

**ORIGINAL RESEARCH**

# The effect of insurance-driven medication changes on patient care

Nearly one-quarter of patients in this study encountered problems filling their prescriptions; that led to a mix of adverse outcomes, decreased satisfaction, and increased practice burdens.

**Abstract**

**Purpose** ► Insurance plans periodically change their formularies to enhance medical efficacy and cost savings. Patients face challenges when formulary changes affect their treatment. This study assessed the impact of insurance-driven medication changes on primary care patients and examined implications for patient care.

**Methods** ► We mailed questionnaires to a cross-sectional random sample of 1200 adult patients who had visited one of 3 family medicine practices within the past 6 months, asking them to describe problems they had encountered in filling medication prescriptions. We performed descriptive analyses of the frequency and distribution of demographic variables and conditions being treated. Using logistic regression analysis, we identified demographic and health-related variables independently associated with patient-reported problems caused by formulary changes.

**Results** ► Three variables—a greater number of prescription medications taken, younger patient age, and reliance on government insurance—were independently associated with an increased likelihood of encountering a problem filling a medication. Patients who reported an insurance-related issue filling a new or existing prescription over the past year

(23%) encountered an average of 3 distinct problems. Patients experienced adverse medical outcomes (41%), decreased satisfaction with the health care system (68%), and problems that burdened the physician practice (83%). Formulary changes involving cardiac/hypertension/lipid and neurologic/psychiatric medications caused the most problems.

**Conclusions** ► Insurance-driven medication changes adversely affect patient care and access to treatment, particularly for patients with government insurance. A better understanding of the negative impact of formulary changes on patient care and indirect health care expenditures should inform formulary change practices in order to minimize cost-shifting and maximize continuity of care.

To maintain the cost-effectiveness of health insurance, many organizations, including government agencies, routinely evaluate and choose to adopt alternative treatment modalities. But how do such changes affect patient outcomes? And do near-term cost savings from formulary changes lead to long-term cost benefits?

Chronic disease management and associated complex medication regimens account for most health insurance expenditures.<sup>1,2</sup> Changes to prescription formularies

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**➤**  
**Twenty-three percent of patients reported at least one problem obtaining a prescribed medication due to insurance restrictions.**

are common,<sup>3</sup> with medications being added or removed to reduce costs or to respond to revised practice guidelines.<sup>4,5</sup>

Researchers have examined the clinical risks and merits of changing from one drug to another, as well as the impact of implementing formulary changes on administrative and other costs, overall effectiveness of disease management, and the operational adeptness of health systems.<sup>6-10</sup> Routine formulary changes may yield immediate cost savings, but net costs may increase downstream due to disruptions in patient care.<sup>11,12</sup> Insurance-driven medication changes have also been shown to negatively affect patient adherence to medical treatment and also disease outcomes.<sup>13,14</sup>

Patient-level data related to formulary restrictions are limited,<sup>15</sup> and analyses of patients' experiences of medication changes are rare. A better understanding of patients' experiences in this context could guide interventions to minimize treatment delays and improve outcomes. Our study assessed the effect of insurance-driven medication changes on primary care patients; specifically, the prevalence of difficulty in filling a prescription, resultant problems, and patient characteristics associated with reporting a problem.

## Methods

### Data collection

We mailed questionnaires to a random sample of 1200 adult patients (≥40 years) who had been seen within the previous 6 months at one of 3 family practices in northeastern Ohio. We asked respondents to quantify and describe any insurance-driven problems they encountered while attempting to fill or refill a prescription over the past year. We recorded each respondent's insurance status, the name of the medication at issue and other medications they were taking, and demographic data. Comparative data for age and sex were collected for nonrespondents. The University Hospitals Case Medical Center Institutional Review Board approved all data collection procedures and methods for this cross-sectional study.

