

# 19th International Conference on Pharmacoepidemiology & 1st International Conference on Therapeutic Risk Management

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**Content Area:** Birth defects

**Research Design:** Descriptive / Ecologic

**Presentation format:** Oral presentation preferred

**Alternate Presentation Format:** Yes

**Disclosure:** Yes: Abbott Laboratories, Agouron Pharmaceuticals, Inc., Boehringer Ingelheim Pharmaceuticals, Inc., [br] Bristol-Myers Squibb Company, Gilead Sciences, Inc., GlaxoSmithKline, F. Hoffmann-La Roche Ltd., Merck & Co., Inc. [br].

**I would like to be considered for a Student Award:** No

**Title:** The Antiretroviral Pregnancy Registry: Ten Years of Progress

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**Background:** The epidemiologic approach to registration of drug-exposed pregnancies and follow up of the infants born after such exposures for possible signs of birth defects... the so-called 'pregnancy registry'... has become an institution in American pharmacoepidemiology. The recent promulgation of official guideline of the Food and Drug Administration (FDA Guidance to Industry: Establishing Pregnancy Exposure Registries) to govern the conduct of such registries stands as witness to the progress in the field.

**Objectives:** This presentation will review the experiences of one such registry, the Antiretroviral Pregnancy Registry (APR), which, having officially launched its activities in 1993, celebrates its tenth anniversary this year. Much has been learned along the way.

**Methods:** Among points to be reviewed are: the genesis and criteria for formation of such a registry; initial and evolving governance structures; initial and evolving management and administrative support efforts; development of a data management and scientific follow up protocols; a monitoring, analysis, and termination plan; data privacy protections; information management and dissemination strategies; and lessons learned along the way.

**Results:** The APR is constituted by eight sponsoring manufacturers of antiretroviral products. It monitors pregnancy exposures and their outcomes for 19 products for the treatment of HIV disease and/or prevention of maternal-fetal transmission. With scientific oversight of an Advisory Committee of leading scientists (in maternal and fetal medicine, pediatrics, teratology, infectious disease, epidemiology, biostatistics) from CDC, FDA, NICHD, private practice. The APR summarizes its evolving experiences in published semi-annual reports. The most recent report, the APR provides evidence for decision makers in the field from over 3000 outcomes of exposed, prospectively-monitored pregnancies representing 1283 outcomes with first trimester exposures.

**Conclusions:** Both the significance of the findings to date and the lessons learned in the conduct of such a dynamic registry over the past decade demonstrate the evolution of a successful multi-sponsored program.

While no major teratogenic signal has been detected, the population monitored is only sufficient to detect a two-fold risk of relatively common defects. These findings should provide some assurance when counseling patients. The APR is ongoing; exposures to all antiretroviral therapies during pregnancy may be reported by calling 800-258-4263

(US/Canada) and 910-256-0838 (international).