The Effect of an Rx-to-OTC Switch on Medication Prescribing Patterns and Utilization of Physician Services: The Case of Vaginal Antifungal Products

Jerry H. Gurwitz, Thomas J. McLaughlin, and Leslie S. Fish

Objective. We examined the impact of over-the-counter (OTC) availability of vaginal antifungal products, beginning in January 1991, on medication prescribing patterns and utilization of physician services.

Data Sources and Study Setting. Data on utilization of health care services and prescription medications by female members (ages 11 and older) of the Fallon Community Health Plan (FCHP), a group model health maintenance organization and a component of the Fallon Health Care System of central Massachusetts. The census for such individuals increased from 49,551 in January 1990 to 67,365 in December 1992.

Design. Time-series analyses were employed to assess changes in prescribing patterns of vaginal antifungal products and physician visits for vaginitis from January 1, 1990 through December 31, 1992. Monthly numbers of prescriptions for vaginal antifungal products and physician visits per 100 members were measured. Monetary savings relating to the prescription-to-OTC switch were also estimated.

Data Collection Methods. The computerized management information system of FCHP contains records on utilization of all health care services and prescriptions filled, collected as part of routine fiscal activities. We identified all vaginally administered products on the FCHP formulary used for the treatment of vaginal candidiasis and determined the number of prescriptions filled for these agents during each month of the study period. We also identified the number of physician office visits characterized by the ICD-9-CM code 616.10 ("vaginitis and vulvovaginitis, unspecified") occurring during each month of the study period.

Principal Findings. For the one-year period after OTC availability of vaginal antifungal products (January 1991 through December 1991), we estimated that the number of prescriptions dispensed for these products was reduced by 6.42 per 100 female FCHP members ages 11 and older. Physician visits for vaginitis were reduced by 0.66 per 100 members. Estimated savings to the Fallon Health Care System for the one-year period following OTC availability were $42,528 in medication costs and $12,768 to $25,729 for costs associated with physician visits, depending on use of laboratory testing in patient evaluations.

Conclusions. The findings of this study suggest that the prescription-to-OTC switch of vaginal antifungal treatments reduced health care costs to the insurer in the managed

care setting. These favorable effects on costs for the insurer need to be weighed against shifts in medication costs to consumers and potential adverse consequences to the patient relating to errors in self-diagnosis.

Key Words. Drugs, nonprescription; health maintenance organizations; deductibles and coinsurance

---

Over-the-counter (OTC) drugs are medications directly available to the consumer for self-care. A variety of agents previously available only by prescription have been made OTC. Prominent examples include ibuprofen, naproxen sodium, topical hydrocortisone, diphenhydramine, loperamide, famotidine, cimetidine, clotrimazole, and miconazole (McLeod 1989). The impact of prescription-to-OTC changes has been assumed to be favorable (Temin 1983). Potential benefits to the patient include reduced time from onset to symptomatic or curative treatment. In addition, time and monetary savings may be gained by eliminating the need to visit a physician, with its associated costs due to travel and time lost from work.

While many health plans provide substantial coverage for prescription medications, most do not cover the costs of OTC drugs. Prescription-to-OTC switches have the potential to save costs for insurers through reduced utilization of covered prescription medications and physician visits. Most health plans have small copayments for prescription drugs; these copayments are often lower than the out-of-pocket costs for OTC products equivalent to medications available only by prescription. If the cost to a patient for an OTC medication exceeds the cost for an alternative prescription drug available through a prescription benefit plan, patients may prefer to request the prescription drug from their physician, leading to increased costs to the insurer or health plan.

Dr. Gurwitz is the recipient of Clinical Investigator Award KO8 AG00510 from the National Institute on Aging, Bethesda, MD.

