The Pharmaceutical Industry and Consequences of Copayments

EFFECTS OF PRESCRIPTION DRUG USER FEES ON DRUG AND HEALTH SERVICES USE AND ON HEALTH STATUS IN VULNERABLE POPULATIONS: A SYSTEMATIC REVIEW OF THE EVIDENCE

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Rising pharmaceutical expenditures have led to the use of cost-sharing measures. The authors undertook a systematic review of the effects of cost sharing on vulnerable populations (the poor and those with chronic illnesses). Virtually every article reviewed supports the view that cost sharing decreases the use of prescription drugs in these populations. Copayments or a cap on the monthly number of subsidized prescriptions lower drug costs for the payer, but any savings may be offset by increases in other health care areas. Cost sharing also leads to patients foregoing essential medications and to a decline in health care status.

Rising pharmaceutical expenditures are a fact of life in nearly all industrialized countries. In Canada, spending on drugs increased from 0.44 percent of gross domestic product in 1975 to 1.10 percent in 2000 (1). Over the same period, provincial/territorial government drug spending increased by 3,107 percent, compared with increases of 608 percent for physicians and 472 percent for hospitals (2). Similar increases in drug expenditures are reported for the United States (1, 3).

In an attempt to limit drug program expenditures, public and private drug-payers alike have introduced user fees. User fees require the consumer to assume a portion of the prescription cost; they take many forms, including copayments (a fixed fee for each prescription), coinsurance (a percentage of the total prescription charge), deductibles, removal of drugs from formularies, reimbursement limits, and multitier copayments (4, 5), or a mixture of some or all of these methods. The impact of user fees on drug consumers' costs has likely increased over the last two decades, due to an increased prevalence of user fees (1, 6);

International Journal of Health Services, Volume 34, Number 1, Pages 101–122, 2004

increases in the variety of drugs available, as well as in their prices; and shifts in the location of care from inpatient to outpatient settings, where user fees are typically higher.

In this article we review the literature on the effects of drug user fees on drug use and related outcomes in "vulnerable" groups—that is, those whose drug use is most likely to be affected by user fees. Standard economic theory predicts that the greater the share of one's income spent on drugs, the greater the reduction in drug use following an increase in drug user fees. Intuitively we can predict that as the share of income spent on drugs increases, a given increase in drug fees will further reduce the amount of money available for the consumption of drugs and other commodities, and this will reduce demand for drugs. Hence, drug user fee sensitivity is likely higher among those who spend a large share of their income on drugs—the poor and frequent drug users, such as those with chronic disease. It is for this reason that any adverse effects of drug user fees are probably concentrated in such vulnerable groups. Studies that focus on the sensitivity of drug use to fees in populations that consist largely of healthy individuals, who most likely spend a relatively small share of their income on drugs, will therefore mask the responses of vulnerable individuals.

If consumers had the knowledge necessary to discriminate between drugs that are essential to their health and those that are not essential, they could mitigate the adverse health consequences of reduced drug use. However, because consumers typically lack such knowledge, drug user fees, while effective at reducing program expenditures, might inadvertently result in poorer health outcomes. If health status does decline, one implication is that in a system that includes public subsidies for physicians' and hospital-based services (Medicare in Canada, Medicare and Medicaid in the United States), increased public spending on other health services might offset cost savings on drugs.

Previous reviews on the effects of cost-sharing for pharmaceuticals are dated, have not specifically analyzed the effects on the most vulnerable populations of drug users, or were nonsystematic and focused on studies in the United States (7–10). Our aim is to conduct a review of the international literature focusing on the effects of cost sharing on drug use, physician prescribing behavior, patient health status, individual and drug plan expenditures and use, and expenditures on physicians' and hospital-based services among the poor and those with chronic health problems.

METHODS

Information on cost sharing was gathered in English and French from MEDLINE (JL) and in English from HealthSTAR and EconLit (PG), covering the period January 1, 1977, to August 31, 2002. The MEDLINE and HealthSTAR searches used the following terms alone and in combination: budgets, copayment, cost control, cost sharing, deductibles and coinsurance, drug costs, drug utilization, fee,

reimbursement mechanisms. The search terms for EconLit were (drug OR pharma*) AND (cost sharing OR copayment OR fee OR deductible OR coinsurance OR elasticit*). Articles identified through these searches were supplemented with those in our extensive files.

