Impact of Maine's Medicaid Drug Formulary Change on Non-Medicaid Markets: Spillover Effects of a Restrictive Drug Formulary

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Background: Market penetration of HMOs affect physician practice styles for non-HMO patients.

Objective: To study the impact of a restrictive Medicaid drug formulary on prescribing patterns for other patients, ie, so-called spillover effects.

Design: A before-and-after, 3-state comparison study.

Event: On January 1, 2001, Maine's Medicaid program implemented a restrictive drug formulary for the proton pump inhibitor class, with pantoprazole as the only preferred drug.

Main Outcome Measures: The Medicaid and non-Medicaid market shares of pantoprazole in Maine (vs New Hampshire and Vermont) and among Maine physicians with different Medicaid share of practice.

Results: After 3 months, the market share of pantoprazole in Maine (vs 2 control states) increased 79% among Medicaid prescriptions (vs 1%-2%), 10% among cash prescriptions (vs 3%), and 7% among other third-party payer prescriptions (vs 1%). The market shares increased more among Maine physicians with a higher Medicaid share of practice (high vs middle vs low [market]: 16% vs 8% vs 5% [cash]; 11% vs 5% vs 4% [other third-party payers]). Linear regression results indicate that practicing medicine in Maine leads to a 72% increase in pantoprazole share among Medicaid prescriptions ($P < .001$). In addition, for each 10% Medicaid share of practice in Maine, the share of pantoprazole increases 1.8% among cash prescriptions ($P = .01$) and 1.4% among other third-party payer prescriptions ($P < .001$).

Conclusions: Maine's Medicaid drug formulary generated spillover effects in cash and other third-party payer markets, with somewhat stronger effects in the cash market.

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For editorial comment, see page 648.

This research studies the effects of a restrictive drug formulary of one third-party payer on a physician's prescribing patterns, not only for patients of that specific payer but also for other patients. The size of the latter, so-called spillover effects, may be related to the market share of the third-party payer and its drug formulary. The spillover effects affect drug treatment choices for patients covered by other insurers and patients without drug insurance.

Several studies[1-3] have examined the impact of spillover effects of HMO market penetration on physician practice styles for non-HMO sectors or patients. At the market level, increases in HMO market share are associated with reductions in Part A and Part B fee-for-service Medicare expenditures.[1,2] At the physician practice level, differences between the treatment of non-HMO and HMO patients are attenuated as the HMO share of practice increases.[3] To the best of our knowledge, no studies have been performed on the impact of a restrictive drug formulary on physician prescribing patterns for other patients.

In recent years, private insurers and state Medicaid programs have followed different routes in addressing the rising costs of prescription drugs. Private insurers have increasingly turned away from restrictive formularies and have favored patient-side financial incentives, such as 3-tiered copayments, to control drug costs. State Medicaid programs, unwilling and often unable to use high levels of patient cost sharing, have increasingly abandoned open formularies and have adopted more restrictive ones. Such a change in market dynamics makes Medicaid, often a dominant player by market share, a potential source of spillover effects.

In this article, we report the impact on other patients of a more restrictive Medicaid formulary for the proton pump inhibitor (PPI) class of drugs. The PPI class has been demonstrated to be more effective than other agents for acute and chronic gastroesophageal reflux disease.[4] However, there is a lack of consensus on which drug treatment strategy (step up vs step down) is more cost effective owing to the variation in symptoms and

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severity of patients with gastroesophageal reflux disease.[4] The PPIs typically account for a large percentage of a healthcare insurer's drug budget, and they are often the target of cost-control initiatives. On January 1, 2001, Maine's Medicaid program terminated its open formulary for the PPI class and implemented a restrictive formulary, with pantoprazole as the only preferred PPI. Prescriptions for other PPIs require prior authorization and documented medical necessity, such as treatment failure with pantoprazole. Physicians qualify for an exemption from prior authorization if pantoprazole accounts for ≥95% of all their PPI prescriptions.[5] Note that in its plan to save $10 million a year, Maine's Medicaid restrictive formulary was not limited to the PPI class. In February 2001, the prior authorization list included 120 popular prescription drugs.

The switch from an open formulary to a restrictive one provides a natural experiment to test the existence and extent of spillover effects. The Maine Medicaid program's substantial increase in Medicaid pantoprazole prescriptions was widely reported in the news media.[6] Certain retail pharmacies in Maine also observed an increase (although smaller) in pantoprazole prescriptions filled by non-Medicaid patients, indicating possible spillover effects.[6] As Maine's Medicaid program used a private pharmacy benefit management company to administer its restrictive formulary, its spillover effects, if any, should be similar to those of a similarly restrictive private HMO.

THEORETICAL FRAMEWORK

According to Scott-Levin's *Managed Care Formulary Drug Audit*,[7] a formulary is "a listing of prescription medications which are covered to some degree by a health plan." We adopted this definition in this article, although the term "formulary" is used broadly in other settings, such as hospital formularies and the World Health Organization formulary. Drug formularies are often described as being open, incentive based, or closed.[8] In an open formulary, patients are not penalized financially if they are prescribed nonformulary drugs. The HMOs that use open formularies may use compliance programs to encourage physicians to prescribe formulary drugs. An incentive-based formulary, such as a 3-tiered copayment formulary, covers nonformulary drugs but requires a higher copayment than for formulary drugs. A closed formulary provides coverage only for formulary drugs, and patients pay the full costs for nonformulary drugs unless an exception is granted, usually through prior authorization. Maine's restrictive Medicaid formulary for the PPI class is an example of a closed formulary.

Except for those in staff-model HMOs, few physicians have only 1 managed care contract. According to the 1996-1997 Community Tracking Survey of Physicians, 61% of primary care physicians and 64% of specialists had ≥6 managed care contracts.[9] Physicians may be more comfortable using a given product in a therapeutic class if they are more familiar with it. The mix of formularies from HMOs or their pharmacy benefit management companies and, in Maine's case, from Medicaid potentially changes the physician's task of making clinical and financial decisions. For a physician, the time cost of formulary compliance[9] (eg, in gathering formulary information for various therapeutic classes and monitoring subsequent changes) and that of requesting formulary noncompliance (eg, in going through prior authorization processes) can be high. In addition, a physician may have risk-sharing contracts with some managed care plans that are in part based on formulary compliance.