### Data analysis

We tabulated and analyzed data from the surveys using Statistical Package for the Social

Sciences (SPSS). We compared age and sex data (using t-test and chi-square test, respectively) between respondents and nonrespondents. We calculated descriptive statistics for all demographic, control, and outcome variables, and computed measures of association between demographic and health-related variables and insurance-driven problems encountered while filling a prescription. Using logistic regression analysis, we identified demographic and health-related variables independently associated with a problematic prescription.

We calculated the frequencies of problems encountered while trying to fill a prescription, and grouped the problems into 3 mutually exclusive categories: adverse medical outcomes, decreased patient satisfaction, and burden on physician practice. Adverse medical outcomes included missed doses of medication, inability to obtain medication, worsened medical condition, new medication adverse effects, and having to go to the emergency department (ED) because of a medication issue. We sorted medications into categories, and calculated the frequency of problems associated with each category.

We based our decision to mail 1200 surveys on a power calculation assuming a 40% response rate and approximately 25% of patients reporting a problem. A sample size of 480 or more provides 80% power to detect moderate differences in characteristics between those reporting a problem and those not reporting a problem.

## Results

Four-hundred thirty-four patients returned the survey (36% response rate). We excluded 6 participants from analysis due to incomplete data for the primary outcome variable (problem with a prescription). Respondents and nonrespondents were similar in sex ratio, but respondents on average were 3 years older ( $P<.001$ ). The average number of prescriptions taken was 3.4, and most patients (85%) had some form of private insurance (TABLE 1). Most patients were female, in good health, and well educated.

Of the 428 study participants, 100 (23%) reported at least one problem obtaining a pre-

TABLE 1

## Demographic variables for patients who did and didn't report problems filling prescriptions

Variable	Total (n=428)	Problem (n=100)	No problem (n=328)	P
Number of prescriptions, mean (SD)	3.4 (3.2)	4.8 (3.2)	3.0 (3.1)	.001
Age, mean (SD)	60.0 (12)	57.8 (13)	60.6 (12)	.04
Sex, n (%)				.02
Male	139 (32)	23 (23)	116 (35)	
Female	289 (68)	77 (77)	212 (65)	
Health status, n (%)				.002
Excellent/very good	342 (81)	69 (70)*	273 (84)*	
Fair/poor	80 (19)	29 (30)*	51 (16)*	
Education, n (%)				.46
High school or less	112 (27)	30 (31)*	82 (25)*	
Some college/trade	140 (33)	31 (33)*	109 (34)*	
College graduate	166 (40)	34 (36)*	132 (41)	
Insurance, n (%)				.001
Government (Medicaid or Medicare)	65 (15)	27 (27)	38 (12)*	
Nongovernment	356 (85)	72 (73)*	284 (88)*	
Practice, n (%)				.005
Semirural	191 (45)	35 (35)	156 (48)	
Suburban	116 (27)	24 (24)	92 (28)	
Urban	121 (28)	41 (41)	80 (24)	

SD, standard deviation.

\*Some data are missing (<2.5%) from columns 2 and 3.

scribed medication due to insurance. Generally, those who experienced a problem were younger, more likely to be female, and reported poorer health status than those reporting no problem (TABLE 1). Additionally, those who encountered a problem were more than twice as likely to rely solely on Medicaid or Medicare, and were also taking more prescription medications. Problems filling a prescription were also reported more often in an urban setting than in suburban or semirural areas.

Using logistic regression, we analyzed a model that included all significant variables (age, total number of prescription drugs taken, sex, health status, insurance type, and practice location). The final logistic regres-

sion model showed statistical significance for only 3 variables: type of insurance, total number of prescription drugs taken, and age. (When we included type of insurance in the analysis, practice location was not associated with a problem filling a prescription.)

Specifically, the independent predictors of an insurance-related problem in filling a prescription were reliance solely on government-provided insurance, as opposed to private insurance or government insurance supplemented with private insurance (odds ratio [OR]=1.90; 95% confidence interval [CI], 1.02-3.61); taking more prescription medications (OR=1.19; 95% CI, 1.10-1.29); and being younger (OR=0.96; 95% CI, 0.94-0.99).