Sources identified through these two methods were evaluated for original studies on the effects of any form of drug user fees in the ambulatory care setting in vulnerable populations. We a priori defined vulnerable populations as those receiving social assistance, the poor, the near poor or those with low income (as defined by the study authors), those receiving Medicaid, those with chronic diseases, and those in poor health (as defined by the study authors). We included studies that compared people in vulnerable populations that had drug insurance with those that did not, on the grounds that a lack of coverage is equivalent to 100 percent coinsurance. We excluded studies on the elderly (≥65 years of age) unless there was a predefined subset of poor or chronically ill elderly, as this is a heterogeneous group comprised of individuals with a wide range of income and health status.

We considered only results obtained from research in developed countries (those belonging to the Organization for Economic Cooperation and Development). All studies that assessed the effects of actual changes in drug user fees on outcome variables and quantified their results were eligible for inclusion, regardless of methodology. Where possible, results were converted to elasticities, defined as the percentage change in the outcome variable (such as drug use) due to a 1 percent increase in drug user fees, to facilitate the comparison of studies that used heterogeneous drug fee and outcome measurement units. Hence an elasticity of –0.3 means that a 10 percent increase in fees would reduce drug use by 3 percent. In cases of duplicate publication, we chose the most comprehensive report. Earlier reviews were excluded from the analysis, but we identified additional material from reference lists in reviews and in original studies.

The following information was extracted from each article: time period of the study; jurisdiction or geographic location; socioeconomic and/or demographic characteristics of the subjects studied (age, income status, employment status); outcome measurement(s); nature of the variation in user fees; study design; nature of the data used; and results. No attempt was made to blind the studies. Information was abstracted by both authors, and we resolved differences by consensus. Prices are reported in U.S. dollars unless otherwise stated.

RESULTS

Scope of the Research

A total of 25 studies (11–35) satisfied our inclusion criteria. One observational study (35) was excluded from further analysis because it was based on a sample of just 19 Medicaid recipients. Table 1 (pp. 108–117) summarizes the studies that

form the basis for this review. The remaining 24 papers came from either the United States (12–15, 19–31) or Canada (11, 16–18, 32), with the exception of single studies from Belgium (33) and New Zealand (34). The groups analyzed were those with low income (social assistance, Medicaid, poor or near poor) (11–14, 17–24, 26–29, 31–34), those with significant health problems (poor health, chronically ill) (14, 16, 22, 25, 30), and the chronically ill poor (15). All the studies were observational; 14 were before-and-after time series (11, 15, 17–21, 23, 24, 26–28, 32, 33) and the remainder were cross-sectional analyses (12–14, 16, 22, 25, 29–31, 34).

Overall Prescription Drug Use

Studies that compared the use of prescription medications by the poor (13,14, 17, 22, 29) and by those in poor health (14, 16, 22, 25, 30) with and without insurance uniformly found that those with insurance had higher usage. These results were found in single U.S. states (13), in representative samples in the United States (14, 22, 25, 29, 30), and in two Canadian provinces (16, 17). Most, but not all (25), of these studies attempted to control for the fact that individuals with poorer health and higher expected drug use are more likely to find insurance worthwhile. This selection bias can generate a spurious positive correlation between insurance coverage and drug use.

Other studies focused on changes in drug user fees (i.e., copayments, deductibles, or caps on the number of prescriptions dispensed) among insured individuals. Almost all studies found that drug user fees decrease drug use in vulnerable groups (11, 15, 20, 21, 23, 25, 26, 28, 31–33). The two studies with contrary results assessed the effects of drug user fees on use of asthma medicines: one among children in the province of Manitoba (18) and the other from New Zealand that examined patients' collection of asthma drugs once a prescription had been presented to a pharmacy (34). In some studies, drug use was particularly sensitive to fees. Even relatively small copayments (on the order of $0.50, in 1979 dollars) reduced drug use by 26 percent among low-income drug users (21). In the Quebec public drug plan for low-income residents, the introduction of copayments subject to a maximum quarterly out-of-pocket limit of $50 (Canadian dollars) resulted in a nonrenewal rate of inhaled corticosteroids of between 23 and 40 percent, depending on the age group, versus a nonrenewal in the control group of 9 to 13 percent (11).

