Can Restrictions on Reimbursement for Anti-Ulcer Drugs Decrease Medicaid Pharmacy Costs Without Increasing Hospitalizations?

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Objective. To examine the impact of a policy restricting reimbursement for Medicaid anti-ulcer drugs on anti-ulcer drug use and peptic-related hospitalizations.
Data Sources/Study Setting. In addition to U.S. Census Bureau data, all of the following from Florida: Medicaid anti-ulcer drug claims data, 1989–1993; Medicaid eligibility data, 1989–1993; and acute care nonfederal hospital discharge abstract data (Medicaid and non-Medicaid), 1989–1993.
Study Design. In this observational study, a Poisson multiple regression model was used to compare changes, after policy implementation, in Medicaid reimbursement for prescription anti-ulcer drugs as well as hospitalization rates between pre- and post-implementation periods in Medicaid versus non-Medicaid patients hospitalized with peptic ulcer disease.
Principal Findings. Following policy implementation, the rate of Medicaid reimbursement for anti-ulcer drugs decreased 33 percent ($p < .001$). No associated increase occurred in the rate of Medicaid peptic-related hospitalizations.
Conclusions. Florida's policy restricting Medicaid reimbursement for anti-ulcer drugs was associated with a substantial reduction in outpatient anti-ulcer drug utilization without any significant increase in the rate of hospitalization for peptic-related conditions.

Key Words. Medicaid reimbursement policy, pharmaceutical claims, peptic ulcer disease, hospitalization

Among the challenges facing the American healthcare system, perhaps none are more daunting than those related to Medicaid programs. Financing for Medicaid, provided by both the federal and state governments, has costs that account for approximately 20 percent of states' budgets (National Association

of State Budget Officers 1995) and are among the fastest-growing items in both state and federal budgets. Unless the rise in states' Medicaid costs is slowed, eligibility for the program or its benefits will be further restricted, or states' expenditures on other public programs will need to be cut.

A component of rising Medicaid costs that has attracted much attention is the rise in costs due to prescription drug use. Medicaid payments for prescription drugs increased from $3 billion in 1987 to $6.8 billion in 1992 (Colligen 1993). To decrease these costs, many states have restricted reimbursement for certain classes of drugs that may be overprescribed or less cost-effective than alternatives. One class of drugs that has become a prime target is anti-ulcer medications. These medications, which accelerate ulcer healing and reduce ulcer recurrence, are among the most commonly prescribed drugs in the United States and account for 10–13 percent of state Medicaid pharmacy budgets. Moreover, spending on these medications has continued to increase despite the discovery of *Helicobacter pylori*'s role in peptic ulcer disease (PUD). To date, little is known about how restrictions on payment for pharmaceuticals can produce substantial reductions in Medicaid costs without jeopardizing clinical outcomes (Brown and Lipowski 1993; Lipton and Bird 1993; Zimmerman et al. 1994).

To gain insight into the intended and potential unintended effects of one state's policy of reimbursement restriction for anti-ulcer drugs, we analyzed Florida's hospital discharge data and Medicaid pharmacy claims from 1989 through 1993. Our specific aims were to determine (a) whether Florida's

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restrictions on reimbursement for anti-ulcer drugs, implemented in February 1992, were associated with a significant decrease in the Medicaid program's rate of reimbursement for doses of anti-ulcer drugs; and (b) whether those restrictions were associated with an increase in the Medicaid hospitalization rate for PUD-related diagnoses.

METHODS

Policy Description

In August 1991, the Florida Medicaid program announced a policy restricting reimbursement for anti-ulcer medicines prescribed for Medicaid patients. This policy, which affected cimetidine, famotidine, nizatidine, ranitidine, omeprazole, and sucralfate, was implemented on February 15, 1992 and imposed the following restrictions:

1. Payment would be provided for only one anti-ulcer drug prescription at a time.
2. Only one refill would be permitted per written prescription.
3. Coverage for high-dose prescription treatment for acute disorders would be limited to 60 days duration.

Sources of Data

From Florida's Medicaid Pharmacy Services, data were acquired on the number of claims reimbursed, the total dollars spent in reimbursement, and the cost per dose for each specific anti-ulcer drug for each calendar quarter from 1989 through 1993. These claims data applied only to those Medicaid patients not assigned to an HMO. In addition, these data provided only summary information for each reimbursed anti-ulcer drug without linking the drug use data to Medicaid recipient eligibility files, a limitation that precluded calculation of age- and sex-adjusted anti-ulcer drug reimbursement rates.