Although HMOs and Medicaid send physicians copies of formularies and periodic updates, physicians may not realistically have time to keep up with all the formulary changes.[8] The burden of informing a physician of formulary changes sometimes falls on the patients.[8] A patient may first learn of a formulary change at the pharmacy counter. The pharmacist will then contact the physician and seek approval for a prescription of a formulary drug. To guarantee coverage of a nonformulary drug, the physician needs to go through a prior authorization process. In Maine, the physician needs to fax such requests to state pharmacists, documenting that a nonformulary drug is medically necessary and that less expensive drugs have been tried without success. In the first month of prior authorization, there were 1551 such faxes, and approximately 40% were rejected. Sometimes it took more than 1 day to notify a physician or a patient of the decision.

Telephone calls from pharmacists owing to formulary noncompliance and additional paperwork to apply for authorization (coupled with a chance of rejection) consume physicians' practice time but do not generate additional income or reimbursements. Physicians may treat them as nuisances and try to avoid them. In this sense, such nuisances may be more effective than formal formulary communications in alerting physicians of a restrictive formulary. Spillover effects occur when a physician prescribes the preferred drug on a restrictive formulary to a greater extent than otherwise or, in other words, to patients who are not covered by that insurer. Such spillover effects run from the more restrictive insurance plans to the less restrictive ones. We hypothesize that such spillover effects may occur in two scenarios. A physician who cannot keep track of all

formulary changes but dislikes the noncompliance nuisances may consciously or subconsciously choose to prescribe the preferred drug on a restrictive formulary for other patients with "unknown" formularies. Or, a physician who is initially forced to prescribe the preferred drug may gain additional experience with it and later determine that it works well for other patients. Both scenarios are probably true, although the second scenario potentially leads to better health outcomes. In either scenario, spillover effects are likely to be positively associated with the restrictive insurer's share of a physician's practice. A physician with more patients from the restrictive insurer has higher noncompliance nuisances and likely stronger spillover effects. There would be a spillover in the opposite direction for physicians with small Medicaid shares and large shares of less restrictive policies; the Medicaid patient would presumably bear more "hassle" costs, as such patients and their pharmacists keep reminding the physician that Medicaid will not pay for what the physician usually prescribes.

If spillover effects from a restrictive formulary do exist, we expect them to differ by a patient's drug benefit design or out-of-pocket payments for the preferred drug (pantoprazole in this analysis). For an insured patient with no formulary, the higher the copayment for pantoprazole, the less likely it is that he or she will fill the prescription. We therefore expect the highest spillover effects among insured patients with an open formulary and patients with the lowest tier of copayment for pantoprazole (compared with other PPIs). Spillover effects are probably lower among insured patients with higher copayments and lowest (or nonexistent) among insured patients not covered for pantoprazole. The most price-sensitive patient is a cash-paying, uninsured patient (hereafter called a cash patient) who pays the full drug cost. This patient is more likely to explore low-cost alternatives with his or her physician. Average wholesale price is a good proxy for retail prices. In January 2001, pantoprazole was at an approximately 21% discount in average wholesale price per unit compared with other PPIs based on the largest selling package.[10] If a restrictive formulary prefers the cheapest drug in its class, as in this analysis, the cash patient is likely to go with it. Therefore, we expect high spillover effects among cash patients. Other determinants of spillover effects may include patients' underlying health condition(s), substitutability of competing drugs, and rejection rate of prior authorization applications. All things being equal, spillover effects are expected to be smaller for patients with severe or more health conditions, for inferior products, and with a low rejection rate in prior authorization.

Maine's implementation of its restrictive Medicaid formulary provides a natural experiment to test the previous spillover hypothesis. The previous open formulary Medicaid program was probably a receiver of spillover effects from other insurers with more restrictive drug formularies. With its new, closed formulary, Maine's Medicaid program may have become a generator of spillover effects on other insurers in Maine. In the absence of health plan formulary information, we separated the non-Medicaid payers into 3 distinctive markets: cash, other third-party payers, and mail order. Mail-order prescriptions are generally used by patients with chronic health conditions needing longer-term therapy. Without patients waiting at the pharmacy counter, pharmacists have more time to contact physicians and patients and to ensure formulary compliance. Spillover effects are likely to be stronger in the cash market and the other third-party payer market (a mix of open, incentive-based, and closed formularies) than in the mail-order market. In this study, we aim to test the following 3 hypotheses:

1. Maine's restrictive Medicaid formulary generates spillover effects on non-Medicaid markets in Maine.
2. Spillover effects are stronger in the cash and other third-party payer markets than in the mail-order market.
3. The higher the Maine Medicaid share of a physician's practice, the stronger the spillover effects.

DATA AND METHODS

This study used the 2001 (October 1999 to September 2001) Xponent PlanTrak database for the PPI class from IMS Health, a market research service company (Plymouth Meeting, Pa). The Xponent PlanTrak database is a prescriber-level database of dispensed prescriptions. It covers prescriptions dispensed in >34 000 retail pharmacies, or approximately 70% of the US retail prescription volume, with >160 million retail prescriptions and >8 million mail-order prescriptions each month. The other 30% of the prescription volume in noncovered retail pharmacies was projected using a proprietary statistical method based on nearest covered retail pharmacies, adjusted for store distance, direction, and dollar purchase volume (from separate sources). Approximately 95% of the prescriptions are matched to individual prescribers, ie, physicians or physician-supervised prescribers. For each prescriber, the Xponent PlanTrak data set reports his or her projected total prescriptions in a certain therapeutic class by drug, month,

and payer, ie, Medicaid, cash, various other third-party payers, or mail order. Hospital pharmacies, clinics, medical centers, and staff-model HMOs are not covered. No patient or drug formulary information is available in Xponent PlanTrak.

