Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997–2000

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Background: **Generic substitution is one mechanism of curtailing prescription drug expenditures. Limited information is available about the potential savings associated with generic substitution.**

Objective: **To estimate the potential savings associated with broad substitution of generic drugs.**

Design: **Cross-sectional, nationally representative survey of noninstitutionalized adults.**

Setting: **United States.**

Participants: **Adults included in the Medical Expenditure Panel Survey Household Component, 1997–2000.**

Measurements: **Use of a multisource drug (that is, a drug available in a brand-name and ≥1 generic formulation) or a generic drug and the potential cost savings associated with broad generic substitution for all multisource products.**

Results: **Fifty-six percent of all outpatient drugs were multisource products, accounting for 41% of total outpatient drug expenditures. Of these multisource drugs, 61% were dispensed as a generic. If a generic had been substituted for all corresponding brand-name outpatient drugs in 2000, the median annual savings in drug expenditures per person would have been $45.89 (interquartile range, $10.35 to 158.06) for adults younger than 65 years of age and $78.05 (interquartile range, $19.94 to $241.72) for adults at least 65 years of age. In these age groups, the national savings would have been $5.9 billion (95% CI, $5.5 billion to $6.2 billion) and $2.9 billion (CI, $2.6 billion to $3.1 billion), respectively, representing approximately 11% of drug expenditures.**

Limitations: **Specific information about an individual's formulary was not available, so the authors could not estimate how much of the potential savings would benefit an individual or his or her health plan.**

Conclusion: **Although broad substitution of generic drugs would affect only a modest percentage of drug expenditures, it could result in substantial absolute savings.**

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Prescription drug spending is increasing at a rate of over 10% per year and currently represents 11% of all health care expenditures (1). In 2001, expenditures for prescription drugs in the United States were $141 billion (1). The passage of a Medicare prescription drug benefit has resulted in much debate about the cost of this coverage. The program is designed to offer $410 billion in new drug benefits over a 10-year period (2). Containment of drug spending will be central to the stability of this benefit as well as health care expenditures in general.

Generic drugs are typically less expensive than brand-name drugs, and prices for generics have historically increased less than those for brand-name drugs (3). The U.S. Food and Drug Administration examines generic formulations and approves them as bioequivalent to brand-name drugs in safety, strength, and quality (4). Although the bioequivalence of some drugs is controversial (5–7), generic drugs are widely believed to provide the same therapeutic effects as their brand-name alternatives (4).

Use of a generic formulation instead of a brand name for multisource drugs (that is, those with ≥1 generic available) could be one mechanism for limiting drug expenditures. Since the 1980s, almost every state has enacted laws to allow and in some cases mandate generic substitution (8). Patients, physicians, and pharmacists may also influence whether a generic is dispensed for a multisource product (9–15). A study of Medicaid prescription drug spending in 2000 found that $229 million, approximately 1% of the total amount reimbursed for prescription drugs by Medicaid, could have been saved by wider use of generic drugs (16). Despite the importance of this issue, we know of no estimates of the potential savings associated with greater generic substitution in populations other than Medicaid beneficiaries.

The objectives of this study were to estimate the use of multisource drugs, specifically generic formulations, among a nationally representative sample of adults. We also estimated the potential savings associated with broad substitution of generic drugs for all multisource products. Because of their implications for the Medicare drug benefit, our findings are stratified by age.

METHODS

Data

This analysis is based on data from the 1997–2000 Medical Expenditure Panel Survey Household Component

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Web-Only
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Context

The cost of prescription drugs is of great concern to Americans. The substitution of cheaper generic drugs for more expensive brand-name drugs might reduce prescription drug costs.

Contribution

Using data from the 1997–2000 Medical Expenditure Panel Survey Household Component, the researchers estimated that substitution of a generic for a brand-name drug whenever available would have saved approximately $46 per year for adults younger than 65 years of age and approximately $78 per year for older adults.

Implication

While the per capita savings of generic substitution appear modest, national savings would be substantial: about $6 billion for adults younger than age 65 years and about $3 billion for older adults.

