

OBJECTIVES: Regulatory policies, including economic incentivization through patent extensions, have been implemented to stimulate pediatric research, however disparity exists for the neonatal subpopulation. This analysis was conducted to identify the availability of neonate-specific data for frequently used medications in Neonatal Intensive Care Units (NICUs) and to determine the extent to which pediatric exclusivity has increased information for drugs used in neonates. **METHODS:** A search was conducted utilizing the FDALabels database to identify all FDA-approved NDA, BLA and ANDAs from 01/01/1980 to 08/01/2013 searching for the terms “neonate”, “newborn” and “infant” present in any of the following label sections: “Indication and Usage”, “Dosage and Administration” and “Pediatric Use”. The results were cross-referenced with a recently published list of 100 frequently prescribed drugs in NICUs and drugs granted pediatric exclusivity by the FDA as of August, 2013. **RESULTS:** A total of 737 unique labels for 110 distinct drugs were identified (including 18 combination products and 15 modified versions of previously marketed drugs). “Newborn” was identified in 450 labels; “infant” in 414 labels and “neonate” in 167 labels. More than one search term was found in 294 labels. Only 19% of drugs frequently used in NICUs mentioned neonates, newborns or infants on their labels. Mention of neonates, newborns or infants occurred in 4.5% (n=9) of the drugs with pediatric exclusivity; while 8.7% (n=17) of drugs granted pediatric exclusivity were used frequently in the NICU. Only two drugs frequently used in NICUs mentioned neonate, newborn or infant on their label and had pediatric exclusivity. **CONCLUSIONS:** Despite regulatory incentives, a paucity of neonatal data exist for drugs frequently used in NICUs. Our data suggest that pediatric exclusivity did not yield sufficient neonatal data.

PIH57

IMPACT OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT CONTRACEPTIVE COVERAGE MANDATE ON UTILIZATION OF REFILLABLE AND LONG-ACTING REVERSIBLE CONTRACEPTIVES

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OBJECTIVES: One provision of the Patient Protection and Affordable Care Act (PPACA) requires that most insurers make prescription contraceptives—including refillable and long-acting reversible contraceptive methods (LARCs)—available at no out-of-pocket cost to beneficiaries. The objective of this study was to determine if the implementation of the mandate increased contraceptive utilization. **METHODS:** We conducted a retrospective analysis using integrated pharmacy and medical claims for three cohorts of commercially-insured females aged 15 to 49. Each cohort (n= 360143, n=352,169, and n=391,138) was continuously enrolled for 12-month periods, respectively. “Pre-PPACA-Period 1” (January 1, 2011 to June 30, 2011) considered cost and utilization two years prior to PPACA. “Pre-PPACA-Period 2” (January 1, 2012 to June 30, 2012) looked at the year prior to PPACA implementation, and the “Post-PPACA Period” (January 1, 2013 to June 30, 2013) captured the early experience immediately after implementation of the coverage mandate. Two pre-PPACA-periods allowed for better understanding of underlying secular trends occurring prior to the mandate. The incidence of new refillable and LARC methods, discontinuation and switching patterns and cost were measured across each time period. **RESULTS:** The incidence of refillable contraceptive use increased minimally: from 3.45% in the first half of 2011 to 3.59% in the first half of 2012, and to 3.72% in the first half of 2013. The incidence of LARC use increased substantially (44.4% from 0.50% to 0.65% between the first half of 2011 and the first half of 2013). The initiation rate of LARCs was significantly higher after the mandate compared to previous periods (OR=1.45, 95% CI =1.36-1.54), possibly due to increased switching from refillable to LARC methods. **CONCLUSIONS:** We found little evidence that the PPACA contraceptive coverage mandate rule has yet resulted in meaningful increases in refillable contraceptive use, but it was associated with an increase in the initiation of LARCs.