Elasticity estimates were produced in several studies. Coulson and Stuart (12) estimated the drug user fee elasticity associated with the introduction of a $4 copayment in a low-income Medicare population at –0.34. Grootendorst and colleagues (16) estimated elasticities for the number of different drugs consumed with respect to drug fees to be in the range of –0.11 to –0.13 in a population with lower health status. Low-income single elderly men in British Columbia were particularly responsive to drug fees (elasticity of approximately –0.50),

although low-income single elderly women were much less price responsive (17). These values are broadly in line with a study from Belgium with an elasticity estimate of –0.40 for low-income retirees (33).

Physician Prescribing Behavior

In a study of Medicaid beneficiaries, there was no change in prescription size following the introduction of a copayment of $0.50 (21). Doctors in Minneapolis prescribed 27 percent fewer high-cost and 27 percent more low-cost antibiotics to near-poor children following the introduction of a copayment (24). Fortess and coworkers (15) noted that physicians working in group practices or clinics are somewhat more able to mitigate the effects of a cap on the number of monthly prescriptions than those practicing solo or in small groups.

Use of Health Services and Patient's Health Status

Most of the literature assesses the effects of drug fees on drug use; relatively few reports consider the implications of changes in drug use for health status, which is perhaps the more relevant outcome for policy purposes. Several studies, however, address this latter issue indirectly by assessing the effects of drug fees on the use of various essential medications—that is, drugs that prevent deterioration in health or extend life. Other studies have tracked the use of health service–based indicators of health deterioration (such as admission to long-term care facilities). One study monitored mortality rates after drug user fees were increased.

Tamblyn and colleagues (32) found that increases in drug fees (from $0 to a system of coinsurance and deductibles, subject to a maximum of $50 per quarter in patient's expenditure), led to a 14 percent reduction in the use of a group of essential medications, including insulin, antihypertensives, anticoagulants, lipid-reducing medication, antiarrhythmics, antiviral medication, thyroid medication, and neuroleptics. The reduction in essential medications use, in turn, was associated with a 78 percent increase in emergency room admission rates and an 88 percent increase in adverse events rates (defined as the first occurrence of acute care hospitalization, long-term care admission, or death). Blais and colleagues (11) found that the same cost-sharing changes in Quebec led to 14 to 27 percent reductions (depending on age) in refill rates for inhaled corticosteroids among low-income asthmatics. However, there was no discernible impact on hospitalizations or emergency room visits in the 11 months after cost sharing was introduced.

Three studies of U.S. Medicaid beneficiaries have documented decreases in the use of essential medications as a result of monthly caps on the number of allowable prescriptions (15, 20, 26). Martin and McMillan (20) found that the tightening of a cap from six to five reimbursable prescriptions per month led to a decrease in the use of essential medications in several, but not all, therapeutic

groups, but they did not examine the consequences on health services or health. Soumerai and colleagues conducted several analyses of drug and health services use by New Hampshire Medicaid beneficiaries before and after the introduction of a cap of three reimbursable prescriptions per month. Trends in the same outcomes for Medicaid beneficiaries in a neighboring state (New Jersey), where no such cap was imposed, were used to control for secular trends. The finding was that the introduction of the cap reduced essential drug use by 28 percent (26). In this same Medicaid population, among those who were chronically ill, there was a decrease of 34.4 percent in standard doses of essential medications, with the largest relative reductions associated with the presence of diagnoses of psychoses/bipolar disorders, anxiety/sleep problems, and chronic pain (15). The cap also resulted in an overall 1.8-fold increase in the relative risk of admission to nursing homes (27) and an increase in the use of emergency mental health services among those with schizophrenia (28).

Expenditures on Medications by Drug Plans and by Individuals

In a study of Medicaid patients in South Carolina, the use of a relatively small copayment ($0.50) led to an average 39 percent reduction in the cost to Medicaid of a prescription (21) and to a decrease in overall cost for four of ten drug groups (23). A second study of Georgia Medicaid patients found that a reduction in the monthly limit from six to five reimbursable prescriptions led to an almost 10 percent increase in out-of-pocket expenses (20).

