

**2017 International Conference on Pharmacoepidemiology (Montreal, Canada)
Vaccines Special Interest Groups (SIG) Symposium**

90 minute session

Topic: Maternal Immunization

Title: Overcoming Challenges of Studying the Safety of Maternal Immunizations

Panelists/Presenters:

- Alex Dodoo, University of Ghana, Accra, Ghana
- Andy Stergachis, University of Washington, Seattle, WA
- Janet Hardy, ECCPH Group and University of South Florida, Tampa, FL
- Miriam Sturkenboom, Erasmus Medical Center, Rotterdam, Netherlands

Background: Maternal vaccines that reduce maternal and neonatal mortality and morbidity, especially in low and middle-income countries (LMIC) are under development. Monitoring the safety of these potentially transformative vaccines presents challenges, however. Many of these outcomes are poorly studied in developed countries, let alone LMIC. The recently completed Global Alignment for Immunization Safety Assessment in Pregnancy (GAIA) initiative was designed to a) develop guidance for the collection, analysis, and presentation of safety outcome data on immunization in pregnancy, b) create standardized case definitions for 21 obstetric and neonatal outcomes, and c) assess their applicability in high and LMIC.

Objectives: 1) To identify and better understand the challenges of implementing the GAIA obstetric and neonatal outcomes case definitions in high and LMIC; 2) To review and learn from past relevant studies; and 3) To identify potential solutions for overcoming the identified challenges.

This symposium would benefit researchers who implement vaccine clinical trials or conduct vaccine post-marketing surveillance and studies among pregnant women in developed and LMIC.

Description: This symposium will be devoted to exploring how well the GAIA definitions can be translated for use in observational research. Perspectives from researchers, regulators, and field operators from high and LMIC will be shared and discussed. Lessons learned will inform future modifications of case definitions and propose guidance for subsequent research.

Symposium format:

1. Introduction of symposium and description of maternal vaccines (TBD)
2. Overview of GAIA and next steps (Sturkenboom)
3. Lessons learnt from monitoring the safety of antimalarial drugs during pregnancy in LMIC (Stergachis)
4. Pharmacovigilance in LMIC: challenges and lessons (Dodoo)
5. Maternal child health LMIC field experience: considerations for program operations (Hardy)
6. Panel discussion