Data also were acquired from Florida's Center for Health Statistics for all Medicaid and non-Medicaid discharges from nonfederal, short-stay hospitals in Florida from January 1989 through December 1993 (totaling 8,951,859 discharges). For each hospitalization, we abstracted data on patient age, sex, and type of health insurance; the year and calendar quarter of discharge; and the International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM) code for the primary discharge diagnosis. We relied on primary diagnosis codes, rather than on both primary and secondary codes, to

maximize the likelihood of capturing hospitalizations that occurred because of the ulcer-related diagnosis.

We obtained age-specific monthly Medicaid eligibility data from 1989 through 1993 as well as the total number of HMO-assigned Medicaid patients in each calendar quarter from the Florida Medicaid Office of Program Analysis, and age-specific census data for Florida's total population from the U.S. Census Bureau.

Definition of PUD-Related Conditions

We used the primary discharge diagnosis code to identify hospitalizations related to complicated PUD and uncomplicated PUD. A hospitalization was attributed to PUD when the primary diagnosis code indicated the presence of an ulcer in the stomach, duodenum, or jejunum (ICD-9-CM codes 531.00–534.99). PUD was defined as "complicated" when a code indicated hemorrhage, perforation, or obstruction in association with the ulcer (ICD-9-CM codes 531.xx–534.xx, where xx = 00, 0l, 10, 11, 20, 21, 31, 40, 41, 50, 51, 60, 61, 71, or 91).

We defined an additional category of hospitalization, non-ulcer peptic conditions, for other conditions for which anti-ulcer drugs are likely to be prescribed. A hospitalization was attributed to a non-ulcer peptic condition when the primary diagnosis code indicated a disorder likely to involve acid-pepsin in its pathogenesis (i.e., esophagitis, gastritis, acute gastritis, gastroduodenitis, and duodenitis: ICD-9-CM codes 530.1, 535.0, 535.4, 535.5, and 535.6.

Other Exclusions

Hospitalization records for patients over 64 years old were excluded because the database identified only the primary payer, precluding identification of individuals eligible for both Medicare and Medicaid. Patients dually eligible would have been identified only as Medicare-eligible even though Medicaid paid for their prescriptions. This exclusion was applied to patients older than 64 years because the majority of such patients have Medicare coverage, but not to patients 64 years old and younger because very few patients in this latter age group have Medicare. In addition, hospitalization records for HMO-assigned Medicaid patients were excluded because Medicaid patients assigned to HMOs received medical benefits as governed by the policies of their respective HMOs and, therefore, were not "exposed" to restrictive Medicaid policy.

STATISTICAL ANALYSIS

Our analysis of the per capita rates of paid prescriptions included all anti-ulcer drugs regulated by Florida's restrictive policy: cimetidine, famotidine, nizatidine, ranitidine, omeprazole, and sucralfate. The number of doses paid for by Florida's Medicaid program for these six drugs from 1989 through 1993 was calculated using quarterly data. Because the drug reimbursement data were not age- or sex-specific, we calculated crude rates of reimbursement for anti-ulcer drugs for Medicaid patients of all ages who were not assigned to an HMO. The denominator for these rates was the total number of Medicaid-eligible recipients minus the number of HMO-assigned Medicaid patients in each calendar quarter.

Because Florida's restrictive policy was implemented in February 1992, we designated calendar quarters from 1989 through 1991 as "pre-policy" quarters and those from 1992 through 1993 as "post-policy" quarters. The statistical significance of differences between pre- and post-policy rates of reimbursement for anti-ulcer drug prescriptions was analyzed using student's *t*-test (Microsoft® Excel version 5.0a Windows™ 1993).