Jerry H. Gurwitz, M.D., is Assistant Professor of Medicine, Program for the Analysis of Clinical Strategies, Gerontology Division, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School. Thomas J. McLaughlin, Sc.D. is Instructor, Department of Ambulatory Care and Prevention, Harvard Medical School, and Harvard Community Health Plan. Leslie S. Fish, Pharm D. is Clinical Coordinator, Division of Drug Utilization, Fallon Health Care System, Worcester, MA. Address correspondence and requests for reprints to Jerry H. Gurwitz, M.D., Program for the Analysis of Clinical Strategies, Brigham and Women's Hospital, 221 Longwood Avenue Suite 341, Boston, MA 02115. This article, submitted to *Health Services Research* on May 18, 1994, was revised and accepted for publication on March 6, 1995.

Vaginitis, one of the most common problems in clinical medicine, accounts for over 10 million office visits per year (Kent 1991). Candida vulvovaginitis is the second most common diagnosis in women with vaginal symptoms (Reed and Eyler 1993). The Food and Drug Administration granted its first approval for an OTC product to treat vaginal candidiasis (clotrimazole) on November 30, 1990. This product was first available for purchase by consumers without a prescription in January 1991. Subsequently, other vaginal antifungal products containing miconazole were made available OTC. Manufacturers have extensively promoted all of these agents to consumers. The diagnosis of vaginal candidiasis can be difficult to make based on symptoms alone. Warnings on the packaging of all of these products state that the medications are not intended for women with a first occurrence of vaginal symptoms or for women with recurrence of symptoms within two months of therapy.

The primary objective of our study was to examine the impact of OTC availability of vaginal antifungal products on medication prescribing patterns and on the use of physician services in the setting of a large health maintenance organization. A second objective was to investigate the impact of a subsequent increase in the prescription drug copayment on these outcomes.

METHODS

STUDY PERIOD AND SETTING

The time period examined in this study encompassed January 1, 1990 through December 31, 1992. The Fallon Community Health Plan (FCHP) is a group model HMO in operation in central Massachusetts since 1977. The Fallon Health Care System includes the FCHP in addition to a large multispecialty physician group, a community hospital, and an in-house pharmacy. There are two categories of membership in the FCHP; junior plan members are less than 65 years of age and senior plan members are ages 65 and older. Over the study period, the membership census increased from 115,747 in January 1990 to 156,457 in December 1992. In the final month of the study, there were 137,705 junior plan members (68,746 male and 68,959 female) and 18,752 senior plan members (8,088 male and 10,664 female). For the purpose of this investigation, the study population of interest was women 11 years of age or older. The census for such individuals increased from 49,551 in January 1990 to 67,365 in December 1992.

Members are covered for all inpatient, outpatient, and prescription medication costs, with the exception of a small copayment for physician visits and prescription medications. The Fallon pharmacy dispenses essentially all prescription medications to members. Medications available OTC are not covered under the plan. The copayment for prescription medications increased from $2.00 to $5.00 on January 1, 1992 for all members. The copayment for physician office visits is $2.00. However, prior to January 1, 1992, there was no copayment for physician visits for senior plan members.

DATA SOURCE

The computerized management information system of FCHP contains records on utilization of all health care services and prescriptions filled, collected as part of routine fiscal activities. Prescription records identify the specific product and the date that it was dispensed. Records regarding physician office visits are characterized by ICD-9-CM codes (International Classification of Diseases, Ninth Revision, Clinical Modification). Member enrollment files are continually updated and the census is summarized monthly according to age, gender, and membership category (junior or senior plan).

PRESCRIPTIONS AND PHYSICIAN VISITS

We identified all vaginally administered products on the FCHP formulary used for the treatment of vaginal candidiasis and determined the number of prescriptions filled for these agents during each month of the study period. These products included butoconazole, clotrimazole, miconazole, nystatin, and terconazole. Various clotrimazole and miconazole-containing products became available OTC during the period after January 1991 (clotrimazole in January 1991 and miconazole in March 1991). All butoconazole, nystatin, and terconazole vaginal antifungal products were available only by prescription throughout the entire study period.