Lack of drug coverage for those below the poverty line and those with five or more chronic conditions led to significantly higher out-of-pocket spending on medications. The poor with coverage spent 3.3 percent of their total income on drugs, compared with 27.8 percent for those without coverage; figures for the chronically ill were 3.1 and 11.0 percent, respectively (14). Although those below the poverty line and those with poor health status who lack coverage spend less overall on prescription drugs and use fewer drugs than those with coverage, their annual average out-of-pocket expenditures are significantly higher (below the poverty line: with coverage, $200 vs. without, $368; poor health status: with coverage, $423 vs. without, $749) (22).

Overall Health Care Costs

Two studies have examined the effects of drug user fees on the costs of hospital and physicians' services. A study of the introduction of a three reimbursable prescription limit among New Jersey Medicaid beneficiaries with schizophrenia found that while the policy reduced psychiatric drug costs by $5.14 per beneficiary per month, there was a corresponding increase of $139 per month in the use of other psychiatric services (28). Lingle and colleagues (19) assessed the impact of

the introduction of drug subsidies for low-income elderly in New Jersey on the change in the cost of hospital and physicians' services provided to this group; an external comparison group (Pennsylvania Medicare beneficiaries) was used to control for secular trends. The drug subsidy did not appear to affect outpatient health care costs, but was associated with a drop of $239 per beneficiary in inpatient hospital costs. Since there was no change in inpatient hospital utilization, the authors speculate that the savings in hospital costs were due to a change in either the length of stay or the number of services utilized, or some combination of both.

DISCUSSION

Virtually every article we reviewed supports the view that cost sharing through the use of copayments or deductibles decreases the use of prescription drugs by the poor and the chronically ill. All these studies are observational, raising the possibility that the observed negative correlation between drug fees and drug use is due to their respective correlation with a third, unmeasured variable. Nevertheless, the conclusions of these studies were largely invariant with respect to the study design used: cross-sectional with regression-based adjustment for differences in subject characteristics (12, 16, 25, 31); before-and-after time series, with regression controls for secular time trends and other covariates (15, 17, 20, 23, 32, 33); or time series with an external comparison group not exposed to changes in drug prices that was thought to be otherwise similar to the group that was exposed (11, 18, 21, 26, 28). Only one study—the one showing no effect of drug prices on prescription pickup rates from pharmacies (34)—failed to use any form of statistical adjustment. In the other study that did not show any negative effects of user fees, the change in coverage was structured such that for a family with typical prescription costs of $980 (Canadian dollars) per year, the absolute amount paid out-of-pocket in deductibles for low-income families (2 percent for family income ≤ $15,000) was lower than under the former scheme. For higher-income families (family income > $15,000), the 3 percent deductible meant that once family income exceeded $17,800, out-of-pocket expenditures were greater than they had previously been (18).

Overall, our findings are consistent with the prediction of economic theory that the larger the share of income spent on prescription drugs, the higher the degree of price sensitivity. We generally found drug price elasticities among vulnerable groups—those with low income and/or chronic illnesses—to be –0.34 to –0.50. These estimates are considerably larger than the –0.10 to –0.20 range reported by Smith and Kirking (36) for nonvulnerable populations. (The exception was Grootendorst and coworkers' finding (16) of similar elasticities (–0.11 to –0.13) in a population with lower health status. However, unlike most other studies, their outcome measure—the number of different drugs taken—is responsive to the number of drugs dropped or added as a result of changes in drug fees, but not to

Table 1

Synopsis of studies on the effects of prescription-drug cost sharing on drug use

Authors	Dates	Study population (data source)	Outcomes	Price variation	Design	Results
Blais et al. (11)	1995–1997	Quebec social assistance recipients (administrative claims data)	Use of inhaled corticosteroids for asthma and use of health services	Change from no copayment or deductible to quarterly deductible of $50 (Canadian dollars)	Before-and-after time series; historical control group	Age group 18–34, 40% nonrenewal of medication vs. 13% in controls; age group 35–64, nonrenewal rates 23% and 9%, respectively; ↔ in use of health services (hospitalizations or emergency department visits) in first 11 months after change
Coulson and Stuart (12)	1990	4,066 low-income Pennsylvania Medicare recipients, age 65+ (mail survey merged with administrative claims data)	Number of prescriptions filled in 2-week period	Introduction of $4 copay in supple-mental state drug subsidy program for low-income	Cross-sectional; regression controls; adjustment for sample selection	Elasticity –0.34