For our analysis of hospitalizations, we categorized each discharge record as either Medicaid or non-Medicaid (all other payers) based on the record's primary payer code. In addition, we categorized each hospitalization as either pre-policy (1989–1991) or post-policy (1992–1993) on the basis of each record's discharge date. We then determined quarterly hospitalization rates between 1989 through 1993 for each category of Medicaid and non-Medicaid PUD-related conditions. The denominators for the Medicaid hospitalization rates were derived from Florida's monthly age- and sex-specific Medicaid eligibility data. The denominators for the non-Medicaid hospitalization rates in each year were calculated for each sex by subtracting the average number of eligible Medicaid recipients, ages 0–64 years, in that year, from the U.S. Census Bureau's estimate of Florida's total population, ages 0–64 years, for that same year. By direct standardization, we calculated age- and sex-adjusted hospitalization rates using 1990 census estimates of Florida's 0–64-year-old population as the standard population.

The resulting adjusted quarterly hospitalization rates were plotted to compare trends in rates between Medicaid and non-Medicaid PUD-related conditions.

The statistical significance of changes in pre- versus post-policy quarterly Medicaid hospitalization rates for each PUD-related diagnostic category was tested in a Poisson regression model. We constructed this model to compare

hospitalization rates for PUD-related diagnoses in the Medicaid and non-Medicaid populations, as follows:

$$\text{Hospitalization Rate} = \beta_0 + \beta_1(\text{Medicaid}) + \beta_2(\text{Policy}) + \beta_3(\text{Medicaid} * \text{Policy})$$

The Medicaid variable is used to distinguish Medicaid hospitalizations (Medicaid = 1) from non-Medicaid hospitalizations (Medicaid = 0), and the resultant β_1 coefficient estimates the relative rate of hospitalization in the pre-policy period for Medicaid beneficiaries versus those not covered by Medicaid. The Policy variable is a temporal one that distinguishes hospitalizations that occurred in the "post-policy" period (1992–1993, Policy = 1) from those that occurred in the "pre-policy" period (1989–1991, Policy = 0). The β_2 coefficient that results estimates the relative rate of post- versus pre-policy hospitalizations in the non-Medicaid population. The variable of primary interest is the interaction term, Medicaid * Policy. If post-policy hospitalization rates increased significantly, but equally, for both the Medicaid and non-Medicaid populations, we would expect that β_2 would have a positive value significantly greater than zero, but that β_3 (for the interaction between the restrictive policy and Medicaid hospitalizations for PUD-related conditions) would not be significantly different from zero. Conversely, if the post-policy Medicaid hospitalization rate for PUD-related conditions increased significantly relative to that of the non-Medicaid population, we would expect to find a positive and statistically significant β_3 coefficient.

RESULTS

Changes in Anti-Ulcer Drug Reimbursement

The number of paid anti-ulcer drug doses per 100,000 Medicaid beneficiaries gradually increased from mid-1989 through 1990, but fell in the third quarter of 1991 when Florida's policy restricting reimbursement for anti-ulcer drugs was announced (Figure 1). This decline continued through the second quarter of 1992, but in 1993 utilization climbed again. Overall, the average quarterly number of prescription anti-ulcer doses reimbursed per 100,000 Medicaid beneficiaries fell from 807,272 pre-policy to 539,543 post-policy ($p < .001$), a 33 percent decrease.

Hospitalizations for PUD-Related Conditions

Table 1 shows the annual number of hospitalizations, and age- and sex-adjusted hospitalization rates among Medicaid beneficiaries and among

non-Medicaid patients for the three PUD-related diagnosis groups. The age- and sex-adjusted hospitalization rates are plotted in Figure 2.

The hospitalization rates for complicated PUD, for uncomplicated PUD, and for non-ulcer peptic conditions in Medicaid beneficiaries do not suggest policy-associated changes. As Figure 2 suggests, the two-way (Medicaid * Policy) interactions in the Poisson regression model were not statistically significant for complicated PUD conditions, for uncomplicated PUD, or for non-ulcer peptic conditions (Table 2), indicating that the restrictive policy was not associated with a relative increase in the Medicaid hospitalization rate for any of the three peptic-related diagnostic categories.

Even when these multivariate analyses were conducted across all three PUD-related diagnostic categories to increase the statistical power of the models, no significant policy-associated increase was found in Medicaid PUD-related hospitalizations.