The diagnostic information used in this study was derived from uniform patient encounter forms that include a listing of common outpatient diagnoses with the corresponding ICD-9-CM codes and are used by all providers. The physician indicates the diagnosis relevant to the clinic visit by placing a check mark in a box adjacent to the condition and its ICD-9-CM code. The sole coding option available to characterize a clinic visit for vaginitis is ICD-9-CM code 616.10 ("vaginitis and vulvovaginitis"). There is no possibility of ambiguity with any other diagnosis on the encounter form. No changes were made in the encounter forms over the study period. We identified the number

of physician office visits, characterized by the ICD-9-CM code 616.10, that occurred during each month of the study period.

The number of enrolled female FCHP members ages 11 or older was determined for each month of the study period for use as the denominator in calculating rates of prescriptions filled or physician visits.

STATISTICAL ANALYSIS

We used segmented time-series analysis (Gillings, Makuc, and Siegel 1981) to estimate the effects of OTC availability (January 1991) and the increase in the prescription medication copayment (January 1992) on rates of prescriptions filled for vaginal antifungal products and physician visits for vaginitis. Monthly numbers of prescriptions or physician visits per 100 members were plotted. Regression models were fit to these time-series with use of the SAS AUTOREG procedure (SAS Institute 1988). The dependent variables in the respective models were the number of prescriptions per 100 members or the number of physician visits for vaginitis per 100 members. The models included a constant term, a linear time trend, and terms indicating changes in the level of prescriptions or physician visits per 100 members for the periods during which vaginal antifungal products were available OTC, and the copayment increase for prescription medications was in effect. Finally, terms were included for changes in linear time trend (slope) after OTC availability and the copayment increase for prescription medications. (A mathematical description of the general model is included in the appendix.) The statistical significance of the effects of these factors was tested with t-statistics; correlated errors in the regressions were taken into account by assuming first-order autocorrelated errors. A p-value of less than or equal to .05 was considered statistically significant. The adequacy of the models was tested by residuals analysis.

COST ANALYSES

The following estimates of costs were employed in the economic evaluations. The average cost to the Fallon Health Care System in 1992 for vaginal antifungal products that were available only by prescription and were on the formulary was $13.30.[1]

During the study period, the listed charge for a limited office visit with a physician was $35.00. Laboratory charges were $12.50 for a potassium hydroxide preparation and $21.00 for a vaginal culture. During the study period, there was no established protocol at Fallon for the use of laboratory testing in patients with vaginitis, and we were not able to link individual

physician visits with ordered tests. For the purpose of this study, we considered the costs of four different scenarios for the use of laboratory testing performed in association with an evaluation for vaginal candidiasis: (1) no testing (2) potassium hydroxide preparation only (3) vaginal culture only and (4) potassium hydroxide preparation with vaginal culture. Under these four different situations, the costs for physician and laboratory services would be $35.00, $47.50, $56.00, and $68.50, respectively.

Savings to the Fallon Health Care System relating to the OTC availability of vaginal antifungal products were estimated for a one-year period (January 1991 through December 1991). In determining these savings, copayments were deducted from the cost of the prescription vaginal antifungal products and physician visits. Despite the fact that no copayment was required of senior FCHP members for physician visits before January 1, 1992, the deduction was made uniformly for all physician visits to determine the most conservative estimates of savings. Costs for prescription vaginal antifungal products did not include expenses associated with the stocking and dispensing of medications by the FCHP pharmacy. In separate analyses for medications and physician visits, the area under the regression line based on observed data was subtracted from the area under the regression line based on projections for utilization of medications and physician visits that would have occurred if vaginal antifungal products had not become available OTC.