Coulson et al. (13)	1990	4,509 low-income Pennsylvania Medicare recipients, age 65+ (mail survey)	Number of prescriptions filled in 2-week period	Supplemental insurance coverage status for drugs and physician visits	Cross-sectional; regression controls; adjustment for sample selection	Those with supplemental drug and doctor insurance refill 1.42× more prescriptions over a 2-week period than those with no coverage; those with just supplemental drug insurance refill 1.05× more prescriptions
Department of Health and Human Services (14)	1996	Medicare recipients across United States (Medicare Current Beneficiary Survey), stratified by self-reported health status	Number of prescriptions filled; total drug expenditure; percent not able to afford needed drug	Presence or absence of prescription drug coverage	Cross-sectional comparison of means with and without drug insurance, by level of self-assessed health status	Cf. those without coverage, those with drug coverage fill 10%–26% more prescriptions and incur 45%–101% higher drug expenditures, depending on level of health status; percent of those below poverty line not receiving prescription medication because of cost: with coverage 7.6%, without coverage 21.0%

Table 1 (Cont'd.)

Authors	Dates	Study population (data source)	Outcomes	Price variation	Design	Results
Fortess et al. (15)	1980–1983	Chronically ill Medicaid recipients in New Hampshire—49% age 60–74; 51% age 75+ (administrative claims data)	Standard monthly dose of essential medications	Introduction of cap of 3 reimbursable prescriptions per month	Before-and-after time series; regression controls	↓ 34.4% in standard doses of essential medications; comorbidities associated with largest relative reduction: psychoses/bipolar disorders, anxiety/sleep problems; chronic pain; patients in group practices, clinics, or hospitals had smaller dose reductions than those whose physicians work solo or in small groups
Grootendorst et al. (16)	1990	Noninstitutionalized Ontario residents, age 55–75 (1990 Ontario Health Survey)	Number of different drugs taken in 4-week period	Provision of first-dollar public drug coverage at age 65 (equivalent to comparing those with and without supplemental insurance)	Cross-sectional; regression controls	↑ in use of prescription drugs upon eligibility, primarily among persons with lower health status (elasticity –0.11 to –0.13)

Grootendorst (17)	1985–1992	Noninstitutionalized British Columbia residents who turned 65 during time period of study (administrative claims data)	Real annual prescription drug expenditures	Provision of enhanced public drug coverage at age 65 (<65: varying deductibles; ≥65: 100% of ingredient cost + dispensing fee copay)	Before-and-after time series; regression controls	↔ for most individuals; ↑ for low-income males (elasticity –0.50)
Kozyrskyj et al. (18)	1995–1998	Children with asthma in Manitoba, by family income level—family income below and above $15,000 (Canadian dollars) (administrative claims data)	Use of inhaled corticosteroid medication	Change from fixed deductible and copayment system to income-based deductible system; before change, annual family deductible of $237, after deductible reached 40% copayment; after change, deductible of 2% if income ≤$15,000 and 3% if income >$15,000, no copayment	Before-and-after time series; control group (children insured under other drug programs); regression controls	↓ in use of corticosteroids by higher-income group with severe asthma cf. control group; ↔ in use by low-income children cf. control group
Lingle et al. (19)	1975, 1979	Medicare recipients in New Jersey, age 65+ (administrative claims data)	Use and costs of hospital, physician, and other health care services	Introduction in 1977 of state drug subsidies for low-income elderly in New Jersey	Before-and-after time series with control group (Pennsylvania Medicare)	↓ $238.50 in inpatient expenses (likely due to less intensive care per hospital admission)

Table 1 (Cont'd.)