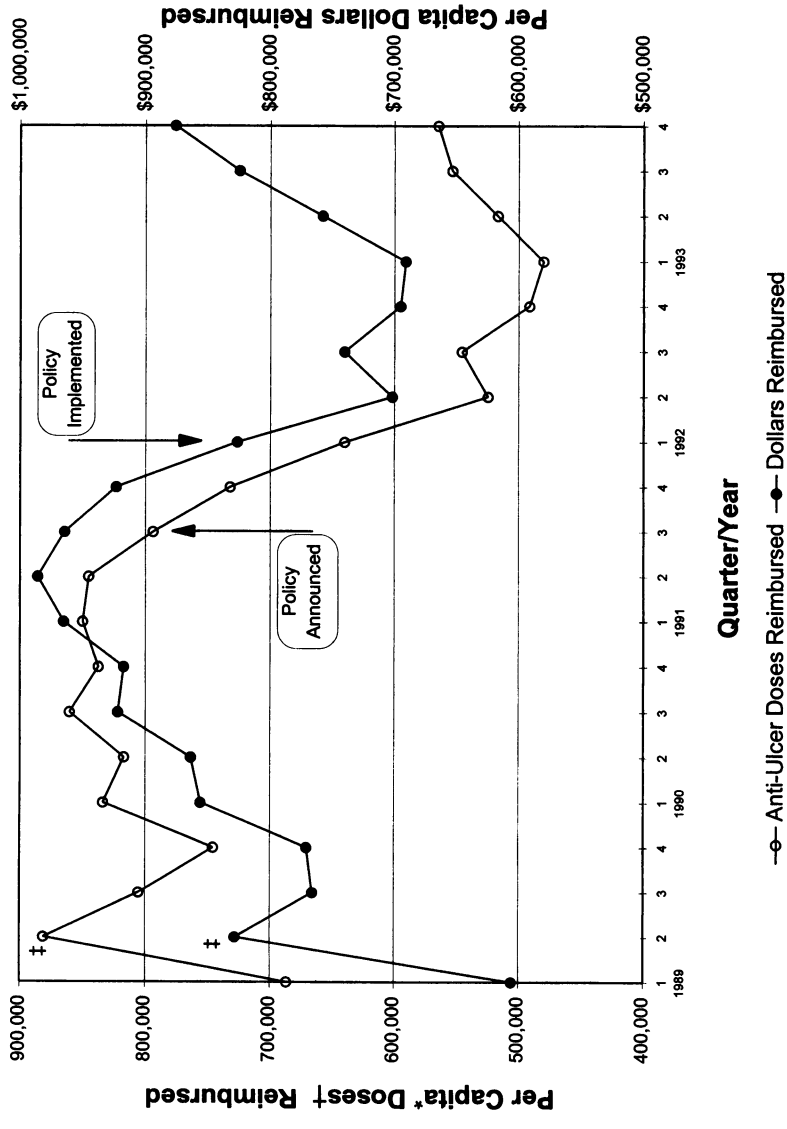
Table 2 also indicates that compared to individuals not covered by Medicaid, Medicaid beneficiaries had an increased risk of hospitalization in the pre-policy period for complicated PUD (RR = 2.24; 95% C.I., 2.03–2.50), for uncomplicated PUD (RR = 2.09; 95% C.I., 1.84–2.38), and for non-ulcer peptic conditions (RR = 2.40; 95% C.I., 2.23–2.59).

DISCUSSION

A 33 percent decrease in the rate of reimbursement for anti-ulcer drugs among Florida's Medicaid beneficiaries accompanied Florida's implementation of a policy restricting Medicaid payment for anti-ulcer drugs. One potential explanation for the decrease is that Medicaid beneficiaries may have begun to use over-the-counter medications instead of prescription anti-ulcer drugs. This explanation is unlikely because nonprescription H_2-receptor antagonists were not available until 1995, and the available nonprescription antacids were not reimbursed by Medicaid and, therefore, would likely have been prohibitively expensive for Medicaid beneficiaries to use as single therapy for a PUD-related disorder. In addition, the antacid regimens that have been shown to compete with acid suppression in relieving dyspepsia and in healing ulcers require an intensive frequency of dosing that would challenge even the most compliant patient populations, and these regimens frequently cause diarrhea as a side effect (Weburg, Aubert, Dahlberg, et al. 1988; Hunter, Walker, Crowe, et al. 1991; Berstad and Weberg 1986).