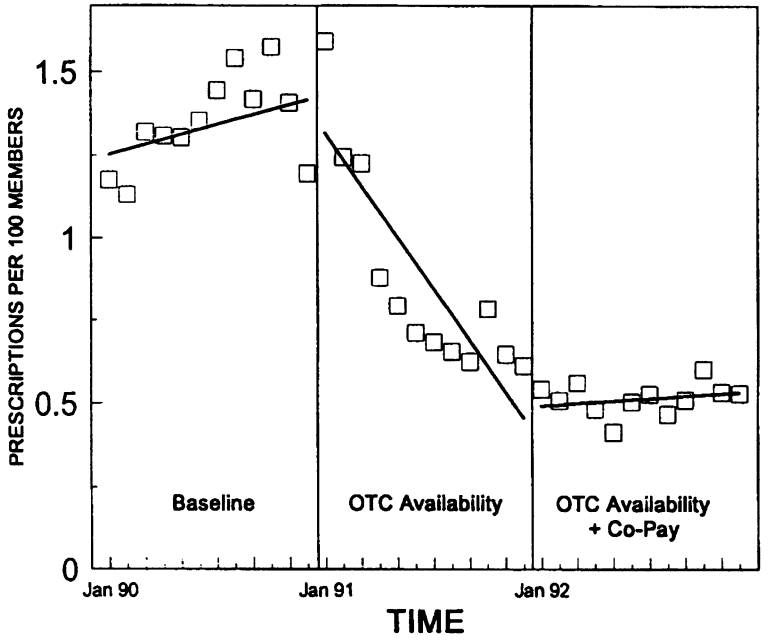
RESULTS

EFFECTS ON PRESCRIPTIONS

The monthly numbers of prescriptions filled per 100 members for all vaginal antifungal products are plotted in Figure 1. With OTC availability, there was a significant reduction in prescribing (beta estimate = 0.093; standard error = .018; $p = .0001$). While monthly prescribing levels averaged 1.35 prescriptions per 100 members for the one-year period prior to OTC availability (January 1990 through December 1990), this level had declined to 0.61 one year later (December 1991). This reduction was sustained over the remainder of the study period (December 1991 through December 1992).

Figure 2 describes the time-series of monthly number of prescriptions per 100 members for products that became available OTC after January 1, 1991. These products continued to be dispensed to members when specifically prescribed by a physician after their availability OTC on a limited basis due to remaining inventories that were essentially depleted by July

Figure 1: Time Series of Monthly Number of Prescriptions Filled per 100 Members for All Vaginal Antifungal Products

