financial reasons). Biological licenses and tentative approvals were excluded from analysis. Results were obtained using descriptive statistics and chi-squared tests.

RESULTS: FDA databases contained a total of 2093 drug product and combination approvals between February 1939 and December 2008. Of those products, 42.3% had general patient use, and 2.3% had off-label use. A total of 555 (26.4%) drug products were discontinued during the study period. Discontinued products included 37.2% of the brand products and 15.6% of the generic products (p < 0.001). Safety was the reason for discontinuation for 39 drug products, which represented 2.8% of the approved drugs and accounted for 9.9% of the product discontinuations. Databases contained 23,931 approvals, including 8,174 NDAs and 15,757 ANDAs. Discontinued applications accounted for 42.3% of all applications, and included 43.9% of the NDAs and 41.8% of the ANDAs approved during the study period. CONCLUSIONS: One-third of the drugs approved by the FDA and more than 40% of the applications were discontinued during the study period. Safety discontinuations constituted a small, but significant, percentage of the discontinuations. Other reasons for discontinuation included product obsolescence and financial reasons. Drug discontinuations pose significant implications for research, product development, and determining societal needs for innovative pharmaceutical products.

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CONTENT ANALYSIS OF OFF-LABEL DRUG USE: REPORTING PRINT MEDIA COVERAGE

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OBJECTIVES: To assess newspaper coverage of ‘off-label drug and medical device use’ over the period of 1990 to 2008, explore key themes of discussion, and identify the tone of coverage. METHODS: The ProQuest media database was accessed for news articles published from January 1990 to July 2008 from the top six selling national newspapers. From the initial 166 articles retrieved, 153 were selected for analysis based on inclusion and exclusion criteria. Main outcome measures were the number of articles published; type of themes covered; headline, content and overall article tone (positive, negative or neutral); specific concerns and benefits discussed with off-label use; and primary individual interviewed for the article. RESULTS: The articles published on off-label drug use steadily increased over the period of study. The primary themes discussed were concerns over safety and efficacy (44.4%), benefits of off-label prescribing (26.8%), general announcements by the FDA (9.2%), insurance coverage issues (6.5%), and combination of benefits and concerns (12.4%). The tone of the headlines was mainly neutral (60.1%), although one quarter was positive (25.5%). Within the articles, however, the overall tone was judged more negative for off-label use (39.9% of articles). The majority of articles (58.8%) used clinicians as the primary commenter with other articles using government representatives (11.1%) patients and patient advocates (7.8%), and drug company spokespeople (5.9%) for comments. Inter-coder reliability were in the acceptable ranges, Cohen’s kappa (0.7-0.85) and percentage agreement (>80%). CONCLUSIONS: Off-label drug use has gotten increasing media attention over the years. An understanding of the media’s coverage enables us to get a better understanding of public perception on this issue. Overall, coverage has been more negative than positive with articles expressing more concerns than benefits. Moreover, off-label prescribing is an important and a sensitive issue and hence, media sources should be urged to present this topic with a neutral approach.

WASTED MEDICATION: HOW BIG IS THE PROBLEM?

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OBJECTIVES: To quantify medication wastage for Lipid Lowering Agents, Anti- hypertensive Therapy, and Proton Pump Inhibitors. METHODS: This study focused on drug waste for new to therapy patients. The therapy classes under consideration were Lipid Lowering Agents (N = 12,978), Antihypertensive Therapy (N = 15,975), and Proton Pump Inhibitors (N = 14,365). The claims came from an aggregate of a segment of Medco Health Solutions clients. We calculated overall percentage of patients that wasted medication as well as percentage of days supply that they wasted. To focus on avoidable waste, we defined a wastage event as a switch within therapeutic class. We also stratified the days supplied into 3 categories less than or equal to 30 days, between 30 and 90 days, and greater than or equal to 90 days. RESULTS: For Lipid Lowering Therapy: Overall 1.5% of patients had waste of 6.7% days supplied. Stratification by days = days <= 30: 1.2% of patients and 0.4% of days, 30 < days <= 90: 2.4% of patients and 0.9% of days, days > 90: 2.9% patients and 1.2% of days. For Anti- hypertensive Therapy: 6.2% patients had waste of 2.2% days supplied. Stratification by days: days <= 30: 6.3% of patients and 2.1% of days, 30 < days <= 90: 5.1% of patients and 2.1% of days, days > 90: 5.2% patients and 2% of days. For PPIs: 1.9% patients had wastage of 0.7% days supplied. Stratification by days: days <= 30: 1.9% patients and 0.7% of days, 30 < days <= 90: 0.9% of patients and 0.3% of days, days > 90: 1.8% patients and 0.7% of days. CONCLUSIONS: The drug wastage for these three classes has shown that the use of the Local Health Unit (LHU) of New York demonstrates significant differences in the wastage of the three medication classes when stratified by days supplied. Therefore drug wastage should not be a major concern when choosing different plan designs.