In the Maine natural experiment, we adopted an intention-to-treat approach and defined *treatment* as Maine's switch to the restrictive Medicaid formulary (hereafter also called Maine's rule) and *treatment intensity* as Maine Medicaid's share of a physician's practice (hereafter also called Medicaid share). We also used a 3-state comparison design to control for the time trend. New Hampshire and Vermont, both with an open formulary in their Medicaid programs, serve as control states. The main outcome measures are changes in pantoprazole's market share after the implementation of Maine's rule in January 2001, with changes in the non-Medicaid markets representing spillover effects.

We first selected PPI prescriptions in the 3 states and separated them into 4 distinctive markets: Medicaid, cash, other third-party payers, and mail order. In the market-level analyses, we report pantoprazole's market share of all PPI prescriptions in each market by month in the treatment and control states. More than 100 000 formulary change notices were mailed in November 2000, with a 1-month grace period for nonformulary prescriptions. Consequently, pantoprazole's share in Maine's Medicaid market started increasing in December 2000, 1 month earlier than the official implementation of Maine's rule. Therefore, we define the 3 months from September to November 2000 as the baseline period.

For the physician-level analysis, we first identified the top 30% of physicians in terms of the total number of PPI prescriptions in each state; these physicians jointly accounted for approximately 90% of PPI prescriptions in their state at baseline. (The term *physician* also includes a few physician-supervised nurse practitioners and physician assistants who prescribed PPIs.) We limited the study sample to high-volume PPI physicians to more accurately measure the physician-level variable Medicaid share of practice (*MEDICAID*%), which is defined as the number of PPIs prescribed for Medicaid divided by the total number of PPIs prescribed by a physician at baseline. To study the effect of treatment intensity (Medicaid share of practice) on physicians' prescribing patterns, the top 30% of physicians in Maine were further separated into 3 equal-sized groups by Medicaid share of practice at baseline. We then reported pantoprazole's share in each market by month for the high, middle, and low Medicaid share physician groups in Maine.

In addition to the market share analyses just described, we used a linear regression framework that uses baseline physician characteristics to quantify the effects of treatment (Maine) and treatment intensity (Medicaid share of practice in Maine) on physicians' prescribing patterns after switching to a restrictive Medicaid formulary. As mentioned previously, we defined the baseline period as the 3 months from September to November 2000. To allow prescribing patterns to stabilize, we defined the study period as the 3 months from March to May 2001, after the implementation of Maine's rule. Alternative specifications using later study periods led to similar results. For each market, ie, Medicaid, cash, other third-party payers, and mail order, the physician-level linear regression model is as follows:

$$PANTO\%_{i,m,t} = \alpha PANTO\%_{i,m,t-1} + \beta \boldsymbol{X}_i + \gamma MEDICAID\%_{i,t-1} + \mu N\_MEDICAID_{i,t-1} + \tau MAINEi + \eta MEDICAID\%_{i,t-1} * MAINE_i,$$

where i represents a physician; m, a market; t, the period after the implementation of Maine's rule; $t - 1$, the baseline period; *PANTO*%, pantoprazole's market share at baseline or after the implementation of Maine's rule; $\boldsymbol{X}$, a vector of binary variables for physician specialties (vs internal medicine) plus New Hampshire (vs Vermont); *MEDICAID*%, Medicaid share of practice at baseline; *N_MEDICAID*, the number of PPI prescriptions for Medicaid at baseline; *MAINE*, a binary variable for treatment (Maine); and the interaction term *MEDICAID%*MAINE*, treatment intensity. The statistical software used is the REG procedure in SAS version 8.01 (SAS Institute Inc, Cary, NC).

Our statistical model is a variation of the difference-in-difference-in-difference model (difference 1: before vs after; difference 2: Maine vs 2 control states; and difference 3: high vs low Medicaid practice in Maine). Difference 1 is not explicitly specified on the right-hand side of the equation but is implicitly built into the model. Specifically, the dependent variable, pantoprazole's market share after the implementation of Maine's rule, is explained by a prescriber's practice characteristics beforehand, and the intercept includes difference 1, or the time trend. Such a specification controls for the unobserved characteristics of a physician practice, which do not change over time. Pantoprazole's market share at baseline serves as a proxy for the mix of patients/health conditions and non-Medicaid drug formularies in a physician's practice plus his or her prescribing habits. The use of market share, instead of the actual number of prescriptions, adjusts for the increasing volume of PPI prescriptions during the study period.

To test the existence of spillover effects, we asked whether physicians in Maine prescribed more pantoprazole in the non-Medicaid markets after the imple-

mentation of Maine's rule (the direct effect) and whether such effects were stronger among Maine physicians with a higher Medicaid share of practice (the interaction effect). The direct spillover effect is represented by a significantly positive coefficient for *MAINE*, while the interaction spillover effect is represented by a significantly positive coefficient for the interaction term *MEDICAID%*MAINE*. Compared with the direct effect, the interaction effect is a stronger test of spillover effects and it tests both hypothesis 1 and hypothesis 3. Comparing the coefficients for the direct or interaction effects in the non-Medicaid markets tests hypothesis 2. For each market, we further limited the regression sample of physicians to those with at least 5 PPI prescriptions in that market at baseline and after the implementation of Maine's rule to more accurately measure the physician-level variable *PANTO%*. For the same reason, the linear regression model is weighted by the number of PPI prescriptions in that specific market at baseline.

