

POSTER ABSTRACTS

15th Annual HMO Research Network Conference
April 26-29, 2009 – Danville, PA

11:45 am – 2:00 pm
Tuesday, April 28th • Lobby

PS2 – 07

Medication Use in Pregnancy and Birth Outcomes Program

Susan E Andrade, ScD, Meyers Primary Care Institute; Robert L Davis, MD, MPH, Kaiser Permanente Georgia; Sally Beaton, PhD, Lovelace Health Systems; Craig Cheetham, PharmD, MS, Kaiser Permanente Southern California; Sascha Dublin, MD, PhD, Group Health Cooperative; Kimberly Lane, MPH, Harvard Pilgrim Health Care; De-Kun Li, MD, PhD, Kaiser Permanente Northern California; Marsha A Raebel, PharmD, Kaiser Permanente Colorado; Sharon J Rolnick, PhD, Health Partners Research Foundation; David H Smith, PhD, Kaiser Permanente Northwest; April Duddy, BA, Harvard Pilgrim Health Care; Richard Platt, MD, MS, Harvard Pilgrim Health Care

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.