Authors	Dates	Study population (data source)	Outcomes	Price variation	Design	Results
Martin and McMillan (20)	1991–1992	Georgia Medicaid recipients, nonelderly and elderly low-income, who filled at least 6 prescriptions per month for 6 months before policy change (administrative data)	Number of prescriptions filled, both Medicaid-paid and beneficiary-paid	Reduction in monthly limit from 6 to 5 reimbursable prescriptions	Before-and-after time series; regression controls	↓ 6.6% in total prescription use; ↓ 9.9% in prescriptions reimbursed by Medicaid; ↑ 9.7% in prescriptions paid out-of-pocket; ↓ in use for some essential therapeutic groups but not others
Nelson et al. (21)	1976–1979	Medicaid recipients in South Carolina using 5+ prescriptions in year prior to copay; two-thirds age ≥60, one-third age <60 (administrative claims data)	Number of prescriptions; average cost per prescription	Introduction of $0.50 copay	Before-and-after time series with control group (Tennessee Medicaid recipients)	↓ 26% in number of prescriptions; ↓ 39% in average cost per prescription; ↔ in number of units per prescription

Poisal and Chulis (22)	1996	Medicare beneficiaries across United States (1996 Medicare Current Beneficiary Survey)	Number of prescriptions; total drug expenditures	Presence or absence of drug insurance coverage	Comparison of mean outcomes among those with and without drug insurance, by level of self-assessed health status	Cf. those without coverage, those with drug coverage fill 19%–43% more prescriptions and incur 45%–100% higher drug expenditures, depending on level of health status
Reeder and Nelson (23)	1976–1979	Medicaid recipients in South Carolina using 6+ prescriptions in year prior to copay; two-thirds age ≥60, one-third age <60 (administrative claims data)	Drug expenditures in 10 different therapeutic drug groups	Introduction of $0.50 copay	Before-and-after time series; regression controls	↓ in long-term use and Medicaid costs in 4 of 10 groups: cardiovascular, cholinergic, diuretic, and psychotherapeutic (cardiovascular and diuretic considered essential)
Scott et al. (24)	c. 1983	Near-poor, Medicaid ineligible children in urban health center in Minneapolis (retrospective patient chart review)	Percent of episodes of upper respiratory and otitis media infections, treated with low-cost vs. high-cost antibiotic	Introduction of copay (of unknown size) for prescription drugs	Before-and-after time series; control group (Medicaid eligible children)	↓ 27% in use of high-cost antibiotics; ↑ 27% in use of low-cost antibiotics

Table 1 (Cont'd.)

Authors	Dates	Study population (data source)	Outcomes	Price variation	Design	Results
Shih (25)	1993–1997	Patients enrolled in Medicare End Stage Renal Disease program (Dialysis Morbidity and Mortality Study data)	Number of medications dispensed	Variation in supplemental drug insurance status (Medicaid, employment plans, Medicare HMOs)	Cross-sectional; regression controls; no adjustment for sample selection bias	↑ 9%–10% in number of prescription drugs per person with supplemental drug insurance coverage
Soumerai et al. (26)	1980–1983	Medicaid recipients in New Hampshire; nonelderly, average age 56 ± 19 (administrative claims data)	Number of prescriptions for discretionary and essential drugs	Introduction of cap of 3 reimbursable prescriptions per month; replacement of cap by $1.00 copay	Before-and-after time series; control group (New Jersey Medicaid recipients)	After cap: ↓ 30% in number of prescriptions; ↓ 58% in discretionary drugs; ↓ 28% in essential drugs (however, largest reductions in absolute drug use for several essential drugs) After copay: return to just below precap levels
Soumarai et al. (27)	1980–1983	Medicaid recipients in New Hampshire; elderly, age >60 (administrative claims data)	Admissions to nursing homes and hospitals	Introduction of cap of 3 reimbursable prescriptions per month; replacement of cap by $1.00 copay	Before-and-after time series; control group (New Jersey Medicaid recipients)	After cap: ↑ 1.8 relative risk of admission to nursing home; ↔ hospital admission After copay: end of excess risk of nursing home admission