The previously described linear regression model has 1 drawback—its dependent variable needs to be between 0 and 1. As a sensitivity analysis, we used the following prescription-level logit model:

$$P_{i,m,t} = \alpha PANTO\%_{i,m,t-1} + \beta X_i + \gamma MEDICAID\%_{i,t-1} + \mu N\_MEDICAID_{i,t-1} + \tau MAINE_i + \eta MEDICAID\%_{i,t-1} * MAINE_i,$$

where P is a binary variable indicating the choice between pantoprazole ($P = 1$) and the other PPIs ($P = 0$); the other explanatory variables are the same as those in the physician-level linear regression model. The prescription-level logit regression has a much larger sample size, as its unit of observation is 1 prescription instead of 1 physician. Ideally, we wanted to control for physicians' fixed effects by introducing physician identifiers into the logit model, but its maximum likelihood procedure cannot accommodate so many dummy variables. We only used the prescription-level logit model to validate the findings from the linear regression model. The statistical software used for this sensitivity analysis was the LOGISTIC procedure in SAS version 8.01.

Table 1. Baseline Market and Physician Characteristics in Maine, New Hampshire, and Vermont

Variable	Maine	New Hampshire	Vermont
Market			
Proton pump inhibitor prescriptions, No. (%)			
Medicaid	20 686 (28.7)	6646 (11.5)	11 605 (30.4)
Other third-party payers	42 411 (58.8)	41 898 (72.8)	20 881 (54.7)
Cash	5148 (7.1)	4738 (8.2)	3467 (9.1)
Mail order	3836 (5.3)	4305 (7.5)	2228 (5.8)
Physician (top 30% of prescribers)*			
Specialty, No. (%)†			
Internal medicine	241 (26.7)	214 (29.2)	120 (28.9)
Family/general practice	365 (40.5)	262 (35.8)	165 (39.8)
Gastroenterology	27 (3.0)	27 (3.7)	14 (3.4)
Others	268 (29.7)	229 (31.3)	116 (28.0)
Practice characteristics, mean (SD)‡			
Medicaid, %	28.2 (20.6)	11.6 (12.6)¶	29.8 (19.7)
Other third-party payers, %	59.1 (22.7)	73.3 (21.3)¶	55.0 (21.3)‖
Cash, %	7.0 (8.7)	8.0 (7.5)§	8.7 (8.1)¶
Mail order, %	5.6 (18.9)	7.1 (20.4)	6.5 (18.3)
Proton pump inhibitor prescriptions, No.	70.7 (68.2)	70.3 (67.6)	83.0 (78.4‖
Pantoprazole, %	2.3 (5.9)	1.3 (3.4)¶	1.9 (4.8)

*The top 30% of prescribers in each state jointly accounted for approximately 90% of all proton pump inhibitor prescriptions in their state at baseline, ie, between September and November 2000.
†χ^2 Test of specialty distribution (vs Maine): $P = .88$ (Vermont); $P = .23$ (New Hampshire).
‡Pairwise t test for each practice-level variable (vs Maine).
§$P < .05$.
‖$P < .01$.
¶$P < .001$.

RESULTS

Baseline Market and Physician Characteristics

At the market level, Maine was similar to Vermont in terms of Medicaid share of total PPI prescriptions (29% vs 30%) (**Table 1**). New Hampshire had fewer PPI prescriptions paid by Medicaid (12%) but more PPI prescriptions paid by other third-party payers (73% vs 59% in Maine and 55% in Vermont) (Table 1). In these states, most pharmacy benefit management companies and HMOs are national ones. For example, the top 3 third-party payers (after Medicaid) are Merck-Medco, Advance PCS, and Express Scripts in Maine; Anthem Blue Cross Blue Shield, Express Scripts, and Advance PCS in New

Hampshire; and Advance PCS, Centrus Pharmacy Solutions, and Express Scripts in Vermont. The PPI prescriptions paid by cash (7%-9%) were more than those paid by mail order (5%-8%) in all 3 states (Table 1). A prescription purchased through mail order typically lasts 90 days, or 2 times longer than that purchased in a retail pharmacy. Except for a slight decrease in PPI prescriptions paid by cash, these market-level percentages remained similar after the implementation of Maine's rule.

Baseline characteristics of the top 30% of prescribers in each state, who jointly prescribed approximately 90% of all PPIs in their state at baseline, are also reported in Table 1. In each state, physicians in the top decile accounted for more than half of all PPI prescriptions, those in the next decile accounted for >20%, and those in the third decile accounted for approximately 10%. New Hampshire (P = .23, χ^2 test vs Maine) and Vermont (P = .88, χ^2 test vs Maine) were similar to Maine in the distribution of physician specialty. Baseline characteristics at the physician practice level were often significantly different between Maine and the 2 control states (pairwise t tests vs Maine) (Table 1). Physicians in New Hampshire had a lower mean Medicaid share of practice (12% vs 28% in Maine and 30% in Vermont; P < .001 for both) and a higher mean share of practice from other third-party payers (73% vs 59% in Maine and 55% in Vermont; P < .001 for both) at baseline. Physicians in Vermont prescribed more PPIs per physician at baseline (mean: 83 vs 71 in Maine and 70 in New Hampshire; P = .006 for both). Pantoprazole's mean market share (across all markets) at baseline was slightly lower in New Hampshire (1.3% vs 2.3% in Maine and 1.9% in Vermont; P < .001 for both). Compared with the baseline period, the average Medicaid share of practice dropped slightly in all 3 states (<1%, measured as the before-vs-after difference for each physician) during the study period, without significant differences across the states.