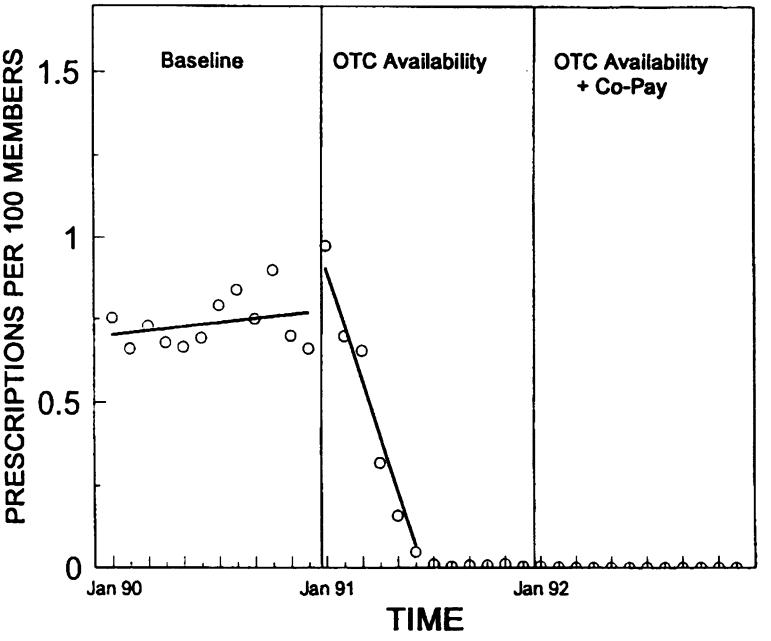


1991. Figure 3 depicts the time-series for vaginal antifungal products that have remained available only by prescription throughout the entire study period (butoconazole, nystatin, and terconazole). After January 1991, prescription rates for these products significantly declined in level (beta estimate = 0.118; standard error = 0.052; $p = .03$), but not in slope. The increase in the copayment for prescription medications on January 1, 1992 was associated with a decline in the level of the prescription rate (beta estimate = 0.178; standard error = 0.052; $p = .002$), but there was no change in slope. The R^2 for this regression equation was 0.55, indicating a reasonably good fit.

EFFECTS ON PHYSICIAN VISITS

Monthly numbers of physician visits per 100 members for vaginitis over the study period are plotted in Figure 4. Following OTC availability, there was a significant decline in the slope of visit rates (beta value = 0.009; standard error = 0.005; $p = .02$). The increase in the copayment for prescription

Figure 2: Time Series of Monthly Number of Prescriptions per 100 Members for Vaginal Antifungal Products that Became Available OTC

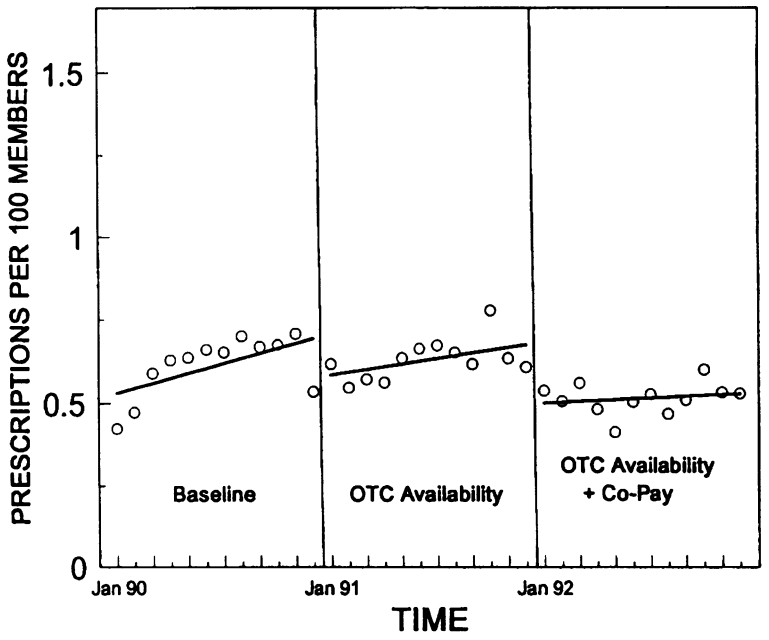


medications was not associated with any significant change in visit rates in terms of level or slope. The R^2 for this regression equation was 0.63.

ECONOMIC IMPLICATIONS

For the one-year period following the OTC availability of vaginal antifungal products (January 1991 through December 1991), we estimated that the number of prescriptions dispensed for these products was reduced by 6.42 per 100 female FCHP members ages 11 and older. Physician visits for vaginitis for this population were reduced by 0.66 per 100 members. With an average monthly census during the specified one-year period of 58,622 members, estimated savings to the Fallon Health Care System resulting from OTC availability were $42,528 in medication costs. Under the four different scenarios for use of laboratory testing associated with the evaluation of vaginal candidiasis, the estimated savings to the Fallon Health Care System would be: (1) $12,768 if no tests were performed; (2) $17,604 with a potassium hydroxide preparation alone; (3) $20,893 with a vaginal culture alone; and

Figure 3: Time Series of Monthly Number of Prescriptions per 100 Members for Vaginal Antifungal Products that Remained Available Only by Prescription after December 1990