PIH58

THE RATIONALE OF EARLY PRESCRIPTION OF ANTIBIOTICS IN ORGANOPHOSPHORUS POISONING PATIENTS

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OBJECTIVES: To study the rationale of early prescription of antibiotics in case of patients with Organophosphorus poisoning. **METHODS:** In this study patients admitted to the ICU due to organophosphorus poisoning during a six-month period were included. Patients were grouped into group-A and group-B on the basis of antibiotics prescribed and not prescribed respectively. The prescription of antibiotics was classified as prophylactic, empirical and definitive depending on the time of prescription. The effect of antibiotic prescription on the length of stay, cost and clinical outcome was observed. The cost of treatment was obtained from the finance department of the hospital. The length of stay and cost of treatment for the two groups were compared using the non-parametric Mann-Whitney U test. **RESULTS:** There were 54 patients categorized in three groups according to the severity of poisoning as mild (22%), moderate (48%) and severe (30%). Antibiotics were prescribed for 74.07% of the patients. Prophylactic antibiotics were prescribed in 53.7% cases. The median cost of treatment for group-A patients was INR 60,216 and for group-B patients was INR 27,225 (p=0.001). The median length of stay for group-A and group-B was 14 days and 10 days respectively (p=0.011). The median cost of treatment for moderately poisoned patients prescribed with prophylactic antibiotics was INR 74595.6 as compared to INR 30,902 for moderately poisoned patients of group-B (p<0.05). **CONCLUSIONS:** Early prescription of antibiotics without any evidence of infection in case of organophosphorus poisoning patients showed a higher cost of treatment and inferior outcomes as compared to OPP cases where a prophylactic antibiotic was not prescribed. The use of higher antibiotics in these cases also lead to increase in antibiotic resistance. There is a need to revise the antibiotic prescription guidelines in case of Organophosphorus poisoning patients.

PIH59

PREVALENCE AND DETERMINANTS OF USE OF POTENTIALLY INAPPROPRIATE MEDICATIONS IN ELDERLY INPATIENTS: STOP AND START CRITERIA

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OBJECTIVES: Use of potentially inappropriate medications (PIMs) among the elderly is a serious public health problem because it is intrinsically linked to increased morbidity and mortality, causing the high costs to public health systems. Objectives of this study were to determine the prevalence and predictors of PIM prescribing in elderly inpatients using STOP and START criteria. **METHODS:** The prospective observational study was carried at a private tertiary care hospital. Prescriptions of elderly inpatients aged 60 years and above were collected and analyzed. PIMs were identified with the help of STOP and START criteria. Predictors associated with use of PIMs were identified by bivariate and multivariate logistic regression analysis. **RESULTS:** The results were based on data of 60 patients. More than half (56%) were males and 50% were aged between 60–69 years with a mean average age of 69 years. Mean number of diagnoses and medications were two and nine, respectively. A total of 18 (30%) patients were prescribed with at least 1 PIM according STOP Criteria. Most commonly prescribed PIMs were systemic corticosteroids (29%) followed by theophylline (18%) and betablockers (10%). On multivariate regression, important predictors for PIM prescribing were found to polypharmacy, number of diagnoses. **CONCLUSIONS:** The results show that PIMs prescribing is high in Indian elderly inpatients STOP and START criteria, it is more effective in identifying the PIMs. This study is ongoing and we will present the data upto 250 patents before the presentation.

PIH60

EVALUATING FRACTURE-RELATED EXPENSES AND HEALTH CARE RESOURCE UTILIZATION AMONG POST-MENOPAUSAL WOMEN IN THE U.S. MEDICAID POPULATION