Pantoprazole Market Share Changes

Figures 1 through **4** show pantoprazole's market share of all PPI prescriptions by month in the Medicaid and non-Medicaid markets in the 3 states. The implementation of Maine's rule led to a substantial increase of pantoprazole's share in Maine in the Medicaid market (as one would expect). It also led to more than a quadrupling of the relatively small pantoprazole share, from approximately 2%

Figure 1. Pantoprazole's Market Share, by Month, in Maine, Vermont, and New Hampshire in the Medicaid Market

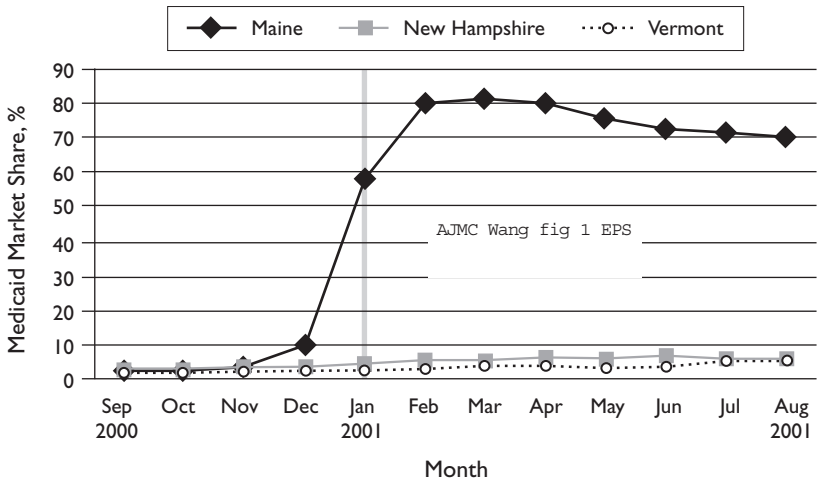
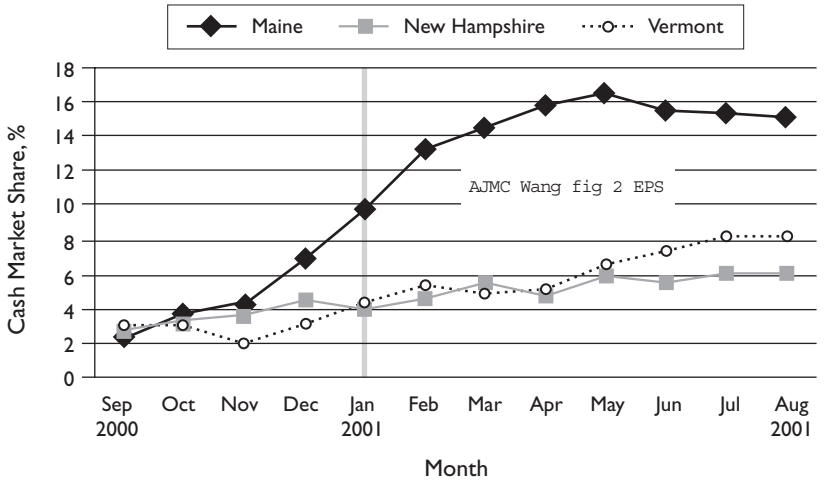


Figure 2. Pantoprazole's Market Share, by Month, in Maine, Vermont, and New Hampshire in the Cash Market



to >10%, for other third-party payers and cash patients. Between November 2000 and March 2001, pantoprazole's share in the Medicaid market increased 79% in Maine compared with 2% in New Hampshire and 1% in Vermont. The ratio of new to total PPI prescriptions in Maine's Medicaid program increased from the historic average of 34% in December 2000 to 62% in January 2001, indicating that refills of other PPIs were also switched to pantoprazole. Between November 2000 and March 2001, pantoprazole's market share in the cash and other third-party payer markets increased more rapidly in Maine than in Vermont or New Hampshire, with a bigger increase in the cash market (cash: 10% in Maine vs 3% in Vermont and New Hampshire; other third-party payers: 7% in Maine vs 1% in Vermont and New Hampshire). There was no similar trend in the mail-order market, as the difference in pantoprazole's market share was consistently <1% between Maine and Vermont through August 2001. Pantoprazole's share in Maine's Medicaid market peaked in March 2001 and dropped approximately 11% by August 2001.

The top 30% of Maine physicians (n = 901) are further separated into high, middle, and low Medicaid share of practice groups (mean [range]: high, 52% [36%-100%, n = 301]; middle, 25% [16%-36%, n = 300]; and low, 7% [0%-16%, n = 300]). **Figure 5** shows pantoprazole's market share of all PPI prescriptions by month in these 3 groups. After the implementation of Maine's rule, pantoprazole's market share increased in the Medicaid, cash, and other third-party payer markets, with the biggest increases in the high Medicaid share group (**Figures 5** through **8**). Between November 2000 and March 2001, pantoprazole's market share in Medicaid rose 82% in the high Medicaid share group (vs 78% in the middle and low Medicaid share groups). During the same period, pantoprazole's market share in the high Medicaid share group rose 16% in the cash market (vs 8% in the middle and 5% in the low Medicaid share groups) and 11% in the other third-party payer market (vs 5% in the middle and 4% in the low Medicaid share groups). These findings indicate that spillover effects exist in the cash and other third-party payer markets and that they are stronger among Maine physicians with a higher Medicaid share of practice. There is no similar evidence of spillover effects in the mail-order market (**Figure 8**).

Figure 3. Pantoprazole's Market Share, by Month, in Maine, Vermont, and New Hampshire in the Other Third-Party Payer market