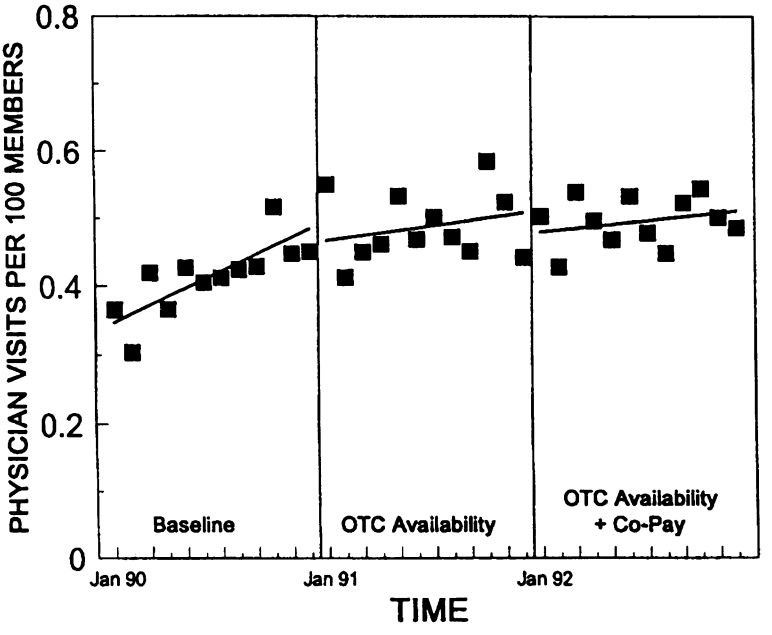
(4) $25,729 if both a potassium hydroxide preparation and vaginal culture were performed.

DISCUSSION

The pros and cons of OTC availability of prescription medications receive careful consideration before a change is made to nonprescription status (Feldman 1993; *The Lancet* 1993). A product's safety and efficacy record is weighed against the risks of improper diagnosis and treatment as well as the occurrence of potentially dangerous side effects and important drug-drug interactions. Prior to an OTC switch, information on drug side effects and efficacy is usually substantial, having been gathered over years of premarketing and postmarketing experience with the product.

In contrast, before the OTC switch occurs, information is generally not available regarding the levels to which patients will choose self-treatment

Figure 4: Time Series of Monthly Number of Physician Visits for Vaginitis per 100 Members



with an OTC product and the overall impact that OTC availability will have on utilization of health care services. Changes in the use of health care services relating to an OTC switch must be estimated by relying on a variety of assumptions and suppositions concerning the behaviors of both patients and physicians (Oster, Huse, Delea, et al. 1990). Even after an OTC switch occurs, these effects are difficult to assess, because the costs of OTC products are generally out-of-pocket for the consumer and utilization of these products can be extremely difficult to track. However, to some extent these effects can be inferred by examining trends in utilization of prescription products with indications identical to those of OTC products, as well as rates of physician visits for medical conditions that would be treated by the OTC product of interest. The switch of some vaginal antifungal products to OTC status provides a model for studying such effects.

In a managed care setting, we observed substantial effects on the utilization of prescription vaginal antifungal products and more modest effects on physician visits subsequent to OTC availability of these agents. Reductions in

the use of medications and physician services were associated with substantial monetary savings for the managed care organization. For prescription vaginal antifungal agents, statistically significant declines in prescription rates were observed; however, the observed declines were small. Since there is a lack of clear superiority of any one azole agent in the treatment of vulvovaginal candidiasis (Doering and Santiago 1990; Ernest 1992; Sanford 1993), clinical factors do not explain the limited impact on utilization of these prescription products after the OTC availability of vaginal antifungal agents. It has been speculated that patients may ask their physicians for a prescription product to take full advantage of a prescription drug benefit. For health plan members, the cost of the OTC product far exceeds the cost of the prescription drug copayment. The reduction in utilization of prescription vaginal antifungal products resulting from the increase in the copayment for prescription drugs suggests that increasing out-of-pocket costs for prescription drugs affect patient choices in regard to the use of OTC products.

