

## Abstracts

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co-payment groups. Analysis used the auto-regressive integrated moving-average model in STATA 9.0. **RESULTS:** The overall number of outpatient visits significantly decreased after policy implementation due to a reduction in the number of patients using outpatient facilities, but total costs of care remained unchanged. The policy had its greatest impact on the number of visits to regional and local community hospitals (secondary), but had no influence on those the medical centres (tertiary). Medical utilisation in physician clinics (primary) decreased due to an audit of reimbursement declarations. Overall, the policy failed to encourage referrals from primary care to higher tiers. **CONCLUSIONS:** Further research needs to explore how patients' out-of-pocket payment affects medical utilisation and which forces (not susceptible to co-payment) act in tertiary facilities. It also needs to investigate, whether the reduction in outpatient numbers was due to an affordability barrier to accessing essential care, with a potentially negative impact on the region's health.

PHP12

#### HOW NON-REFERRAL OUTPATIENT CO-PAYMENT IN TAIWAN IMPACTS ON PATIENTS' OUT-OF-POCKET COSTS AND PRESCRIPTION PATTERNS

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**OBJECTIVES:** To deter non-essential visits and encourage initial contact in primary care, Taiwan's National Health Insurance's (NHI) implemented a differential co-payment policy on July 15, 2005. A previous study has examined the impact of this policy on medical utilization and total cost to NHI using a regional reimbursement dataset. This study aimed to explore the impact of this policy on outpatient co-payment and prescription patterns across different co-payment groups and tiers of medical facilities. **METHODS:** A segmented time-series analysis on regional weekly outpatient medical claims (January 2004 to July 2006). Outcome variables for co-payment and prescription patterns were stratified by tiers of medical facilities and co-payment groups. Analysis used the auto-regressive integrated moving-average model in STATA 9.0. **RESULTS:** Despite the decrease in outpatient visits, the overall co-payment to patients increased by 1.2% after policy implementation and also increased in most medical facilities (4.8% to 17.9%). Number of general prescriptions decreased across different medical facilities; the average cost and duration per general prescription decreased in medical centers and regional hospitals. The number of continuous prescriptions did not change, except for non-significant decreases in medical centers and regional hospitals. There was an increase in the number of continuous prescriptions dispensed in pharmacies (7.0%). **CONCLUSIONS:** The policy significantly increased patients' out-of-pocket payment for outpatient visits. In response to the policy, physicians might prescribe more expensive drugs and extend prescription duration to help patients get the most benefit from the co-payment, and physician in medical centers are more likely to prescribe continuous prescriptions for patients with stable chronic diseases. Further research needs to identify vulnerable subgroups in obtaining necessary treatment, and to explore the impacts of cost-saving strategies on patients' quality of medical care.

PHP13

#### COST-RELATED UNDERUSE OF MEDICINE DUE TO MEDICAID PHARMACY COST-CONTAINMENT POLICY ACTIONS

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**OBJECTIVES:** We sought to evaluate the impact of pharmacy cost-containment policy actions by state Medicaid programs on cost-related underuse of medicine, controlling for concurrent non-pharmacy cost-containment policy actions and socio-environmental differences among states. **METHODS:** We used the data from the 2003 Community Tracking Study (CTS) household survey, and linked them with the census demographic data and the cost containment policy actions based upon 50 States Surveys on state Medicaid spending growth and cost containment policy actions by the Kaiser Family Foundation in 2003. A cross-sectional study was performed to evaluate the impact of policy actions, by comparing Medicaid beneficiaries to non-Medicaid-pharmacy-cost-containment-action-eligible residents. The outcome measures included: patients do not receive needed medical care, patients cannot afford needed prescriptions, patients postpone needed medical care, and patients worry about the medical care cost. The outcomes were analyzed using logit model, with prior authorization, generic drugs required, copayment method, step therapy of fail-first requirement, limit on number of prescriptions and number of refills per month, preferred drug list, over the counter coverage, and prescription drug payment practices (payment and purchasing policies) as predictors. Additionally, non-pharmacy cost-containment policy actions, patients' demographics and states' socio-environmental variables were controlled. **RESULTS:** On average, each state has implemented 6.5% pharmacy cost containment policy actions in 2003. Only the worrying about costs was statistically significantly associated with individual pharmacy cost-containment policy action; however, such significance disappeared after other concurrent pharmacy cost-containment policy actions were controlled for. When the total number of pharmacy cost-containment policy actions was entered in the regression instead of individual policy action, each incremental policy action was associated with 14% increase in odds ratio for unmet medical needs ( $p = 0.003$ ), and 5% increase in odds ratio for postponing medical needs ( $p = 0.02$ ). **CONCLUSIONS:** There was variable impact of pharmacy cost-containment policy actions when assessed concurrently, and collectively.

#### HAVE YOUR CAKE OR EAT IT: DO DECISIONS BASED ON COST-EFFECTIVENESS UNDERMINE INCENTIVES FOR RESEARCH AND DEVELOPMENT?