Another potential explanation for the observed decrease in Medicaid anti-ulcer drug prescriptions is that expanded knowledge of the etiologic

Figure 1: Per Capita Prescription Anti-Ulcer Doses Paid For and Dollars Reimbursed by Florida's Medicaid Program, 1989–1993



Note: Implementation of Florida's policy restricting Medicaid reimbursement for anti-ulcer drugs was associated with a significant 33 percent reduction in the number of doses reimbursed per 100,000 Medicaid enrollees not assigned to an HMO ($p < .001$). Florida Medicaid reimbursements for anti-ulcer drugs per 100,000 Medicaid enrollees not assigned to an HMO also decreased. Florida's total savings from reduced Medicaid reimbursement for anti-ulcer drugs exceeded $3 million for their 1,090,932 Medicaid enrollees not assigned to an HMO in the first quarter of 1992. In 1993, the reimbursements appear to resume their pre-policy climb, suggesting that the duration of effect of the restrictive policy was limited.

* Per capita = per 100,000 Medicaid enrollees not assigned to an HMO.

†Doses of prescription anti-ulcer drugs including cimetidine, famotidine, nizatidine, ranitidine, omeprazole, and sucralfate.

‡The magnitude of this deflection is likely due to a claims processing change implemented by Florida in the second quarter of 1989 that reduced the lag time between dispensing and reimbursement.

Table 1: Number of Hospitalizations and Age- and Sex-Adjusted Hospitalization Rates for Peptic-Related and Control Conditions in Florida, 1989–1993

	1989		1990		1991		1992		1993	
Payer and Diagnostic Category	n*	*Rate*†	n	*Rate*	n	*Rate*	n	*Rate*	n	*Rate*
Medicaid										
Complicated PUD§	175	87	174	74	252	88	279	77	345	82
Uncomplicated PUD**	103	38	112	42	112	34	139	31	166	35
Non-ulcer peptic conditions‡	540	134	767	161	910	150	1271	180	1246	159
Non-Medicaid§§										
Complicated PUD	3670	36	3596	35	3565	34	3610	34	3747	35
Uncomplicated PUD	1876	19	1729	17	1363	13	1258	12	1234	12
Non-ulcer peptic conditions	5889	60	5656	56	5501	54	5870	58	5778	56

Note: Data presented in this chart are annualized; statistical models and graphs use quarterly data. PUD = peptic ulcer disease.

*Number of hospitalizations. †Rate = Age- and sex-adjusted hospitalization rate per 100,000 persons.

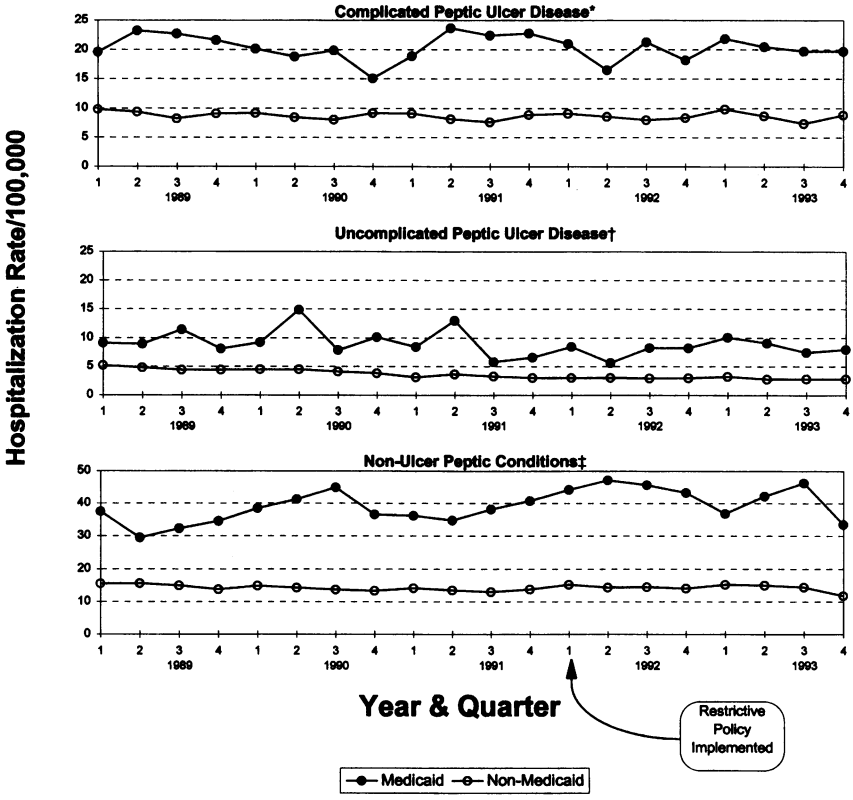
§Includes peptic ulcers of the stomach and duodenum with hemorrhage, perforation, or obstruction.

