OBJECTIVES: Long-term continuous use of HMG-CoA inhibitors (statins) has been shown to be beneficial to patients with coronary artery disease in several large clinical trials. This study demonstrates a promising model to assess the relationship between medication adherence with statins and the risk of adverse event (hospitalization or emergency visit) in a managed care population.

METHODS: Conventional outcomes assessments for medication compliance often encounter the problem of identifying the causal relationship between adherence and outcomes (e.g., adverse event). It is not unusual that medication discontinuation occurs after and possibly due to a hospitalization event. To determine the strength of the relationship between statin adherence and risk of hospitalization, a Cox proportional hazard model was developed with the time-varying variable defined as proportion of days covered by statins (PDC) as of the date of first adverse event. For censored subjects, PDC was chosen as of the end of study period or the date of disenrollment, whichever occurred first. 68,974 adult patients were identified as new statin starters during a 2-year period from June 1998 to June 2000. Other covariates included demographics, payer types, previous drug, medical and procedure uses, and comorbidities. RESULTS: The time varying covariate (PDC) was the second most significant predictor of time to adverse event (chi-square < 1610.9, p < 0.0001). The most significant predictor of an adverse event was the existence of a previous adverse event (chi-square = 2043.1, p < 0.0001). Patients with higher age, comorbidities and previous high utilization have higher risk. In addition, patients in HMO and POS have significantly lower risk than patients with FFS and PPO. CONCLUSIONS: Time-varying PDC is one of the strongest predictors of the risk of an adverse event. Persistence is significantly associated with lower risk of occurrence of hospitalization or emergency visit.

DRUG POLICY

RELATIONSHIP BETWEEN DIRECT-TO-CONSUMER ADVERTISING AND PRODUCT INNOVATIVENESS

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OBJECTIVE: The purpose of this study is to determine if there is a relationship between product innovativeness and direct-to-consumer advertisement. METHODS: Products advertised directly to the consumer (DTC) were divided into two categories using the FDA therapeutic and chemical classification system. New molecular entities and products with priority reviews were classified as ‘innovative’; all other standard review products were classified as ‘standard’. Information on product classification and the total number of products approvals was obtained from FDA prescription drug approval data. The amount spent on DTC advertising between 1997 and 2001 was obtained from published data. Products with less than a 0.1% share of annual DTC expenditures were excluded, as were products launched before 1990, and vaccines and biotech products. The average annual expenditure on DTC advertisement from 1997–2001 was calculated for each product. Data were analyzed using chi-square and t-tests. RESULTS: The inclusion criteria were met by 106 distinct products. The proportion of products advertised in the innovative group was significantly higher than the standard group (p < 0.006). Innovative products are 1.7 times more likely to be advertised directly to the consumer than the standard products. There was no statistical difference in the average annual DTC expenditure per product in each group (p = 0.63). CONCLUSION: Innovative products are more likely to be advertised directly to the consumer which may increase patients’ request for those medications. This information may help decision makers understand potential product demand during the formulary decision making process.

ECONOMIC IMPACT OF PROZAC® PATENT EXPIRATION AND THE 180-DAY GENERIC FLUOXETINE EXCLUSIVITY IN A PUBLICLY-FINANCED PRESCRIPTION PROGRAM

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OBJECTIVE: The purpose of this study was to describe the economic impact of generic fluoxetine entry on trends in utilization and costs of new generation antidepressants (Celexa®, Effexor®, Luvox®, Paxil®, Prozac®, and Zoloft®) within the Texas Medicaid Program. Additionally, diffusion of market share among generic manufacturers following the 180-day marketing exclusivity period was also examined. METHODS: Retrospective prescription claims data from January 2001 through August 2002 were analyzed. Claims were grouped across study agents: 1) Prozac®, 2) fluoxetine, and 3) other (Celexa®, Effexor®, Luvox®, Paxil®, and Zoloft®) antidepressants. Costs were based on payments to pharmacies. RESULTS: A total of 1,154,665 prescription claims were analyzed. Prior to the introduction of generic fluoxetine, market share for Prozac® was 19.0% (10,754 claims) in July 2001. In August 2002, market share for Prozac® decreased to 2.2% (1,479 claims), of which, 952 claims (64.3%) were for the Prozac® 20mg weekly dose, while market share for “other antidepressants” grew to 86.7% (57,259 claims). Generic fluoxetine market share was 11.0% (7,281 claims) in August 2002. Within the generic fluoxetine market, manufacturers with exclusivity experienced a decrease in market share from 100.0% (7,184 claims) in January 2002 to 63.6% (4,629 claims) in August 2002. The estimated average payment per unit (post-rebate) for Prozac® 20mg capsules prior to its patent expiration (January–July 2001), during the 180-day generic exclusivity period (August 2001–January