Soumerai et al. (28)	1980–1983	Medicaid recipients in New Hampshire with schizophrenia; nonelderly (administrative claims data)	Use of psychotropic drugs, acute mental health care, overall mental health care costs	Introduction of cap of 3 reimbursable prescriptions per month; replacement of cap by $1.00 copay	Before-and-after time series; control group (New Jersey Medicaid recipients)	After cap: ↓ 15%–49% in use of various psychotropic drugs; ↑ in use of emergency mental health services and partial hospitalization; ↑ in mental health care costs 17× greater than drug savings After copay: drug use and services revert to precap levels
Steinman et al. (29)	1995–1996	Americans age ≥70 (Survey of Asset and Health Dynamics among the Oldest Old)	Indicator of use of fewer medications than prescribed due to medication cost	Variation in prescription coverage (none, some, full)	Cross-sectional; regression controls	For those with income <$10,000, odds of noncompliance 15× higher in those with no drug coverage vs. those with full coverage
Stuart et al. (30)	1996	Medicare recipients across United States (Medicare Current Beneficiary Survey)	Number of prescriptions used	Variation in prescription coverage	Cross-sectional; no adjustment for sample selection bias	Among those in poor health, those with no coverage filled 35% fewer prescriptions than those always covered

Table 1 (Cont'd.)

Authors	Dates	Study population (data source)	Outcomes	Price variation	Design	Results
Stuart and Zacker (31)	1992	Medicaid-eligible, typically lower-income, seniors (Medicare Current Beneficiary Survey)	Probability of any prescription drug use; number of prescriptions filled in subsample of users	Variation in state-specific Medicaid copays: 18 states without copayment and 21 with ($0.50–$3.00)	Cross-sectional; regression controls; copayment dependent on place of residence	↓ 12% in probability of prescription drug use, and ↓ 7% in prescriptions filled among users in copayment states cf. states without copayments; differences in drug use more pronounced for those in poor health
Tamblyn et al. (32)	1993–1997	Social Assistance recipients in Quebec (administrative claims data)	Use of prescription drugs (both essential and discretionary); ambulatory and inpatient health services	Change from no copayment to coinsurance and deductibles with maximum quarterly charge of $50 (Canadian dollars)	Before-and-after time series; no control group	↓ 22% in use of discretionary drugs, and ↓ 14% in use of essential drugs; ↑ 78% in adverse event rate (first occurrence of acute care hospitalization, long-term care admission, or death); ↑ 88% in emergency department visit rate

Van Doorslaer (33)	1977–1981	Belgian National Health Insurance beneficiaries (administrative claims data)	Total number of prescriptions reimbursed	Replacement of fixed copay with proportional copay differentiated by therapeutic and beneficiary class	Before-and-after time series; regression controls	Elasticity –0.6 for general population; –0.40 for low-income retirees; 0 for higher income retirees
Watt et al. (34)	May–June 1991	Asthma patients in Wellington area of New Zealand (primary data collection at 30 pharmacies)	Patients' collection of asthma drugs after prescription presented to pharmacy	Increased copayment from $2 to $5 (New Zealand dollars) for children, chronically ill, and low-income; increase from $5 to $15 for all others; concurrent increase of maximum annual patient expenditure from $125 to $150	Cross-sectional; no regression or other controls	No effects of copayments once prescription presented for dispensing

changes in the amount of a particular drug taken.) More recent studies support the conclusion that spending a larger percentage of income on prescription drugs is associated with greater price sensitivity. For example, Motheral and Henderson report that working individuals who receive drug insurance as an employment benefit do not discontinue chronic medications when copayments are increased (37); nor does their use of other medical resources increase (5).

Instituting copayments or placing a cap on the monthly number of subsidized prescriptions does lower drug costs for the payer (21, 23), but this is probably at the expense of transferring costs onto the poor and chronically ill (14, 20). Similarly, any savings in drug costs may be illusory, as increases in other health care areas more than offset the decrease in medication costs (28). On the other hand, easing access to prescription drugs for the poor lowers hospital costs (19).

Physicians have a dominant role in the prescription decision, including the decision to use medications versus other forms of health care, and the choice of medication used. It is possible that physicians mitigate the effect of drug user fees on costs borne by their vulnerable patients by substituting lower-cost drugs or perhaps increasing prescription size (if the cost-sharing is a fixed amount per prescription). At this point, there has been too little research to reach any definite conclusions about the effects of cost sharing on prescribing patterns.

Finally, and most importantly, in most studies reviewed, cost sharing leads to patients foregoing essential medications and increases in use of emergency services, nursing home admissions, and serious adverse events. Blais and colleagues (11) found that although the group affected by copayments in Quebec had a greater reduction in the use of inhaled corticosteroids than a control group, there was no increase in hospitalizations or emergency department visits in the first 11 months after the policy change. The lack of an effect on use of health services may have been due to either a focus on short-term events or the inappropriate use of inhaled corticosteroids before the cost-sharing increase.