**TABLE 2**

**Resultant problems when patients had at least one insurance-related issue filling a prescription in the previous year**

Problem encountered	Percent of patients reporting problem* (n=100)
<b>Adverse medical outcomes</b>	
Missed doses of medication	23
Couldn't get any medication	19
Medical condition got worse	8
New medication adverse effects	6
Had to go to emergency department	5
<i>Overall any adverse outcome</i>	41
<b>Decreased patient satisfaction</b>	
Got upset with insurance company	44
Got upset with pharmacist	15
Got upset with doctor	12
<i>Overall any decreased satisfaction</i>	68
<b>Increased practice burden</b>	
Had to wait for pharmacist authorization	69
Made extra phone calls to practice	36
Had to get a different medication	36
Had extra doctor visits	13
<i>Overall any increased burden</i>	83

\*Patients reported, on average, 2.9 problems; therefore, categories exceed 100%.

Respondents reporting at least one insurance-driven impediment to filling a prescription encountered an average of 2.9 different types of resultant problems (TABLE 2). Insurance-related problems with medications were not limited to new prescriptions. Of the 100 patients reporting a problem with a medication, 21% had a problem with a new prescription, 42% with a medication they were already taking, and 37% with both a new and a previously prescribed medication.

Forty-one percent of patients reporting a problem experienced adverse medical outcomes. The most serious adverse medical outcomes were reported least often, but occurred nonetheless: worsening of medical condition (8%), new medication adverse

effects (6%), and requiring a visit to the ED (5%). More commonly reported was decreased satisfaction with the health care system (68%). Patients were less likely to report being upset with their physician than their insurance company or pharmacist. Problems that burdened the physician practice were reported most frequently (83%).

TABLE 3 shows the medication categories that were affected when respondents reported at least one problem. Formulary changes or restrictions involving cardiac/hypertension/lipid and neurologic/psychiatric medications were linked to the most problems.

**Discussion**

Nearly one quarter of patients in our sample (23%) experienced problems caused by insurance constraints while they attempted to follow the treatment regimens prescribed by their physicians. Although the most commonly reported insurance-related problems (waiting for pharmacist authorization, making extra phone calls to the physician's office) could be perceived as minor inconveniences, serious consequences were also common. Our study showed that patients who rely solely on Medicaid or Medicare bore the greatest burden of insurance-related obstacles when filling prescriptions, although others were also affected.

Consistent with prior research in Medicare and Medicaid populations, our study found that medication access restrictions can negatively affect patient adherence.<sup>13,16,17</sup> Our study showed that 41% of patients who encountered a problem experienced a medically meaningful adverse outcome; 19% reported they received no medication for their condition. Similarly, a study of Medicare beneficiaries who had failed to fill or refill a prescription found that 20% cited lack of insurance coverage for the medication as a reason for not filling the prescription.<sup>17</sup>

In our study, 23% of patients reported missing doses of their medication due to insurance-related difficulties, and 8% reported a worsening of their medical condition. The increased costs associated with poor chronic care management are well documented.<sup>18</sup> Less well described is the potential net savings produced when insurance formularies

TABLE 3

## Which medication categories were most affected when patients had a problem filling a prescription?

Medication category	Frequency of occurrence
Cardiac/HTN/lipids	23
Neurologic/psychiatric	23
Metabolic/endocrine	16
Gastrointestinal	15
Pain	13
Respiratory	11
Other	9
Dermatologic	7
<b>Total</b>	<b>117*</b>

HTN, hypertension.

\*Total exceeds 100 because some of the 100 patients had problems with medications in more than one category.

are adjusted to expand coverage and lower patient costs for prescription treatments for chronic conditions. In an analysis of cost data from the Pitney-Bowes Corporation, Mahoney<sup>12</sup> revealed a significant net savings in health care costs and lost productivity when treatments for chronic conditions were moved to the lowest tier of the formulary, thereby making them available to health plan participants at the lowest cost.