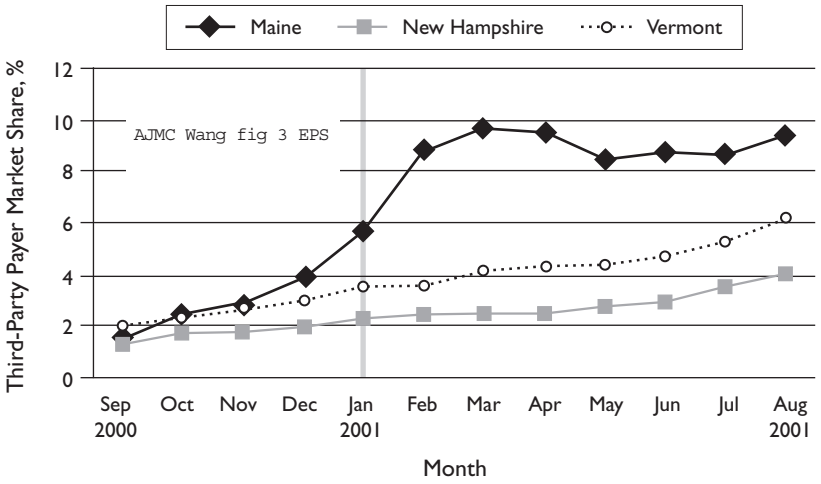
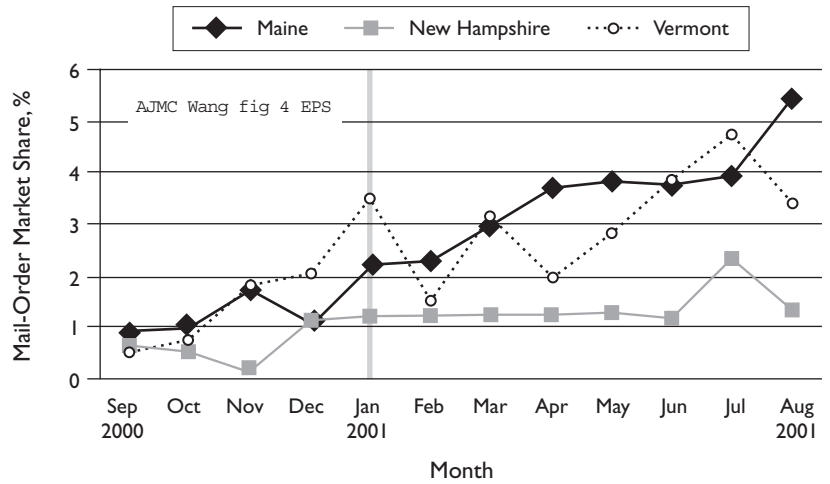


Figure 4. Pantoprazole's Market Share, by Month, in Maine, Vermont, and New Hampshire in the Mail-Order Market



Linear Regressions

The linear regression results verified that pantoprazole's market share increased significantly in the Medicaid, cash, and other third-party payer markets in Maine after its Medicaid formulary change, with a significant effect of *MAINE* in the Medicaid regression and a significant interaction effect between

MAINE and *MEDICAID%* in the cash and other third-party payer regressions (**Table 2**). The coefficients for *MAINE* indicated that for a physician with no Medicaid patients at baseline, practicing in Maine is associated with a 72% increase in pantoprazole's market share among Medicaid prescriptions ($P < .001$), a 4% increase among cash prescriptions ($P = .11$), and a 1% increase among other third-party payer prescriptions ($P = .08$). In addition to the fixed *MAINE* effect, the coefficients for the interaction term *MEDICAID%*MAINE* indicated that for each 10% increase in Medicaid share of practice in Maine, pantoprazole's market share increased 0.8% among Medicaid prescriptions ($P = .11$), 1.8% among cash prescriptions ($P = .01$), and 1.4% among other third-party payer prescriptions ($P < .001$). In these regressions, we also tested the interaction effect between the quadratic term of *MEDICAID%* and the indicator variable *MAINE* and found it to be nonsignificant. No significant increase in pantoprazole's market share was found among mail-order prescriptions.

Figure 5. Pantoprazole's Market Share, by Month, in 3 Maine Physician Groups Differing in Medicaid Share of Practice in the Medicaid Market

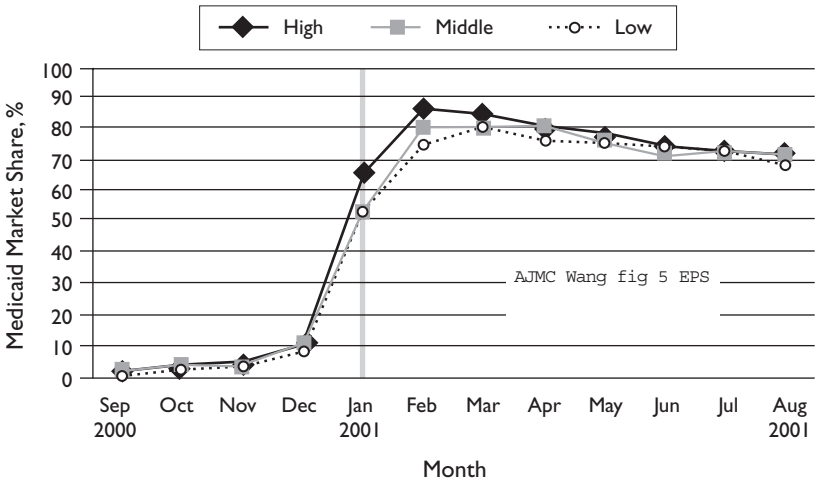
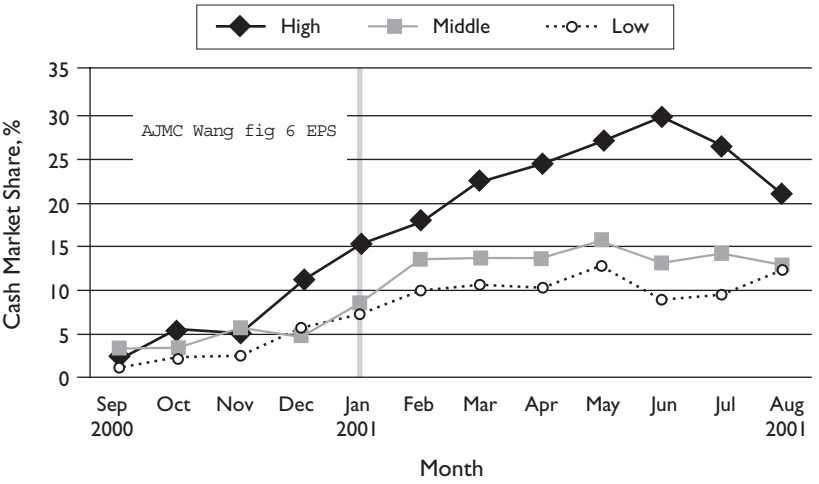


Figure 6. Pantoprazole's Market Share, by Month, in 3 Maine Physician Groups Differing in Medicaid Share of Practice in the Cash Market



Not surprisingly, pantoprazole's market share at baseline, a proxy for the mix of patients and drug formularies in a physician's practice, was a strong and significant predictor of its market share after the implementation of Maine's rule in all 4 markets (Table 2). There seems to be no difference among physician specialties except that gastroenterologists prescribed significantly more pantoprazole in the cash and other third-party payer markets (Table 2).