**Includes peptic ulcers of the stomach and duodenum *without* hemorrhage, perforation, or obstruction.

‡Includes esophagitis, gastritis, and duodenitis.

§§Includes all payers other than Medicaid.

Figure 2: Age- and Sex-Adjusted Hospitalization Rates for Peptic-Related Conditions in Florida's Medicaid and Non-Medicaid Populations, 1989–1993



Note: No restrictive policy-associated increase occurred in Medicaid hospitalization rates for peptic-related conditions relative to non-Medicaid hospitalization rates. Medicaid hospitalization rates were significantly higher than non-Medicaid rates for all diagnostic categories ($p < .001$). Post-policy hospitalization rates were lower than pre-policy rates for all diagnostic categories except non-ulcer peptic conditions.

*Complicated PUD includes peptic ulcers of the stomach and duodenum with hemorrhage, perforation, or obstruction.

†Uncomplicated PUD includes peptic ulcers of the stomach and duodenum without hemorrhage, perforation, or obstruction.

‡Non-ulcer peptic conditions include esophagitis, gastritis, and duodenitis.

role of *Helicobacter pylori* led to the increased use of antibiotic therapy and a decreased use of anti-ulcer drugs. However, it is unlikely that *H. pylori* eradication therapy had gained widespread acceptance by late 1991. The

Table 2: Regression Analyses of the Association Between Implementation of a Medicaid Policy Restricting Anti-Ulcer Drug Reimbursement and Changes in Age- and Sex-Adjusted Hospitalization Rates for Peptic-Related Conditions in Florida, Ages 0–64 Years, 1989–1993

Diagnostic Category	*Parameter*	*Rate Ratio*	*95% C.I.*†	
Complicated PUD‡	Medicaid vs. non-Medicaid	2.25	2.03	2.50
	Post- vs. pre-policy	0.98	0.95	1.02
	Medicaid*Policy interaction§§	0.95	0.82	1.10
Uncomplicated PUD§	Medicaid vs. non-Medicaid	2.09	1.84	2.38
	Post- vs. pre-policy	0.73	0.69	0.77
	Medicaid*Policy interaction	1.12	0.93	1.35
Non-ulcer peptic conditions††	Medicaid vs. non-Medicaid	2.40	2.23	2.59
	Post- vs. pre-policy	1.01	0.98	1.05
	Medicaid*Policy interaction	0.91	0.83	1.01

†C.I. = Confidence Interval. PUD = peptic ulcer disease.

‡Includes peptic ulcers of the stomach and duodenum with hemorrhage, perforation, or obstruction.

§Includes peptic ulcers of the stomach and duodenum without hemorrhage, perforation, or obstruction.

††Includes esophagitis, gastritis, and duodenitis.

§§Interaction terms are denoted by variables separated by an asterisk.

best available indication of the medical community's acceptance of *H. pylori*'s role in PUD is the Consensus Statement of the National Institutes of Health, which was issued in 1994, after our period of observation (NIH Consensus Statement 1994).

A third possible explanation for fewer observed Medicaid anti-ulcer drug prescriptions is that the Medicaid population's average risk of developing PUD decreased as the total number of Medicaid-eligible patients increased from 700,000 in 1989 to 1.6 million in 1993. While this possibility is an important consideration, it, too, is unlikely because Florida did not change its Medicaid eligibility criteria during those five years of rapid growth in Medicaid enrollment. Instead, the rapid growth has been attributed to a period of economic recession.