The OTC availability of vaginal antifungal products had an effect on rates of physician visits for vaginitis. This effect occurred in spite of the fact that the cost for a physician visit was minimal (copayment of $2.00). This finding may reflect the desire by a proportion of affected patients to avoid such things as the costs and inconvenience associated with missing work, arranging for child care, and time needed to travel to the doctor's office and to wait for an appointment with a physician. In addition, there are other potential benefits to the patient relating to self-treatment, including the avoidance of delays in treatment and cure, further encouraging patients to choose self-diagnosis and treatment. However, the opportunity for prompt access to treatment does not always result in better care. An erroneous self-diagnosis can lead to prolonged patient discomfort and the costs associated with the purchase of an inappropriate and ineffective therapy.

Observational studies employing data collected for administrative purposes have a number of limitations. In the performance of this study we did not have access to medical records, and this prevented both further determination of the etiology of the patients' symptoms as well as obtaining additional information regarding demographic and clinical characteristics. Vaginal candidiasis is the second most common diagnosis in women with vaginal symptoms. Other etiologies, including *Trichomonas* and *Gardnerella*, were likely responsible for a proportion of the physician visits characterized by the ICD-9-CM code 616.10 ("vaginitis and vulvovaginitis, unspecified"). This misclassification would most likely have served to obscure any observed effects on physician visits in our study. When considered in this context,

our estimates of effect must be considered quite conservative. The absence of data on patient characteristics (e.g., history of previous infections) precluded adjustment for potential confounders in our analyses (Salem-Schatz et al. 1994).

While this study was performed in the context of a health maintenance organization, we believe that the results are broadly generalizable. The rates of physician visits for vaginitis in our study are comparable to those observed in the general U.S. population according to data available from the 1991 National Ambulatory Medical Care Survey (Schappert 1994). Our findings indicate that an OTC switch can reduce expenditures for medications by HMOs and other insurers with prescription drug plans. Furthermore, expenditures for health care services including physician visits and diagnostic testing may also be reduced with the availability of an OTC product previously available only by prescription. Therefore, medical assistance programs with more generous drug plans that cover OTC products might still reap meaningful savings related to an OTC switch as a result of reduced use of physician services.

Savings that accrued to the FCHP were achieved partially as a result of shifting medication costs to patients. However, no cost shifting occurred in relation to physician visits; patients electing self-treatment did avoid the costs of the copayments for medications and physician visits. While the choice of self-diagnosis and treatment by the patient with vaginal symptoms has numerous advantages, the use of OTC therapy for the wrong indications may lead to delays in appropriate diagnosis and treatment, increased utilization of health care services, and increased health care costs. Yet the findings of this study suggest that potential adverse consequences of self-treatment resulting in increased utilization of health care services were not a major issue. However, patient-specific clinical information was not available to fully assess this issue.

With the expectation that several prescription products currently used to treat a variety of medical conditions will achieve OTC status over the coming years, the impact of these changes on health care service utilization will need to be examined carefully. The findings of this study suggest that the prescription-to-OTC switch of vaginal antifungal treatments reduced health care costs for the insurer. To examine comprehensively the economic and clinical implications of prescription-to-OTC switches, both the magnitude of shifts in medication costs to consumers and the potential adverse clinical consequences to patients relating to errors in self-diagnosis must be more fully considered.

APPENDIX

The general regression models employed in this study include variables that indicate both slope and level changes in the respective time periods during which time vaginal antifungal products were available OTC and, later, during the time when the copayment increase for prescription medications was in effect. In addition, the model contains terms for intercept as well as calendar time (in months where month 1 = January 1990):

$$E(y) = \beta_0 + \beta_1(x_1) + \beta_2(x_2) + \beta_3(x_3) + \beta_4(x_4) + \beta(x_5)$$

where y is the dependent variable (number of prescriptions or visits per 100 members) and x_1 through x_5 are the covariates of interest.

