using OCs before the reference date (fracture date for cases; randomly assigned dates based on distribution of case dates for controls) were asked, for each episode of use, their age and length of use. A life events- calendar tool was available to interviewers. Computerized pharmacy information was obtained on OC fills back to 1977. OC use was based on GH pharmacy and First Data Bank OC class, key ingredients [e.g. ethinyl estradiol, levonorgestrel], and name. OC use was evaluated using >1 fill or >2 fills within a 1-year period. Ever use, use since ages 35, 38, and 40, and 5 years before reference date were examined. Women were required to be enrolled for the designated time period except for the ever-use category. We calculated kappa (K), the chance-corrected measure of agreement, and the prevalence–adjusted bias-adjusted kappa (PABAK). **Results:** The agreement between self-reported OC use and OC fills was highest for more recent use (PABAK=92% for OC use within 5 years of reference date and 55% for use at ages >38). **Conclusion:** In women around the menopausal transition, agreement between self-reported OC use and computerized OC prescription fills was moderate for use after age 38 and excellent for OC use within 5 years of the reference date.

Keywords: Oral Contraceptive; Self-Reported; Pharmacoepidemiology
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CC5-01:

Evaluation of the Validity of the Gestational Length Assumptions Based Upon Administrative Health Plan Data

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Background/Aims: A common algorithm using delivery date and preterm birth diagnosis codes recorded in health plan databases to define gestational length had not been rigorously validated. **Methods:** We identified live born deliveries among women aged 15-45 years in 2001-2007 within 8 HMORN health plans participating in the Medication Exposure in Pregnancy Risk Evaluation Program. We compared the descriptive statistics between the gestational length derived from an algorithm based upon health plan data and that obtained from the birth certificates (“gold standard”). We calculated the proportions of deliveries for which the two gestational length estimates differ by 0, ±1- 7, ±8-14, ±15-21, ±22-28, or more than ±28 days, stratified by health plan data-defined term/preterm delivery status. We compared the prenatal exposure status to fluoxetine (representing medications used chronically) and amoxicillin (representing medications used for acute conditions) defined using the algorithm-derived gestational length versus the gold-standard gestational length. **Results:** The study population comprised 225,384 deliveries. The mean algorithm-derived gestational length was lower than the mean obtained from the birth certificates among singleton deliveries (267.9±8.3 vs. 273.5±14.3 days) but not among multiple-gestation deliveries (253.9±19.0 vs. 252.6±23.1 days). The difference between the two gestational length estimates was within ±7 days in 46% (103,506/225,384) of all deliveries, 45% (91,964/206,492) of term deliveries, and 61% (11,542/18,892) of preterm deliveries. The corresponding proportions for a difference within ±14 days were 77% in both term (159,101/206,492) and preterm (14,565/18,892) deliveries. Among women with continuous enrollment and pharmacy benefit from 100 days before pregnancy through delivery, 2.7% (3,912/146,173) used fluoxetine and 14.0% (20,510/146,173) used amoxicillin during pregnancy based on the gold-standard gestational length. The algorithm-derived prenatal exposure to fluoxetine had sensitivity and positive predictive value (PPV) both above 96% and specificity and negative predictive value (NPV) close to 100%. The accuracy was slightly lower for amoxicillin, with the sensitivity and PPV above 90%, and specificity and NPV above 99%. **Discussion:** A gestational length algorithm based upon health plan data correctly classified the prenatal exposure status of drugs intended for chronic and short-term use in most deliveries, but exposure misclassification might be higher for a drug typically prescribed for acute conditions.

Keywords: Pregnancy; Pharmacoepidemiology
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CC5-02:

A Descriptive Study of Vaccinations Occurring During Pregnancy, 2002-2006

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Background/Aims: Trivalent influenza vaccine (TIV) is the only vaccine recommended by the Advisory Committee on Immunization Practices (ACIP) for routine administration during pregnancy. The ACIP categorizes remaining vaccines as, “should be considered if indicated”, “contraindicated”, or with “special/conditional recommendation.” The objective of this study was to describe rates of vaccination during pregnancy in seven Vaccine Safety Datalink (VSD) sites. **Methods:** Using the VSD Pregnancy Algorithm, we identified all pregnancies ending in 2002-2006, including both live births and other birth outcomes (e.g., miscarriages, terminations). We then identified all vaccinations administered during pregnancies occurring in the study period. **Results:** We identified 595,929 pregnancies and 68,839 vaccinations. The most commonly administered vaccine was TIV, with 58,683 doses and an incidence rate of 98.47 doses per 1,000 pregnancies. TIV was more likely to be administered during the 2nd or 3rd trimester (98.12 per 1,000 pregnancies), versus the 1st trimester (21.98 per 1,000). The total number of indicated vaccinations was 6,743 (11.32 per 1,000) and the most common vaccines in this category were tetanus-diphtheria and hepatitis B (6.65 and 4.31 per 1,000, respectively). Indicated vaccines were more likely to be given during the 1st trimester (7.42 per 1,000) than during the 2nd or 3rd trimesters combined (5.02 per 1,000). A total of 882 contraindicated vaccines were administered during the study period (1.48 per 1,000), and the majority of these were measles-mumps-rubella (MMR) (0.64 per 1,000), varicella (0.49 per 1,000) and live-attenuated influenza vaccine (LAIV) (0.19 per 1,000). The majority of contraindicated vaccines were administered during the 1st trimester (1.02 per 1,000) versus the 2nd or 3rd trimesters (0.58 per 1,000). **Discussion:** TIV, which is recommended during pregnancy, was the most commonly administered vaccine in our study population. MMR, varicella, and LAIV were the most common contraindicated vaccines administered. With the exception of TIV, other vaccines were more likely to be administered during the 1st trimester of pregnancy, suggesting that vaccinations may occur during a period when either the woman and/or provider are unaware of the pregnancy. Given that some women were also vaccinated during later pregnancy, clearer recommendations and improved provider education may be needed.

Keywords: Vaccine Safety; Pregnancy; Pharmacoepidemiology
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CC5-04:

Predicting the Risk of *Clostridium difficile* Infections Following an Outpatient Visit: Development and External Validation of a Pragmatic, Prognostic Risk Score

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Background/Aims: Few studies have assessed risk for *C. difficile* infection (CDI) among patients seeking routine care. We developed and validated a prognostic risk score for CDI in the one year following an outpatient healthcare encounter. **Methods:** Our development cohort included Kaiser Permanente Northwest (KPNW) patients with an index outpatient visit between 07/01/2005 and 09/30/2008. Applying Cox regression, we synthesized a priori predictors into a CDI risk score, in which a higher number of points indicates higher risk. We validated and recalibrated the risk