MEDICATION COSTS AND UTILIZATION IN A HOSPICE CARE

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OBJECTIVES: To analyze medication costs and utilization in hospice care using PBM data from hospices in Ohio. METHODS: A retrospective analysis was conducted using claims from January 1 to December 31 2007 from five hospices in Ohio. The data contains information regarding prescription medication utilization and their costs. Descriptive analyses were conducted to identify ten therapeutic drug classes with the most frequent utilization rates and largest percentage of expenditures. Further, descriptive analyses were conducted to examine the differences in prescription drug count and total cost by therapeutic class and by drug name for each hospice and for all hospices combined. RESULTS: The average number of unique drugs per hospice for the calendar year 2007 was 527, 50.6% being male. The drug expenditures for each hospice averaged $498,301 per year. Approximately 1020 different medications under 246 therapeutic classes were found to be utilized in the five hospices. The most frequently utilized therapeutic class of medications, based on prescription medication count included analgesic-narcotics (14.9%) followed by laxatives-cathartics (7.2%), and anti-anxiety drugs (6.7%). Therapeutic classes contributing to the majority of drug expenditures included opioid analgesics (16.3%), SSRIs (4.7%), and anti-anxiety drugs (6.4%). Medications whose frequency of use contribute to significant expense include morphine sulfate (5.3% - utilization 4.4% - expenses), and lorazepam (4.4% & 3.1%). Individual drug products not frequently utilized, although significantly contribute to expenses include fentanyl (3.5%) and low molecular weight heparin products (3.1%). CONCLUSIONS: Although the overall costs for hospice care is low compared to the costs incurred by the conventional palliative focused care, the cost for medications in a hospice program is significant. Hospices should place emphasis on the utilization of cost effective drugs that can be used among terminally ill patients to provide a high level of quality care with fiscal responsibility.

A PROGRAM EVALUATION OF A POLYPHARMACY SUB-POPULATION: MEDICATIONS, EMERGENCY ROOM VISITS, AND HOSPITALIZATIONS

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OBJECTIVES: We characterized a sub-population of Premera BlueCross members on multiple chronic medications and evaluated an educational, mail-based program designed to address the safety of multiple prescription users. METHODS: Polyphe- rmary was defined as early 2005 chronic prescription. Selected members were >=19 years of age and were continuously eligible for both prescription and medical benefits during the evaluation period (August 2004-January 2007). Pharmacy and medical claims were analyzed to compare monthly medication frequen- cies and safety-related medical events (emergency room (ER) visits and hospitaliza- tions) between the pre- and post-intervention periods. Generalized linear mixed modeling was used to test for time-period differences in prescriptions. The top ICD-9 codes for ER visits and hospitalizations, as well as the most frequently prescribed medications were reported. Polypremacy members were grouped into medication- count categories and prescription and medical event profiles were developed. RESULTS: For the final analysis sample of N = 12,962 members (65% female; mean age: 53 years), a comparison of the two periods indicated an increase of approximately 0.5 in mean monthly medication counts during the post-period (6.3 vs. 6.8 prescrip- tions; p < 0.001). GLMM applied to monthly medications indicated significant differ- ences in the mean number of monthly medications at period start as well as in the slope of monthly medication trends during the periods. ER visits and hospitalizations (safety-related events) were reduced by roughly 1% in the post-period (23% to 22%, 13% to 12%, respectively; both p < 0.0001). Reductions in events were observed across medication-count categories. Medications for hypertension, high LDL choles- terol, and diabetes were among the most frequently prescribed in both periods. CONCLUSIONS: This evaluation demonstrates the need for more studies and focus on how populations of health challenged members. Well-designed, controlled studies could further test the effects of medical/pharmacist intervention strategies for members taking multiple medications.

USING EXPLICIT CRITERIA TO EVALUATE INAPPROPRIATE PRESCRIBING IN ELDERLY OUTPATIENTS: A COHORT STUDY

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OBJECTIVES: To establish explicit criteria for potentially inappropriate medication prescribing (PIM) for the elderly and assess the prevalence of and factors associated with PIM among elderly residents with and without co-morbidities. Study design was based on the Local Health Unit (LHU) of Piedmont region of Italy; according to the developed criteria. METHODS: A nine-member expert panel was convened to develop a list of inappropriate medications reflecting the Italian prescribing habits. Using the 2002 Beers criteria as a framework, consensus through a two-round Delphi method was reached to classify the identified 23 inappropriate medications into three categories: 17 medications to be always avoided, 3 medications rarely appropriate, and 3 medications with some indications but often misused. A retrospective cohort study using the 2006 Parma LHU automated outpatient prescrip- tions database was conducted. The cohort comprised 91,741 individuals 265 years.