copayments rise to new heights, concerns emerge about equity and fairness between different groups of patients, especially those with low incomes and those who are chronically ill. To date, most studies have focused on the effects of higher levels of cost sharing among homogeneous study populations. A careful analysis of the effects of higher levels of cost sharing on diverse subgroups of individuals is warranted and would reveal which subgroups have a greater response to changes in cost sharing.

Demand for Prescription Drugs

Most research has focused on varying the price of prescription drugs to the patient, but little emphasis has been placed on assessing the level of demand for prescription drugs. There are 2 implicit assumptions in the current cost-sharing system in which cost-sharing amounts are assessed to the patient at the point of service. Given the findings of this review, in certain cases, either or both of the following assumptions may not be valid and may affect the level of prescription drug use.

The first assumption is that patient demand is valued appropriately. If patients are undervaluing (or overvaluing) prescription drugs, then the demand is too low (or too high) and may result in consumption levels that are too low (or too high). If a drug is undervalued, methods exist to increase the demand for the drug, such as patient and provider education; these will help patients to incorporate unrecognized short-term and long-term benefits (or risks) for the drugs of interest.

The second assumption is that any additional value to society beyond what patients place on prescription drugs, such as to employers (through increased productivity) and to family members (through reduced time off from work), is zero.[59-61] If the benefits of prescription drug consumption extend beyond the patients, then patients may not incorporate these additional benefits into their demand for prescription drugs. Time-tested approaches, such as subsidies, education, and credits, may be used to increase the demand in such situations.

Future Directions

Although the current system of coinsurance and copayments is easy to implement, a one-size-fits-all approach could be replaced with targeted incentives for patients and providers to use the right medications at levels of use that are appropriate to their health conditions. Alternatives, such as benefit-based cost sharing,[62] in which the levels of cost sharing are based on the benefit to the patients, hold promise in this area.

Prescription drug cost sharing has become a widespread and effective means to control prescription drug costs among employer-based and publicly funded health plans. The growing evidence in the literature suggests that, at times, unintended effects on the process and outcomes of therapy may result from cost sharing. The central question for health plan managers and policy makers is whether we will continue to use cost sharing as is or make modifications to reduce unintended effects.

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