We could not link patient reports of treatment disruptions empirically to medical outcomes or increased costs, due to the constraints of our research question and study design. However, it is reasonable to suggest that longer-term insurance costs for these patients could, in fact, negate any short-term cost savings generated from formulary restrictions. In particular, the 5% of our patient sample who reported using the ED as a consequence of an insurance-related disruption of their prescribed treatment likely added significant unnecessary cost to their treatment. This effect has been seen in other studies.<sup>19,20</sup> In our study, cardiac/hypertension/lipid medications and medications for neurologic or psychiatric conditions were the most likely to be problematic. In these categories, competition of branded products may contribute

to more frequent formulary changes. Furthermore, increases in morbidity and mortality associated with inadequate treatment of the conditions represented in these 2 categories of medications represent a significant burden to the US health system, including insurers, employers, and individuals.<sup>21-23</sup>

Although patients were less likely to report being upset with their physician than their insurance company or pharmacist, physicians bore a considerable burden for resolving a number of prevalent patient issues. Most of these problems required extra phone calls to the practice, additional medication authorization, or extra office visits. Physicians and their support staff may serve as buffers between patients and the insurance formulary rules, but at significant cost in their time and effort.

Electronic prescribing systems with real-time pharmacy benefit verification may provide additional efficiencies and help physicians and patients avoid some of the problems cited by our respondents. Providers with such systems receive immediate notification of formulary status, including tier and co-pay levels, which can aid in shared decision-making at the point of prescribing. Physicians without access to e-prescribing



**A little more than 40% of patients reporting an insurance-related problem experienced adverse medical outcomes.**

**> Formulary changes involving cardiac/hypertension/lipid and neurologic/psychiatric medications caused the most problems.**

may want to use newer formulary search engines that can check formulary status of medications across multiple insurance plans. However, these electronic tools often fail to account for variations in formularies within the same insurance plan for different employers based on their benefit structure. Still, when a medication is not on formulary or a co-payment is required, the physician may be forced to play the role of apologist for the constraints imposed by the insurance formulary.

In cases where formularies restrict the patient's potential access to a preferred treatment plan, the burden of prior authorizations continues to be borne by physicians. Coverage limitations lead to financial and medical consequences that must be managed in partnership with the patient. A system should be put in place by insurance companies that facilitates out-of-formulary authorizations to prevent lapses in patient care or deleterious changes in medical management.

#### Study limitations

The findings reported here should be interpreted in light of some limitations of this study. The response rate to our mailed patient survey was modest (36%), although typical for this method. The sex mix of respondents was similar to that of nonrespondents, but nonrespondents were slightly younger. Given that younger age is associated with a greater likelihood of experiencing a problem filling a medication, our findings may underestimate the frequency of this dilemma. In addition, our survey asked patients to recall events that occurred over the past year, introducing a potential for recall bias.

While the overall sample size was relatively small (n=428), it is close to the number calculated for sufficient power to conduct the

analyses (n=480). Furthermore, data were collected from 3 distinct patient populations: urban, suburban and semirural. Although the scope of our study included only one geographic region, variability in practice setting lends some tentative support to the generalizability of the findings.

#### Looking forward

As a standard method to control costs and update treatment guidelines, insurance-mediated medication changes will continue to present unique challenges for patients and health care providers. Formulary changes burden the downstream delivery of medical care with expensive administrative responsibilities and disrupt effective disease management and prevention. Until insurance companies and pharmacy benefit managers start paying heed to total costs of care when contemplating formulary changes, physicians should try to identify formulary conflicts as early as possible in the prescribing process so as to save time for all parties later and improve compliance.

As practices proceed toward adoption of electronic health records, e-prescribing, and the Centers for Medicare & Medicaid Services' "meaningful use" criteria, physicians may use systems that provide real-time formulary information, which can flag issues before the patient leaves the exam room. Future research should explore the ways formulary changes might be implemented to provide the strongest continuity of patient care with the least amount of cost shifting. **JFP**

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