The literature that we reviewed may have actually underestimated the negative consequences of cost sharing, given the relatively short period covered in nearly all studies. For instance, in the longer run, it is entirely possible that if drug fees are deleterious to human health, they could increase drug spending and possibly totally offset any initial savings, so that drug expenditures end up increasing. At this point, this possibility is speculation on our part and will need to be confirmed or refuted through long-term studies.

Limitations of the Review

To some extent our conclusions need to be tempered by the limitations of our review—one internal and the other external. The internal limitation is the possibility that we could have missed some studies, as much of the work in this area is reported in "gray literature" that may have been overlooked by our search

methods. However, our conclusions about the negative economic and health impacts of cost sharing on vulnerable members of the population are widely supported by the studies we did find, and it would take a substantial amount of "hidden" literature to overturn our conclusions.

The external limitation is the quality of the literature that is available for evaluation. To identify the effect of user fees on drug use and related outcomes, one needs to control for variables correlated with both the unobserved component of the outcome variable (i.e., the component of the outcome variable that remains after controlling for confounders) and the user fee. Threats to the validity of conclusions can come from sample selection biases, endogenous policy changes, omitted confounding variables, and regression to the mean.

Sample selection bias is introduced when individuals with a relatively high anticipated need for prescription drugs, who very likely find insurance coverage most valuable, are more likely to obtain coverage. Failure to control for health status and other measures of anticipated drug use might therefore bias upwards the estimated effect of drug insurance coverage on drug use. Most of the studies do not compare subjects with and without drug insurance, but instead exploit cross-sectional (12, 16, 25, 34) or time-series variation (11, 15, 18, 20, 21, 23, 24, 26–28, 32, 33) in user fees. Nevertheless, in some cases changes in user fees might have been endogenously generated. Insurance holders clearly do not "choose" the drug fee, and one might therefore conclude that fees do not depend on drug use. But it is plausible that insurance executives increase drug fees *in response* to growing drug expenditures (38). In this case, the absolute value of the elasticity might be underestimated, unless one controls for the determinants of fee increases.

Even if changes in user fees are exogenously determined, other problems remain. First, in response to substantially higher user fees, drug insurance program beneficiaries might elect to purchase supplementary drug insurance. This confounding effect probably cannot be controlled for in the numerous studies that use administrative claims data (11, 12, 14, 15, 17–21, 23, 26–28, 32, 33), although in a poor and/or chronically ill population the ability to purchase supplementary insurance will be limited and this may not be a significant factor. Second, other, unmeasured variables might be correlated with the fee changes and unobserved outcomes. Finally, studies that examine the effects of drug fees on multiple-drug users (20, 21, 26–28) might be biased by regression to the mean—that is, the drug use of some subjects will have been atypically high and will have declined over time, whereas subjects with atypically low use will have been excluded from the sample.

As with the case of possibly missing studies, the ability of these quality limitations to alter our conclusions must be seen in the light of the overwhelming direction of the message that comes from the literature. We believe that any potential biases introduced cannot seriously weaken the nature of our findings.

Policy Implications

The rising prices of new drugs coupled with the increasing intensity of services will continue to put pressure on governments to contain costs. As we have shown in this review, there are likely to be adverse health and economic consequences to cost sharing for the most price-sensitive groups—low-income and chronically ill. One way of possibly mitigating the effects of cost sharing on these groups would be to encourage physicians who serve large numbers of vulnerable patients to work in large group practices (15).

Whatever policy changes are made in this area need to be closely evaluated. In the past, changes have been made without any prior objective research evidence and without plans to study downstream effects of policy changes. The study by Tamblyn and colleagues (32) on the consequences of the introduction of large copayments in Quebec is the exception. In many cases, it seems that changes were made purely because of an ideological position (39). This review is an attempt to replace ideology with evidence.

Acknowledgments — Joel Lexchin received funding from the Seniors Independence Research Program National Consensus Process, NHRDP Grant No. 6606-6486-006. Paul Grootendorst is the recipient of a Research Career Award in Health Sciences from the Rx&D Health Research Foundation—Canadian Institutes for Health Research.

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