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**OBJECTIVES:** Although cost-effectiveness analysis allows efficient decisions about the use of existing technologies (static efficiency) it has been argued that it will disincentivise the development of innovative technologies (dynamic efficiency). These concerns have also been raised about the report by the UK Office of Fair Trading which recommended that the price of pharmaceuticals should be based on their cost-effectiveness. We aim to establish whether decisions based on cost-effectiveness necessarily undermine incentives for the development of pharmaceuticals. **METHODS:** The arguments put forward as to why cost-effectiveness decisions might undermine incentives for innovation are examined and are used to consider the implications of the type of value-based pricing which has been proposed in the UK. **RESULTS:** The argument depends on whether the purpose of health care is to improve population health or to maximise welfare (consumer and producer surplus). If it is the former, then achieving static and dynamic efficiency requires a clear and predictable signal of value (cost-effectiveness). The private sector can then choose to invest in developments which it believes will be cost-effective and provide a satisfactory return on investment. Manufacturers should be allowed to appropriate some share of the surplus (monopoly rent) to incentivise investment in R&D. However, they should not take it all. The public sector subsidises research and development in many ways. Therefore, even if society was unconcerned about who benefits from innovation it would not be efficient to allow full appropriation. In other markets where innovation is protected, society simply offers monopoly rent during patent protection but does not allow full appropriation by, for example, facilitating perfect price discrimination. **CONCLUSIONS:** The argument that decisions about the use and price of a technology based on cost-effectiveness will undermine the incentives for R&D is misplaced if the objective is to improve population health given a fixed budget constraint.

PHP15

#### ASSESSMENT OF ORPHAN DRUGS DEVELOPED AND DRUG UTILIZATION UNDER THE ORPHAN DRUG ACT: A DESCRIPTIVE EMPIRICAL STUDY

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**OBJECTIVES:** The Orphan Drug Act (ODA) was developed in 1983 to stimulate new drug development to treat rare diseases. The purpose of this analysis was to review the drug development with orphan drug status and to describe utilization of orphan drugs in the Medicaid program. **METHODS:** A literature review about orphan drug approvals was conducted through search engine like PubMed, as well as government and industry Internet websites. Nationwide Medicaid pharmacy data extracted from the Center for Medicare & Medicaid Services were analyzed from 1991 to 2007 regarding quarterly prescriptions, reimbursements, and cost per prescription for selected orphan drugs. Based on utilization patterns, two categories of orphan drugs were studied, including traditional ones with little use (like antizole, fabrazyme, respigam, myozyme, and panhematin) and non-traditional ones with wide usages (like paclitaxel, epoetin alfa, and imatinib mesylate). **RESULTS:** Since 1983, over 1700 drugs have been designated as having orphan status and 325 drugs have marketing approval to treat orphan diseases, focusing on oncology, metabolic and endocrine disorders, and hematology. From Medicaid pharmacy data, there was very little use for antizole, respigam, myozyme, and other traditional orphan drugs, such as fabrazyme from 15 in 2003 to the peak of 375 in 2006. By contrast, non-traditional orphan drug like epoetin alfa prescriptions increased from 17,282 in 1991 to the peak of 824,485 in 2005, and imatinib mesylate prescriptions increased from 3,877 in 2001 to the peak of 20,323 in 2005. Fabrazyme cost per prescription started with \$22,367 in 2003 and decreased to \$5,558 in 2006. Other expensive orphan drugs included myozyme, panhematin, imatinib mesylate, and rituximab ranging from \$3,000 to \$10,000 per prescription. **CONCLUSIONS:** ODA has made a significant impact on drug development for rare diseases. Non-traditional orphan drugs with dramatic increased utilization and spending were observed, which might require safety surveillance and appropriate utilization review.

PHP16

#### MARKET DISCONTINUATION OF PHARMACEUTICALS IN THE UNITED STATES: ANALYSIS OF DRUGS APPROVED BY THE FDA FROM 1939 TO 2008

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**OBJECTIVES:** The pharmaceutical industry serves societal needs by bringing innovative products and therapies to market. However, innovation does not guarantee market longevity. Consequently, some products will be evaluated and considered for market discontinuation. The purpose of this study was to identify drug market discontinuations, provide reasons for discontinuation, and characterize discontinued products by application type. **METHODS:** Data were derived from the FDA databases "Approved Drug Products" and the "Approved Drug Products with Therapeutic Equivalence Evaluations," Federal Register, and Medline. Market discontinuations were classified by approval types (New Drug Application -NDA and Abbreviated New Drug Application-ANDA) and by reasons for discontinuation (safety, efficacy and

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 generic competition. A total of 595 (28.4%) 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 59 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.

PHPI7

#### 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 1066 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 headlines was mainly neutral (60.1%) although one quarter was negative (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 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.

PHPI8

#### WASTED MEDICATION: HOW BIG IS THE PROBLEM?

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**OBJECTIVES:** To quantify medication wastage for Lipid Lowering Agents, Antihypertensive 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 supply 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 wastage of 0.7% 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 Antihypertensive Therapy: 6.2% patients had wastage of 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 the above therapies is very small and so is the difference between the wastage for 30 day supply vs. 90 or greater day supply. 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 claims data from hospices in Ohio. **METHODS:** A retrospective analysis was conducted using claims from January 1 through 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 admissions in each 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 (16.5%), SSRIs (4.7%), and anti-anxiety drugs (4.5%). 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 to Medicare and patients is less as compared to the costs incurred by conventional non-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.

PHP20

#### 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:** Polypharmacy members were selected based on early 2005 chronic prescription claims. 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 frequencies and safety-related medical events (emergency room (ER) visits and hospitalizations) 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. Polypharmacy 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 prescriptions;  $p < 0.0001$ ). GLMM applied to monthly medications indicated significant differences 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 cholesterol, and diabetes were among the most frequently prescribed in both periods. **CONCLUSIONS:** This evaluation demonstrates the need for more studies and focus on sub-populations of health challenged members. Well-designed, controlled studies could further test the effects of medical/pharmacist intervention strategies for members taking multiple medications.

PHP21

#### 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 (PIP) for the elderly and assess the prevalence of and factors associated with PIP among elderly residents in the Local Health Unit (LHU) of Parma, 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 prescriptions database was conducted. The cohort comprised 91,741 individuals ≥ 65 years