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OBJECTIVES: To evaluate fracture-related expenses and health care resource utilization among post-menopausal women in the U.S. Medicaid population. **METHODS:** Female patients diagnosed with fractures (International Classification of Disease, 9th Revision, Clinical Modification [ICD-9-CM] codes: 733.12-.16, 805.0, 805.2, 805.4, 805.6, 805.8, 808.0, 808.4, 808.8, 810.0, 812.0, 812.2, 812.4, 813.0, 813.2, 813.4, 813.8, 814.0, 820.0, 820.2, 820.8, 821.0, 821.2, 823.0, 823.2, 823.4, 823.8) were identified using U.S. Medicaid data from 01/JAN2009 through 31/DEC2009. The initial diagnosis date was designated as the index date. A control cohort that included patients without fractures of the same age, race, region and baseline Charlson Comorbidity Index score was created. The index date for the control cohort was randomly assigned to minimize selection bias. Patients in both cohorts were required to be age ≥50 years, with continuous medical and pharmacy benefits for 1-year pre- and post-index date. Propensity score matching (PSM) was used to compare health care costs and utilizations during the follow-up period. **RESULTS:** Before matching (n=80,516), fracture patients were more likely to be white (71.2% vs. 46.2%), reside in the South U.S. region (39.2% vs. 34.1%) and have chronic obstructive pulmonary disease (26.7% vs. 21.3%). After 1:1 PSM, a total of 22,089 patients with proportionate baseline characteristics were matched from each cohort. Patients in the fracture cohort had higher proportions of inpatient stays (31.0% vs. 8.1%, p<0.0001), emergency room (ER; 47.0% vs. 15.4%, p<0.0001), physician office (73.6% vs. 47.3%, p<0.0001) and outpatient visits (98.9% vs. 71.6%, p<0.0001). Higher health care resource utilizations translated to higher costs for post-menopausal fracture patients than for controls, including long-term care (\$9,191 vs. \$7,212, p<0.0001), physician office visit (\$428 vs. \$293, p<0.0001) and total costs (\$17,698 vs. \$13,032, p<0.0001). **CONCLUSIONS:** Post-menopausal women with fractures had significant health care resource utilization and expenses compared to those without fractures.

PIH61

EVALUATION OF THE POTENTIAL IMPACT OF DRUG-GENE INTERACTION RISK (DGIR) ON HEALTH RESOURCE UTILIZATION (HRU)

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OBJECTIVES: To assess the relationship between DGIR and HRU in elderly patients to evaluate potential benefit from pharmacogenetic testing. **METHODS:** A retrospective cohort of patients age ≥65 years was identified through Inovalon's MORE2@ registry with continuous enrollment, taking ≥3 prescription medications (July 1, 2012 - March 31, 2013) and on ≥1 drug metabolized by a polymorphic drug metabolizing enzyme. Patients were stratified into zero, low, medium, and high DGIR groups via a diagnostic test (Genelex Youscript®). Counts of HRU during 9 months follow-up post index-date (date of first claim for ≥1 drugs with pharmacogenetic implications) included all-cause hospitalizations, emergency-room and clinic visits. Poisson regression was used to test the association between DGIR and HRU counts. The model was adjusted for age, gender, race, Charlson Comorbidity Index (CCI) and number of known drug-drug interactions. **RESULTS:** A total of 252,184 patients were included and the mean age was 74 ± 6 and 60% were female. The median DGIR score was 8.7% [IQR 2.3%-44%]. There were 59,559 (23.6%) with a DGIR score of zero, 82,224 (32.6%) with low risk (0-20%), 33,439 (13.3%) with medium risk (20-40%), and 76,962 (30.5%) with high risk (>40%). Regression analysis revealed that the low and medium DGIR groups were associated with a 9% (95%CI 8.4 to 9.7%, p <0.0001), and 8% (95%CI 7.7 to 9.2%, p <0.0001) increase in the rate of HRU, compared to zero risk. The high DGIR group was associated with a 5% (95%CI 4.2 to 5.3%, p <0.0001) decrease in HRU, compared to zero-risk. **CONCLUSIONS:** Among elderly patients, low and medium DGIR groups were associated with increased rates of HRU. In contrast, high DGIR was associated with lower HRU rates. This may be explained by a time-dependent effect of changing DGIR as a result of medication changes over time.