PS2-07:

Medication Use in Pregnancy and Birth Outcomes Program

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Background/Aims: Our knowledge of safe medication use during pregnancy is limited, due primarily to the lack of rigorous studies evaluating birth outcomes associated with in utero exposure to medications. A collaborative research program, the Medication Use in Pregnancy and Birth Outcomes Program, between the Food and Drug Administration (FDA) and researchers at the HMO Research Network Center for Education and Research in Therapeutics (CERT), Kaiser Permanente Northern and Southern California, and Vanderbilt University, aims to develop common, necessary data linkages to enable the conduct of multiple studies of medication use and outcomes in pregnancy across participating sites. **Methods:** Specific components of the program include: 1) maternal-infant record linkage of all women delivering an infant between 2001 and 2007, 2) linkage to birth certificate data for infants delivered between 2001 and 2007, 3) validation of data elements within the datasets through medical chart abstractions, and 4) annual update of the datasets. **Results:** This collaboration will provide a large ethnically and geographically diverse population, with approximately 90,000 births per year. Data files on maternal and child enrollment, outpatient drug dispensing, and inpatient and outpatient diagnoses and procedures, in addition to data elements obtained from birth certificate data, will be developed and maintained at each of the program sites. The proposed poster will describe the program and the available standard file definitions and data elements. **Conclusions:** The program will be an important resource for the evaluation of birth outcomes (birth defects and other perinatal events) associated with medication use during pregnancy, patterns and trends in medication use during pregnancy, and studies of the risks and benefits of medication use for the pregnant women themselves.

PS2-11:

Characteristics of Medicare Part D Beneficiaries Who Obtain Prescriptions at Pharmacies External to Their Health Plan

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Background: For Medicare Part D beneficiaries, drug costs after reaching the drug benefit threshold (DBT) could contribute to non-adherence and adverse outcomes. Because beneficiaries who reach the DBT might take prescriptions (Rx) to pharmacies that offer low-priced generic drugs, there is potential for loss of integrated care, as those pharmacies may not be affiliated with beneficiaries' health plans. Potential implications of Rx dispensing external to members' health plans include drug interactions, adverse events, lack of monitoring, and inaccurate adherence data. We sought to examine the extent to which Medicare beneficiaries take Rx outside a health plan and to describe those patients. We hypothesized that beneficiaries who reach the DBT are more likely than those who do not reach the DBT to have Rx dispensed at external pharmacies. **Methods:** This retrospective study included all Kaiser Permanente Colorado (KPCO) Medicare beneficiaries with membership in 2006 and 2007 (n=37,092). Data collected from electronic databases included demographics, membership, benefit structure, and comorbidities (Quan comorbidity index, QCI). A random sample of electronic medical records (n=100) was abstracted for information not available from administrative data. Chi-square and Wilcoxon Rank Sum tests were used to compare beneficiaries. **Results:** Among 27,354 beneficiaries who had a DBT, 1,655 (6%) took Rx to external pharmacies in 2007. Of 1,785 beneficiaries who reached the DBT, 12.4% (n=222) had external Rx compared to 5.6% (n=1433) of 25,569 who did not reach the DBT (P<0.001). Of those who reached the DBT, beneficiaries with external Rx had more comorbidity (external Rx mean QCI 4.2 [±2.8]; no external Rx mean QCI 2.4 [±2.1]; P<0.001). Chart review determined that not all Rx written externally were filled at pharmacies offering low price Rx: only 14% were documented taken to pharmacies advertising low price Rx, while 16%, 21%, and 43% were documented taken to military pharmacies, hospice/nursing homes, or no dispensing location, respectively. Additionally, 11% of external Rx were nonformulary drugs. Subsequent prescriptions for 20% of all external Rx were dispensed at KPCO pharmacies. **Conclusions:** KPCO Medicare beneficiaries who reached the DBT more often had Rx dispensed externally. Of those who reached the DBT, beneficiaries with external Rx had more chronic illnesses. Clinical consequences of Rx dispensed outside integrated health plans require further study.

PS2-15:

Sex-Specific Differences in the Protective Effect of Statins on Skeletal Fractures

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Background: Recent reports indicate that HMG-CoA reductase inhibitors (statins), used for prevention and treatment of dyslipidemia and CVD, might have a beneficial effect on bone metabolism. Limitations of previous studies do not allow unequivocal conclusions about bone-sparing effect of statins. **Methods:** This study examined statin use and osteoporosis-related skeletal fractures. Members of a large New Mexico Health Plan served as the study population (n=7,539). The sample included women > 50 years old and men > 60 years old who had > 1 prescription fill or > 1 encounter with a healthcare provider between 1999 and 2005, but excluded patients with cancer, osteomalacia, and end stage renal disease. Patients with incident fractures of the hip, wrist/forearm, and spine occurring between 1999 and 2005 were identified as cases (n=1,880). Controls were selected from the same population based on timing of enrollment to controls in 1:3 ratio (n=5,659). The prevalence of statin use (> 3 fills a year prior to the index date) was compared among study groups by Chi-square analysis in univariate and by logistic regression in multivariate analyses. To explore duration -response effect, statin use was classified as current (3 months prior to the index date) and continuous (> 10 annual fills prior to the index date). **Results:** The mean age was 71.4±10.2 years among cases and 63.8±9.2 among controls, with 72.8% females. 15.9% of cases and 17.1% of controls reported any statin use, and the most prevalent statins were simvastatin followed by lovastatin, atorvastatin, and pravastatin. In men, no association between fractures and either current (OR=0.81; 95% CI: 0.55; 1.20) or continuous statin use (OR=0.86; 95% CI: 0.51; 1.44) was observed after adjustment for age, corticosteroids use, chronic kidney disease, and comorbidities. In women, significant protective effect was observed among both current (OR=0.58; 95% CI: 0.44; 0.78) and continuous (OR=0.66; 95% CI: 0.45; 0.99) statin users independent of age, corticosteroid use, bisphosphonates, chronic kidney disease, comorbidities, and postmenopausal hormone therapy. **Conclusions:** We observed a protective effect of statins on osteoporosis-related fractures in women but not in men. These findings suggest sex-specific effect of statins on bone metabolism.

PS2-17:

Characteristics of Medicare Beneficiaries Who Repeatedly Reach the Drug Benefit Threshold

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Background: Reaching a drug benefit threshold (DBT) (e.g. the Medicare donut hole) has been associated with poor health outcomes. This risk may be greater for those who repeatedly reach the DBT; however there is little information that characterizes this group of Medicare Advantage beneficiaries. We describe a population of beneficiaries who repeatedly reach the DBT over the first two years of Medicare Part D in order to determine if some might