between 1997 and 2006 was conducted. Elderly patients with continuous health plan coverage, ≥ 1 drug prescription per calendar year, and ≥ diagnosis for 1) asthma; 2) cancer; or 3) cardiovascular disease (CVD) were selected. Drug vintage, defined as the ingredient’s earliest marketed date, was drawn from Health Canada Drug Product Database. A multivariate analysis was conducted to estimate the impact of drug vintage on patients’ probability of dying using time-varying Cox proportional hazard model. The covariates used for adjustment in the regression model were: demographics characteristics, guaranteed income supplement (GIS) status, medical resources utilization, concomitant drug utilization, and comorbidities. RESULTS: A total of 6912, 12,341, and 29,394 elderly subjects formed the asthma, cancer, and CVD study populations, respectively, of which 1220 (18%), 3479 (28%), and 6043 (21%) died during the observation period. Overall, mean age was 68 years; 49% of subjects were women. After controlling for confounding factors, the use of recent medications (i.e. Post-1990 ingredients) was consistently associated with a significant risk reduction of mortality (hazard ratios <1.0, p < 0.001 for all disease areas), relative to older ingredients, suggesting that recent drug innovation had a significant beneficial impact on longevity in patients with asthma, cancer, or CVD. Other covariates associated with an increased risk of mortality included age, gender, GIS beneficiaries, hospitalization, and number of comorbidities. CONCLUSION: This analysis showed that drug innovation, in particular medications launched after 1990, had a significant beneficial impact on longevity of elderly patients in three important disease areas.

MARKET DISCONTINUATION OF PHARMACEUTICALS IN THE UNITED STATES: ANALYSIS OF NEW DRUGS APPROVED FROM 1980 TO 2007

Qureshi ZP, Szeinbach SL, Seoane-Vazquez E
The Ohio State University, Columbus, OH, USA

OBJECTIVE: Safety, efficacy, and financial concerns are important considerations when evaluating the reasons for market discontinuation of drugs. In this study, market discontinuation of new chemical entities (NCEs) approved by the FDA in the period 1980–2007 were analyzed according to therapeutic class, regulatory changes, orphan drug status, and priority review. METHODS: Data was derived from the FDA, Micromedex and Medline. A drug was considered discontinued if deleted from the FDA’s Orange book. Withdrawals of approval were also included in the study. Descriptive statistics and chi-square tests were performed. RESULTS: A total of 703 NCEs were approved during the study period. In December 31, 2007, 71.8% NCEs remained in the market; 14.9% were discontinued; 5.4% NCEs had the brand discontinued, but the generic was available; 7.0% had changes in route, dosage form or strength; and 0.9% were over-the-counter drugs. Safety was the primary reason for withdrawal of 30 (4.3%) NCEs; 14 (2.0%) NCEs had Federal Register determination for not being discontinued for safety or efficacy reasons; and 61 (8.7%) had no reasons stated by the FDA. Compared to other classes antibiotics were more likely (p < 0.05) to be discontinued. Analyses of priority review, orphan drug status, and the sponsor company’s country (US or non-US) with respect to market withdrawal were not significant. Comparisons of pharmaceuticals withdrawn due to safety reasons with therapeutic class and implementation of Prescription Drug User Fee Act were also not significant. CONCLUSION: One in seven NCEs approved during the study period were discontinued from the market. A small percentage of drugs were discontinued due to safety or financial reasons. An ongoing evaluation of NCEs in the market place is important to determine which products provide optimal benefits in terms of efficacy, safety, and value compared to other products overall and other products within the same therapeutic class.

RESEARCH ON MEDICARE PART D AND REIMBURSEMENT POLICIES I

MD1

MEDICARE PART D: EARLY EVIDENCE ON PRESCRIPTION DRUG TREATMENT PATTERNS, HOSPITALIZATION OFFSETS AND MEDICARE SPENDING

Zhang Y1, Newhouse JP2, Hanlon J1, Lave J1, Donohue JM1
1University of Pittsburgh, Pittsburgh, PA, USA, 2Harvard University, Boston, MA, USA

OBJECTIVE: The U.S. Medicare drug benefit (Part D) was implemented in January 2006 to reduce cost-related underuse of medications, experienced by 25% of older patients in the US. This study evaluated the impact of Part D on medication use patterns and cost-savings for subsequent medical services. METHODS: We collected all claims of 20,645 members from a large Medicare managed care plan between January 1, 2005 and December 31, 2006. We used a time series and comparison group design to measure the changes in outcomes before and after Part D. Intervention group included members who had no drug coverage or quarterly caps in drug spending and whose coverage became more generous after Part D. The comparison group had no limits on drug spending before and after Part D. We estimated the impact of Part D on 1) out-of-pocket pharmacy spending and non-drug medical spending using generalized linear models; 2) number of monthly drug scripts, medication adherence, and counts of hospitalization and ED visits using Poisson regression models. RESULTS: Part D reduced out-of-pocket expenditures by 20%–50% depending on members’ drug limits. Part D increased number of monthly drug scripts by 0.5, among members without drug coverage who prescribed 3 scripts per month and members with quarterly $150 cap who prescribed about 3.5 monthly scripts in 2005. We did not find improvements on medication adherence for selected drug classes. We found total medical and inpatient spending reduced by 10% (not statistically significant) for members who had a previous $625 quarterly cap. We did not find any cost offsets for members with other drug limits. CONCLUSION: Part D decreased out-of-pocket pharmacy expenditures and increased demand for drugs but did not induce savings from subsequent medical services.

THE IMPACT OF MEDICARE PART D ON THE PERCENT GROSS MARGIN EARNED BY TEXAS INDEPENDENT PHARMACIES FOR DUAL ELIGIBLE BENEFICIARY CLAIMS

Vinegar AL, Shepherd MD, Lawson K, Richards KM
University of Texas at Austin, Austin, TX, USA

OBJECTIVE: Since the implementation of Medicare Part D, numerous anecdotal descriptions and a few small studies have reported low reimbursements to community pharmacies. The purpose of this study was to quantitatively assess the impact of Medicare Part D on percent gross margin earned by independent pharmacies in Texas using prescription claims data collected by a pharmacy claims switching company for dual eligible beneficiaries. METHODS: The study evaluated a total of 457,611 claims for prescriptions dispensed in the fourth quarter of 2003 (n = 152,521) and the second and third quarters of 2006 (n = 305,089). The prescriptions were dispensed by 313 indepen-