–The Editors

(MEPS-HC), which involved a nationally representative sample of the civilian, noninstitutionalized U.S. population and was conducted by the Agency for Healthcare Research and Quality (17). The MEPS-HC sample is drawn from respondents to the previous year's National Health Interview Survey (NHIS). The NHIS uses a stratified, multistage probability cluster sampling design to obtain a representative sample of the U.S. population and oversamples persons of African-American and Hispanic ethnicity (18). The MEPS-HC data include sampling weights that reflect the sampling frame and adjustments for household nonresponse. The MEPS-HC provides data on demographic characteristics, health status, insurance coverage, and the utilization of health care services for all individuals in sampled households. Household respondents provided information on the names of all outpatient medications used by each household member and the names and locations of the pharmacies where each medication was obtained (19). They were also asked for permission to request records from these pharmacies. Pharmacy providers were asked to provide the data necessary to assign a National Drug Code, which is specific for manufacturer, ingredients, strength, package size, quantity dispensed, total charge, and sources of payment. The linkage rate between information provided by respondents and data obtained from pharmacies was 67% in 1997, 79% in 1998, 79% in 1999, and 77% in 2000. The Agency for Healthcare Research and Quality performed detailed matching, imputation, consistency checks, sensitivity checks, and reconciliation algorithms (19).

Data for each drug from the First DataBank National Drug Data File were merged with the MEPS data by using the National Drug Code. The National Drug Data File indicates whether a drug is available only as a brand name or as a multisource product; generic status is assigned annually. The National Drug Data File also includes a categorization of the therapeutic class and the average wholesale price for each product. The average wholesale price is the manufacturer's suggested list price for a wholesaler to charge a pharmacy and is typically higher than a pharmacy's actual acquisition cost, particularly for brand-name drugs (3).

Study Sample

Adults who were older than 18 years of age and used at least 1 outpatient multisource product were included in this analysis. Brand-name drugs were included in the analysis only if a generic alternative was available in an identical strength and form. A median of 4 prescriptions per person (range, 1 to 60 prescriptions per person) was included in this sample.

Calculation of Prices and Potential Savings

Because retail prices for medications vary widely and are not uniformly available, we used data from MEPS about the total expenditures for each drug (that is, the amount spent by an individual out-of-pocket plus the amount paid by any insurance coverage). We then calculated the mean total cost per unit (that is, per tablet, tube, vial, or dropper bottle, as appropriate) for each of the 7056 products used by individuals in our sample (that is, we calculated the average per unit cost for all occurrences of each product). The availability of the actual drug expenditures for each product is an improvement over previous estimates of drug costs, which used a standard discount of the average wholesale price because actual expenditures were not available (for example, estimating that all generic drugs cost 75% of the average wholesale price) (20, 21). We then estimated the annual savings that would result if each person in the sample switched from a brand-name drug to a corresponding generic formulation, using the following equation:

$$\text{Annual savings} = \Sigma\ (\text{total units of brand-name product dispensed per year}) \times (\text{average per unit expenditure for brand-name product} - \text{average per unit expenditure for identical generic product}).$$

Using data from 2000, we calculated overall savings from a population perspective (for example, total saved for all people ≥65 years of age) and as median annual savings per person (for example, out-of-pocket savings plus savings to any insurance plan per person). Calculations were done with SAS, version 8 (SAS Institute, Inc., Cary, North Carolina); the sampling weights described earlier were used to account for differences in the probability of sample selection as a result of the clustered design, planned oversampling, and nonresponse. The weighted results therefore represent estimates for the noninstitutionalized U.S. population.

Table 1. **Characteristics of Adults Using at Least 1 Multisource Drug, 1997–2000***

Variable	Persons <65 Years of Age		Persons ≥65 Years of Age	
	Unweighted, *n*	Weighted Value†	Unweighted, *n*	Weighted Value†
Persons	18 474		6007	
Age				
18–29 y	3826	21.0		
30–39 y	4234	23.2		
40–49 y	4691	25.9		
50–64 y	5723	29.9		
65–74 y			3428	57.1
75–84 y			2011	34.1
≥85 y			568	8.9
Women	11 528	60.3	3620	59.5
Race or ethnicity				
White	12 366	77.9	4526	84.5
Black	2298	10.4	745	8.3
Hispanic	3309	8.7	632	5.2
Asian or other	501	3.1	104	2.1
Education				
High school or less	9971	49.0	4199	68.9
College	4319	24.4	878	16.1
Postcollege	4060	26.6	823	15.0
Median household income	18 474	$54 761	6007	$26 274
Insurance				
Uninsured	3188	14.4		
Employer-sponsored alone	11 755	69.0		
Medicaid or other public program	1803	7.6		
Medicare alone	303	1.4	1962	33.4
Medicare with private insurance	217	1.1	3201	57.1
Medicare with Medicaid or other public program	328	1.4	844	9.5
Other	880	5.1		
Chronic conditions				
0	13 858	75.6	3131	52.6
1	3257	17.4	1533	25.1
≥2	1359	7.0	1343	22.3
Median annual number of prescriptions		3		8

* Data were missing for education (n = 231). Totals may not add to 100 because of rounding. Weighted percentages are representative of the noninstitutionalized U.S. population.
† All values are percentages unless otherwise noted.