Specifically, the variable x_1 represents the slope change after OTC availability, and is defined as

$x_1 = 0$ if month < 13 and

$x_1 = 14 - (26 - \text{month})$ when month ≥ 13;

The variable x_2 represents the level change after OTC availability and is defined as

$x_2 = 0$ if month < 13 and

$x_2 = 1$ if month ≥ 13;

The variable x_3 represents the slope change after the copayment increase for prescription medications and is defined as

$x_3 = 0$ if month < 25

$x_3 = 14 - (38 - \text{month})$ when month ≥ 25;

The variable x_4 represents the level change after the copayment increase for prescription medications and is defined as

$x_4 = 0$ if month < 25

$x_4 = 1$ if month ≥ 25.

The variable x_5 designates the numeric month beginning in January 1990 (month = 1) and extending to December 1992 (month = 36).

NOTE

1. We recognize that charges often do not represent the actual "costs" of delivering health care, which can be extremely difficult to estimate. For the purposes of our study, we employed the charges for physician and laboratory services that would have been incurred by a nonmember of the FCHP to estimate the financial implications of the OTC availability of vaginal antifungal products.

REFERENCES

Doering, P. L., and T. M. Santiago. 1990. "Drugs for Treatment of Vulvovaginal Candidiasis: Comparative Efficacy of Agents and Regimens." *DICP: The Annals of Pharmacotherapy* 24 (11): 1078–83.

Ernest, J. M. 1992. "Topical Antifungal Agents." *Obstetrics and Gynecology Clinics of North America* 19 (3): 587–607.

Feldman, M. 1993. "Pros and Cons of Over-the-Counter Availability of Histamine2-Receptor Antagonists." *Archives of Internal Medicine* 153 (21): 2415–24.

Gillings, D., D. Makuc, and E. Siegel. 1981. "Analysis of Interrupted Time Series Mortality Trends: An Example to Evaluate Regionalized Perinatal Care." *American Journal of Public Health* 71 (1): 38–46.

Kent, H. L. 1991. "Epidemiology of Vaginitis." *American Journal of Obstetrics and Gynecology* 165 (4, Part 2): 1168–76.

McLeod, D. C. 1989. "Nonprescription Drug Approval: Therapeutic Strategy or Marketing Decision?" *DICP: The Annals of Pharmacotherapy* 23 (7–8): 606–609.

"OCs o-t-c?" [Editorial]. 1993. *The Lancet* 342 (8871): 565–66.

Oster, G., E. M. Huse, T. E. Delea, G. A. Colditz, and J. M. Richter. 1990. "The Risks and Benefits of an Rx-to-OTC Switch: The Case of Over-the-Counter H2-Blockers." *Medical Care* 28 (9): 834–52.

Reed, B. D., and A. Eyler. 1993. "Vaginal Infections: Diagnosis and Management." *American Family Physician* 47 (8): 1805–18.

Sanford, J. P. 1993. *Guide to Antimicrobial Therapy 1993.* 15. Dallas, TX: Antimicrobial Therapy, Inc.

SAS Institute. 1988. *SAS ETS User's Guide. Version 6.* Cary, NC: SAS Institute.

Salem-Schatz, S., G. Moore, M. Rucker, and S. D. Pearson. 1994. "The Case for Case-Mix Adjustment in Practice Profiling: When Good Apples Look Bad." *Journal of the American Medical Association* 272 (11): 871–74.

Schappert, S. M. 1994. *National Ambulatory Medical Care Survey, 1991 Summary.* DHHS Publication No. (PHS) 94-1777. National Center for Health Statistics. *Vital Health Statistics* 13 (116). Hyattsville, MD.

Temin, P. 1983. "Costs and Benefits in Switching Drugs from Rx to OTC." *Journal of Health Economics* 2 (3): 187–205.