These findings were confirmed by the results of prescription-level logit regressions. Our results are consistent with all 3 hypotheses on spillover effects from a restrictive drug formulary. Spillover effects from Maine's restrictive Medicaid formulary, in terms of an increase in pantoprazole's market share, were observed in the cash and other third-party payer markets, with somewhat stronger effects in the cash market. In addition, spillover effects were stronger among Maine physicians with a higher Medicaid share of practice. These results were inconclusive regarding the existence of spillover effects in the mail-order market, probably because of its (expected) smallest spillover effects.

COMMENT

We investigated the changes in physicians' prescribing patterns in Maine's non-Medicaid markets after implementation of a restrictive Medicaid formulary. We found consistent evidence supporting spillover effects in

Figure 7. Pantoprazole's Market Share, by Month, in 3 Maine Physician Groups Differing in Medicaid Share of Practice in the Other Third-Party Payer Market

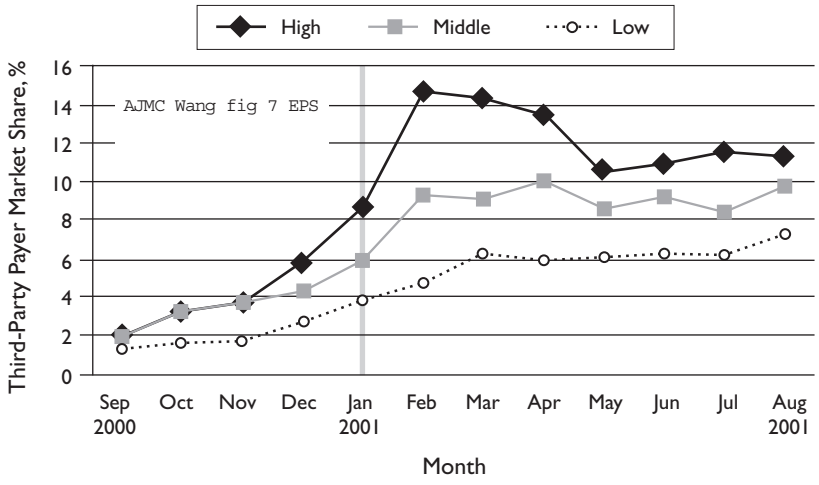
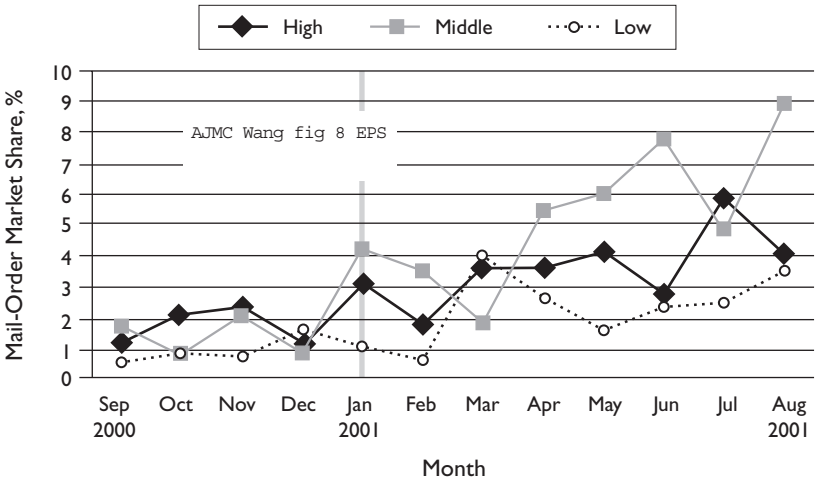


Figure 8. Pantoprazole's Market Share, by Month, in 3 Maine Physician Groups Differing in Medicaid Share of Practice in the Mail-Order Market



the cash and other third-party payer markets, with somewhat stronger effects in the cash market. Among the other third-party payers, spillover effects were probably stronger among those with an open formulary or with pantoprazole on formulary, but the lack of drug formulary information prevents us from testing this hypothesis. We also found consistent evidence that spillover effects are stronger among Maine's physicians with a higher Medicaid share of practice; these findings add further support to the hypothesis that it is the Maine Medicaid formulary change, rather than something else, that is associated with the increases in pantoprazole's market share.

However, although the proportional effect of the Maine formulary was large, the share of the Medicaid-preferred drug remained much smaller among non-Medicaid patients than among Medicaid patients. The main limitation of this study is the lack of formulary information beyond Medicaid. We could not rule out the possibility that rather than spillover occurring, some health plans in Maine (but not health plans in New Hampshire or Vermont) followed the Maine Medicaid formulary change or at least put pantoprazole on their formulary. However, the chance is slim, as most pharmacy benefit management companies and HMOs are national ones with national formularies. Our results are unbiased as long as Medicaid's distribution among physicians is not positively correlated with health plans following Medicaid's formulary change. Because Maine's Medicaid program used a private pharmacy benefit management company to administer its restrictive drug formulary, its spillover effects should be similar to those of a similarly restrictive private HMO for physicians with a high share of patients from that HMO. We do not know to what extent similar spillover effects exist in other therapeutic classes. We expect that spillover effects depend on the underlying health condition(s), the substitutability of competing prescription drugs, the rejection rate for prior authorization, the restrictive formulary's share of a physician's practice, and a patient's drug benefit design.