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RESULTS

Persons Using a Multisource Drug

Fifty-six percent of all prescription medications (345 781 observations that were weighted to represent 3 686 700 000 prescriptions from 1997 to 2000) were multisource drugs, accounting for 41% of total prescription drug expenditures. Of these drugs, 61% were dispensed as a generic. Generic use increased over the course of the study, from 58% in 1997 to 64% in 2000. In 2000, total medication expenditures for adults in MEPS were $53 billion for those younger than age 65 years and $27 billion for those at least 65 years of age.

Among adults who were dispensed a multisource drug in MEPS, approximately 75% were younger than age 65 years and approximately 25% were at least 65 years of age (**Table 1**). Most individuals in both age groups were women and described their race or ethnicity as white. Among individuals younger than 65 years of age, approximately half did not receive education beyond high school; the median household income was $54 761. While most of these working-age adults had employer-sponsored insurance, 14.4% were uninsured and 7.6% were covered by Medicaid or another public program. Most did not report

Table 2. **Characteristics of Multisource Prescriptions Dispensed to Adults***

Therapeutic Drug Class	Persons <65 Years of Age, *weighted %*†	Persons ≥65 Years of Age, *weighted %*‡	Multisource Drugs in Therapeutic Class Dispensed as Generic, *weighted %*	Estimated Annual National Savings Associated with Broad Generic Substitution, *billion $*
Analgesic	10.8	4.9	74.7	0.43
Antiarrhythmic	5.9	4.4	79.5	0.04
Antihistamine	3.9	1.6	24.7	1.23
Anti-infective	7.5	3.4	74.3	0.19
Cardiac	9.9	21.8	35.4	1.93
Central nervous system	2.6	1.0	41.4	0.12
Contraceptive	4.6	0.0	13.8	0.28
Cough or cold	3.4	1.6	76.9	0.04
Diuretic	5.5	12.9	80.4	0.20
Gastrointestinal	4.8	5.3	54.1	1.49
Hormone	6.2	3.4	65.3	0.14
Hypoglycemic	4.1	5.7	43.7	1.37
Psychiatric	10.9	6.2	59.5	0.48
Dermatologic	3.8	2.1	71.3	0.11
Thyroid	0.9	1.3	83.2	0.01
Other§	15.6	24.5	70.5	0.70
Overall			60.7	8.76

* Totals may not add to 100 because of rounding. Weighted percentages are representative of the noninstitutionalized U.S. population.
† 121 920 prescriptions.
‡ 73 893 prescriptions.
§ Includes the following drug classes in persons <65 years of age vs. those ≥65 years of age: anesthetic (0.2% vs. 0.1%); antiobesity (0.2% vs. 0%); asthma (2.8% vs. 2.7%); antineoplastic (0.6% vs. 1.0%); anti-Parkinson (0.6% vs. 0.6%); autonomic (4.8%; vs. 6.7%); hematologic (0.9% vs. 4.2%); electrolyte (1.5% vs. 3.9%); ear, nose, and throat (1.4% vs. 3.0%); immunosuppressant (0.2% vs. 0.1%); sedative (0.6% vs. 0.7%); vitamins (1.5% vs. 1.0%); and unclassified drugs (0.3% vs. 0.6%).

any comorbid conditions. The median annual number of prescriptions dispensed was 3.

Among individuals at least 65 years of age, 68.9% did not receive education beyond high school; the median household income was $26 274. Approximately 33% had only Medicare coverage, 57.1% had additional private coverage, and 9.5% had additional public coverage, including Medicaid. Almost half reported at least 1 comorbid condition. The median annual number of prescriptions dispensed was 8.

Characteristics of Multisource Prescriptions

For individuals younger than 65 years of age, the most common therapeutic classes of multisource drugs dispensed were psychiatric, analgesic, and cardiac (**Table 2**). Among individuals at least 65 years of age, cardiac drugs were the most common drugs dispensed, followed by diuretics and psychiatric drugs. Overall, 60.7% of multisource prescriptions were dispensed as generics. Thyroid medications were most likely to be dispensed as generics, and contraceptives were least likely. Broad generic substitution of antihistamines and cardiac, gastrointestinal, and hypoglycemic agents were each associated with a potential annual savings of more than $1 billion.