Thus, our findings suggest that the restrictive policy itself was responsible for the observed decrease in Medicaid anti-ulcer drug use. However, it should be noted that the decrease in anti-ulcer drug use coincided with the August 1991 announcement of the restrictive policy rather than with its February 1992 implementation. The most likely explanation for the

pre-implementation decrease in use is that many Medicaid providers and pharmacists were unaware of the delay in policy implementation (that resulted from unrelated legal hurdles) and thus altered their prescribing and dispensing behavior when the policy was announced, believing mistakenly that the policy was in effect at the time of their notification. If this is true, the mistaken providers would likely have altered their prescribing behavior to avoid having their patients' prescriptions rejected by the pharmacist, and the mistaken pharmacists would likely have altered their dispensing behavior to avoid having their Medicaid anti-ulcer reimbursement claims denied. It is also possible that Medicaid providers began to change their prescribing and dispensing behavior when the policy was announced in anticipation of policy implementation. In any case, the data clearly show that the rate of reimbursement for anti-ulcer drugs was substantially lower in the post-policy period than in the pre-policy period. By calculating the pre- versus post-policy difference in per capita costs for anti-ulcer drugs reimbursed by Florida's Medicaid program, we estimate that the restrictive policy saved Florida's Medicaid pharmacy budget over $3 million in anti-ulcer drug costs in 1992 (see Figure 1).

It is interesting that the utilization and cost curves shown in Figure 1 suggest a rebound back toward pre-policy levels starting with the second quarter of 1993. It was not possible to determine the magnitude of this rebound beyond 1993 with the data available, but this observation warrants further research investigation.

Our results also suggest that Medicaid restrictions on anti-ulcer drug reimbursement were not associated with an increase in Medicaid hospitalization rates for complicated PUD, for uncomplicated PUD, or for non-ulcer peptic conditions. Our findings regarding complicated and uncomplicated PUD are consistent with those of previous studies. Hospitalization rates for complicated PUD have been stable despite the increased use of H_2-receptor antagonists over the past 20 years (Christensen, Bousfield, and Christensen 1988; Paimela, Tuompo, Perakyla, et al. 1991; McKay and McArdle 1982). While there has been a gradual decrease in hospitalization rates for uncomplicated PUD, this decline began before the introduction and widespread availability of H_2-receptor antagonists (Kurata 1991).

We are unaware of published data quantifying the magnitude of anti-ulcer medicine misuse. In addition, the data provided to us did not permit us to measure the merit of indications for anti-ulcer drug use in Florida's Medicaid patients. However, because the relative number of patients on anti-ulcer medicines for ulcer disease versus non-ulcer dyspepsia could affect the

likelihood of finding a policy-related change in peptic-related hospitalizations, we sought to maximize our ability to detect an unintended increase in hospitalizations for PUD-related disorders by also examining hospitalization rates for non-ulcer peptic conditions. As with hospitalization rates for complicated and uncomplicated PUD, no evidence was found of any significant increase in hospitalization rates for PUD-related conditions. While an increase in hospitalizations among patients taking anti-ulcer medicines without an ulcer might have been surprising, the diverse indications for hospitalization vary widely and include diagnosis codes such as that for unexplained abdominal pain.

An additional possible explanation for not finding a significant increase in ulcer-related hospitalizations is that our study window might have been too brief to detect recurrent ulcers that resulted from reduced access to anti-ulcer drugs. However, the natural history of peptic ulcer disease and its recurrences indicates that 75 percent of ulcer recurrences occur within one-half year of discontinuing therapy (Gudmand-Hoyer, Jensen, Krag, et al. 1978). Therefore, our study window should have been adequate to detect hospitalizations from recurrent peptic ulcers.

The lack of a policy-associated increase in Medicaid hospitalization rates for PUD-related hospitalizations is reassuring in the current healthcare environment, especially given the increasing concerns that efforts to decrease healthcare costs will be achieved only at the expense of compromised clinical outcomes. While our analyses cannot identify the reason why Florida's policy achieved its intended effect without an apparent adverse impact on hospitalization, we find it interesting that the policy's dosing and duration-of-therapy limits were consistent with recommended doses and duration of therapy for each restricted anti-ulcer drug. Other states with policies that are more or less restrictive in their control of anti-ulcer drugs or other medicines might have different results. Unfortunately, the only way to ensure that such restrictive policies do not cause unintended adverse effects on patient access to appropriate therapy is to look for adverse effects, such as an increase in complications requiring hospitalizations.

In our study, which relied on analyses of trends in anti-ulcer drug use and PUD-related hospitalization rates among Medicaid beneficiaries, we used two separate and unlinked data sources that did not contain unique patient identifiers. These databases did not enable us to assess a direct connection between those patients who may have realized a post-policy drop in their anti-ulcer medicine and those who realized a higher risk of post-policy ulcer-related hospitalizations. In addition, we did not have access to ambulatory healthcare claims data. Thus, we cannot rule out the possibility that the

restrictive policy led to an increase in the use of ambulatory healthcare services for PUD-related disorders.