The switch from an open drug formulary to a closed one changed Maine's Medicaid program from a possible receiver of spillover effects from other formularies to a generator of spillover effects for others. With its restrictive PPI formulary, Maine's Medicaid program might have saved a considerable amount of money in its drug

Table 2. Linear Regression Results on Physicians' Pantoprazole Prescribing Patterns by Market After Maine's Rule*

Market† Variable	Medicaid (n = 1200)	Cash (n = 511)	Other Third-Party Payers (n = 1894)	Mail Order (n = 219)
Intercept	0.046 (0.020)‡	–0.012 (0.018)	0.011 (0.006)	0.019 (0.010)‡
Baseline pantoprazole %	0.376 (0.073)‖	0.695 (0.051)‖	0.924 (0.032)‖	0.584 (0.094)‖
Specialty (vs internal medicine)				
Family/general practice	–0.007 (0.010)	0.009 (0.012)	0.005 (0.004)	0.012 (0.012)
Gastroenterology	–0.022 (0.022)	0.074 (0.017)‖	0.014 (0.006)‡	0.013 (0.013)
Others	–0.004 (0.013)	0.014 (0.017)	0.007 (0.005)	0.006 (0.008)
State (vs Vermont)				
Maine	0.719 (0.024)‖	0.036 (0.023)	0.012 (0.007)	0.010 (0.007)
New Hampshire	0.002 (0.016)	0.023 (0.015)	–0.008 (0.005)	–0.016 (0.006)§
Medicaid practice at baseline				
Medicaid%	–0.046 (0.04)	0.067 (0.050)	0.014 (0.017)	–0.064 (0.052)
Number of Medicaid proton pump inhibitors	0.00007 (0.00005)	0.00001 (0.00007)	–0.00002 (0.00003)	0.0002 (0.0002)
Maine*Medicaid%	0.083 (0.052)	0.182 (0.072)‡	0.139 (0.022)‖	–0.0005 (0.049)
R^2	0.865	0.354	0.418	0.273

*The dependent variable is pantoprazole's market share in that market during the study period. Each linear regression is weighted by a physician's total number of proton pump inhibitor prescriptions in that market at baseline. The regression coefficients are given as mean (SE).
†For each market, the sample of physicians includes those with at least 5 proton pump inhibitor prescriptions in that market both at baseline and during the study period.
‡$P < .05$.
§$P < .01$.
‖$P < .001$.

budget. It was reported that (after Medicaid's best-price rebates) pantoprazole cost the state about half the cost of omeprazole. However, we also noticed that compared with the 2 control states, PPI's market share in Medicaid (of total PPI and H_2-receptor antagonist prescriptions) increased faster (about 4%) in Maine during the study period. It is unknown to what extent such savings might be offset by increases in the use of other medical services. The existing literature on the effects of restrictive formularies in the ambulatory setting are not conclusive.[11] Horn et al[12] found that restrictive drug formularies in HMOs are associated with higher resource utilization in certain diseases, especially in elderly patients, but their statistical method to control for pre-existing conditions among study sites has subsequently been criticized.[13] On the other hand, experience with switching patients to a different angiotensin-converting enzyme inhibitor in the Canadian province of British Columbia was not associated with changes in the use of other medical services or mortality during the first 6 months.[14] However, there was a moderate transitional increase in physician visits and hospital admissions through the emergency department in the 2 months after switching (but not subsequently).[14] Prescription drugs in the same therapeutic class share similar mechanisms and are interchangeable to a certain extent. However, for a patient who is successfully treated with one drug, there is the possibility of switching him or her to an inadequate dose of another drug. Some patients might be intolerant of the new drug and will need to be switched back. Although PPIs are often considered to be of similar efficacy, the implementation of therapeutic substitution or switching programs in this drug class in the Veteran Affairs healthcare system[15,16] and in an HMO[17] has been associated with poor symptom control, more adverse effects, and intolerance in a small fraction of patients, which may lead to more use of physician visits and other medical services[16] and a decrease in patient satisfaction.[15,17] To evaluate the net impact from the Maine Medicaid perspective requires usage information on drug, hospital, outpatient, and other medical service costs (plus physician, pharmacist, and patient time costs if from the societal perspective), which, to the best of our knowledge, is not released for research purposes.

The existence of spillover effects indicates that a restrictive formulary affects both patients covered by the restrictive insurer and the other patients treated by the same physician. Managed care organizations compete on coverage, choice, and quality. Spillover effects from a restrictive formulary introduce externalities of a sort into such competition, as they limit a plan's ability to offer unrestricted effective access to the full range of possible therapies. On the other hand, they may also lead to lower costs for other plans.

More generally, it is unknown whether spillover effects are on balance positive or negative on treatment costs and health outcomes for other patients, since that effect depends on whether the practice pattern "spilling over" provides more or less net benefit than the alternative. On one hand, other insurers may have benefited from lower costs without themselves having to make the effort or bear the complaints from using a restrictive formulary; insurers with the same or a similar restrictive formulary may realize synergy and better formulary compliance. If the most restrictive insurer chooses cost-effective products, spillover effects help spread more cost-effective drug therapies in the entire healthcare system. Some health plans or physicians may take a drug's preferred status in the most restrictive formulary as a sign of cost-effectiveness. On the other hand, a restrictive formulary that overemphasizes lower costs may lead to suboptimal drug therapy and worse health outcomes for some patients or may increase their treatment costs; insurers with a different formulary may incur higher costs in prior authorization or may experience worse formulary compliance. To estimate the net impact of spillover effects on costs and health outcomes in the entire healthcare system is an endeavor beyond this study.

Spillover effects may also be relevant in the current debate about the design of adding a drug benefit to Medicare.[18] Should that design permit a restrictive formulary, there would be effects on drug treatment choices for Medicare beneficiaries and on treatments received in non-Medicare markets, with ambiguous effects on potential costs and benefits. Whatever the impact, the potential spillover effects mean that Medicare choices will matter for the treatment of non-Medicare patients.

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