Potential Median Annual Savings Associated with Generic Substitution

For adults younger than age 65 years, the median annual per person savings associated with broad generic substitution was $45.89 (interquartile range, $10.35 to 158.06) (**Table 3**). This savings would be shared between an individual and his or her health plan. Median per person savings increased with age and number of chronic conditions, and men saved more than women. Median per person savings were largest for low-income individuals and varied by insurance status.

For adults at least 65 years of age, the median annual per person savings associated with broad generic substitution was $78.05 (interquartile range, $19.94 to $241.72). Median per person savings increased with the number of chronic conditions and varied by insurance status.

National Savings Associated with Generic Substitution

The estimated national savings associated with widespread generic substitution in 2000 was $5.9 billion (95% CI, $5.5 billion to $6.2 billion) per year for adults younger than 65 years of age (11.1% of all drug expenditures) and $2.9 billion (CI, $2.6 billion to $3.1 billion) per year among those at least 65 years of age (10.7% of drug expenditures). From a national perspective, the potential annual savings associated with generic substitution among adults younger than 65 years of age was $4.1 billion for those with employer-sponsored insurance and $388 million for those with Medicaid or public coverage. For adults at least 65 years of age who were dually eligible for Medicare and Medicaid, the potential savings was $1.7 billion per year.

DISCUSSION

These findings suggest that broad generic substitution of outpatient prescription drugs could save approximately $8.8 billion, or approximately 11% of drug expenditures for adults in this sample, in the United States each year. For individuals at least 65 years of age, who are expected to

be eligible for the new Medicare prescription drug benefit, the annual savings is estimated to be $2.9 billion, or approximately 10% of the annualized cost of this coverage after accounting for inflation (2). Despite these considerable societal savings, absolute per person savings would be small.

Although broad generic substitution would only modestly reduce national drug expenditures, the absolute savings, particularly at a time when employers and public programs are struggling with drug expenditures, are significant. Broad dispensing of generic products would achieve savings without compromising safety. Generic drugs are believed to provide therapeutic effects similar to those of their brand-name alternatives (4). The standards and reg-

Table 3. **Potential Per Person Annual Savings in Total Drug Expenditures Associated with Switching from Brand-Name to Generic Formulation, 2000***

Variable	Median (Interquartile Range) in Persons <65 Years of Age, $†	Median (Interquartile Range) in Persons ≥65 Years of Age, $‡
Overall	45.89 (10.35–158.06)	78.05 (19.94–241.72)
Age		
18 –29 y	26.88 (6.28–74.41)	
30 –39 y	37.88 (8.26–106.20)	
40 –49 y	44.39 (10.15–172.94)	
50–64 y	76.10 (15.63–254.87)	
65–74 y		80.05 (20.06–255.05)
75–84 y		80.04 (20.71–248.72)
≥ 85 y		64.50 (13.10–144.69)
Sex		
Male	50.97 (12.05–167.48)	80.99 (25.12–259.41)
Female	44.07 (8.88–155.08)	74.96 (16.47–224.29)
Race or ethnicity		
White	44.39 (9.68–160.61)	75.62 (20.71–235.92)
Black	55.82 (12.97–170.36)	70.14 (11.76–259.50)
Hispanic	50.29 (11.41–145.25)	142.89 (37.34–337.51)
Asian or other	39.72 (12.77–87.64)	82.14 (6.36–300.00)
Education		
High school or less	51.51 (10.90–172.94)	85.48 (22.48–259.06)
College	41.26 (11.15–144.09)	66.38 (12.72–196.06)
Postcollege	39.72 (8.25–152.60)	70.09 (15.31–232.93)
Household income		
Age <65 y		
<$25 000	61.89 (11.22–249.48)	
$25 000–$49 999	43.78 (9.57–162.60)	
$50 000–$74 999	45.89 (10.76–150.48)	
≥$75 000	40.61 (9.72–119.76)	
Age ≥65 y		
$12 000		91.40 (20.71–313.60)
$12 000–$23 999		76.10 (16.34–197.72)
$24 000–$47 999		75.44 (22.48–241.72)
≥$48 000		75.49 (20.29–248.72)
Chronic conditions		
None	39.06 (9.49–143.72)	72.77 (17.41–201.68)
1	60.78 (12.85–197.54)	87.29 (26.12–237.02)
≥2	83.52 (14.96–268.76)	100.36 (21.00–320.59)
Insurance		
Uninsured	43.88 (12.05–148.55)	
Employer-sponsored	41.26 (9.06–148.10)	
Medicaid or other public program	53.20 (8.83–242.48)	
Medicare alone	132.85 (52.02–366.06)	66.27 (15.64–184.08)
Medicare plus private insurance	105.71 (39.89–317.97)	87.29 (22.61–262.56)
Medicare plus Medicaid or other public program	134.44 (13.27–310.17)	122.29 (34.00–326.61)
Individually purchased or other	51.25 (12.30–108.13)	