With the data available, we were unable to adjust for exposure to nonsteroidal anti-inflammatory drugs (NSAIDs) or antibiotics used to eradicate *H. pylori*. Restrictions on NSAIDs were implemented by Florida's Medicaid program in February 1992. A substantial policy-related decrease in NSAID use could have caused a decrease in PUD-related hospitalizations, thereby masking an increase in hospitalizations associated with anti-ulcer drug restrictions. However, the potential confounding effects of changes in NSAID use are mitigated by the fact that the NSAID restrictions were substantially more lenient than those affecting anti-ulcer drugs, limiting the use of only the most expensive NSAIDs. Similarly, for reasons addressed earlier, we believe that the potential confounding effects of antibiotics used to eradicate *H. pylori* are negligible during the period of observation of this study.

Limitations in data availability also confined us to a comparison of trends in two different populations: the drug utilization analysis included Medicaid patients of all ages, but the analysis of hospitalization rates excluded patients 65 years of age and older. This age exclusion in the analysis of hospitalization rates was necessary because the database did not permit identification of patients who were dually eligible for both Medicaid and Medicare. For dually eligible patients 65 years of age and older, Medicare was preferentially listed as the primary payer. Therefore, including patients 65 years of age and older in our analysis would have resulted in an underestimate of the Medicaid hospitalization rates for PUD-related conditions, because elderly Medicaid patients would have been underrepresented by the primary payer data. Relying on data that required the elimination of the elderly from an investigation of peptic ulcer disease may have reduced the sensitivity of our methods for finding an unintended policy-associated increase in PUD-related hospitalizations. This limitation underscores the importance of pursuing further investigations using linked claims data that would preclude the need to exclude the elderly and would permit the identification, within the larger Medicaid population, of subgroups that may have an increased risk of adverse policy effects.

Previous studies have yielded conflicting results regarding the clinical impacts of statewide policies restricting reimbursement for medications (Soumerai et al. 1993). Soumerai et al. found that a New Hampshire Medicaid program limit of three prescriptions per patient per month was associated with a significant decrease in the number of filled Medicaid prescriptions in that state (Soumerai et al. 1987) and a significant increase in the rate of nursing

home admissions (Soumerai, Ross-Degnan, Avorn, et al. 1991), but no change in the hospitalization rate. It was unclear whether the observed increase in nursing home admissions was related to increased patient morbidity, to lesser restrictions on pharmaceutical benefits in the nursing home setting, or to other factors. An association was found between New Hampshire's overall prescription limit and increased use of community mental health centers and emergency mental health services by Medicaid beneficiaries with chronic mental illness (Soumerai, McLaughlin, Ross-Degnan, et al. 1994). More recently, a prior authorization requirement for nongeneric NSAIDs in Tennessee was found to be associated with a significant reduction in expenditures for NSAIDs without a concomitant increase in expenditures for other types of medical care (Smalley, Griffin, Fought, et al. 1995).

Given increased pressures to control healthcare costs, public and private sector policies designed to reduce healthcare utilization are increasing in prevalence. In addition, recently passed federal legislation grants each state sole responsibility to decide how its Medicaid patients' health services will be administered. In this evolving environment, the availability of methods to determine the clinical as well as economic effects of these policies will be critically important if the quality of healthcare is to be preserved and its efficiency enhanced. The need for such analysis is underscored by the realization that even small increases in the rate of clinical complications can have immense economic and human significance when the increased risk applies to large populations, such as an entire state's Medicaid population. Adjusting for trends in non-Medicaid hospitalization rates for PUD-related conditions, the results of that analytic model indicate that if a policy-associated increase in Medicaid PUD-related hospitalizations did occur, the increase was likely to be no greater than 10 percent for complicated PUD, 35 percent for uncomplicated PUD, and one percent for non-ulcer peptic conditions.

The methods employed in this study provide a means of conducting such analyses with data that are readily available. Increased performance of such analyses can help to identify cost control strategies that can achieve substantial reductions in costs without inducing costly and harmful clinical consequences.

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