* *P* values are from Kruskal–Wallis tests comparing median savings across levels of patient characteristics. Each age category (<65 years and ≥65 years) was considered independently.
† $P < 0.05$ for sex; $P < 0.005$ for age, household income, number of chronic conditions, and insurance.
‡ $P < 0.05$ for number of chronic conditions; $P < 0.005$ for insurance.

ulations for manufacturing generic products are the same as for brand-name drugs (22). Recent efforts to remove barriers to generic drug approval suggest that policymakers see an opportunity to control expenditures through greater use of generic drugs (4, 23). However, some have argued that greater generic substitution could limit drug development by pharmaceutical companies because of decreased revenue (24).

Using aggregate data for Medicaid drug payments from 48 states in 2000, Fischer and Avorn (16) estimated that approximately $229 million (approximately 1% of total drug expenditures) could have been saved through wider generic substitution. These data did not include information on the 56% of Medicaid beneficiaries who were covered by a managed care plan in 2000 (25). Our estimate of the savings for persons covered solely by Medicaid was higher, perhaps because our sample included individuals covered by a managed care plan. Differences in the estimates may also be related to differences in the calculations of the cost of prescription medications. Fischer and Avorn's estimate was based on the lowest generic price for each product paid by Medicaid in a particular state, whereas ours was based on the average total cost reported by individuals in MEPS nationwide. Our analysis also estimated savings for individuals with other types of health coverage. Medicaid beneficiaries are likely to use a different array of brand-name and multisource drugs than adults with other forms of health coverage.

Choosing a brand-name drug when a generic is available may be influenced by a variety of factors. State laws regulate generic substitution. While most states permit pharmacists to substitute a generic unless directed by the physician or patient, a minority of states mandate that a pharmacist substitute a generic unless overridden by a physician's order (8). Health plan policies may facilitate the use of generic drugs. However, although tiered formularies may encourage the use of generics, they may also lead to greater out-of-pocket expenditures and even to the discontinuation of long-term medications (26). Reference pricing may encourage greater use of generic drugs by offering reimbursement for the lowest-priced therapeutically equivalent drug (27). Some patients may believe that a brand-name formulation is superior (9, 10), perhaps because direct-to-consumer advertising influences patient beliefs about medications (28). Previous research has shown that physicians and pharmacists play an important role in the decision to choose a brand-name or generic formulation of a drug (11–15).

Our analysis does not include the substitution of drugs within a class (that is, therapeutic substitution). We included only brand-name drugs with an identical generic. Therapeutic substitution of angiotensin-converting enzyme inhibitors has been shown to reduce expenditures without adverse clinical outcomes (29). Future research should more broadly examine the effect of therapeutic substitution on clinical outcomes and expenditures.

Our study has several additional limitations. Because retail drug pricing in the United States varies widely and is proprietary, there are no nationwide data to calculate actual costs or savings. For this reason, we used costs reported in MEPS. We do not have information about formularies or copayments required by health plans for specific products, both of which may influence the utilization of specific medications (26, 30). We also cannot calculate how much of the potential savings would benefit individuals or their health plans. Regardless of the distribution, however, we believe that the savings are important from a societal perspective because they result from curtailing unnecessary expenditures for drugs that have an identical generic available.

Our study examined the potential savings associated with generic substitution through 2000. In subsequent years, several "blockbuster" drugs have lost patent protection (31, 32). Because detailed pharmacy data were available for 67% to 79% of the MEPS sample (depending on the year), our findings underestimate total drug expenditures in the United States. We do not know whether MEPS respondents who used a multisource drug were more or less likely to be matched with a pharmacy claim. Finally, we did not examine the potential savings associated with greater generic substitution among children.

These data provide per person and national estimates of the potential savings associated with broad generic substitution of outpatient prescription drugs for adults. Interventions to stimulate competition in the generic market, to reduce the approval times for generic drugs by the U.S. Food and Drug Administration, and to limit opportunities to extend the patent life of brand-name drugs could increase the potential savings (33, 34). Greater use of generic medications could result in important health care savings in the United States while maintaining quality of care.

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