Methods of monitoring the safety of vaccines during pregnancy

Background: Influenza and tetanus, diphtheria, and acellular pertussis (Tdap) vaccines are routinely recommended during pregnancy, potentially exposing entire cohorts of pregnant women and their newborns to the benefits and risks of maternal vaccination. Since pregnant women are often excluded from pre-licensure vaccine trials, observational studies offer an opportunity to generate safety data on vaccines administered during pregnancy. This includes data on inadvertent and off label use of vaccines that are provided during the first-trimester when women may be unaware of their pregnancy.

Objectives: This symposium will focus on methodological challenges and solutions related to monitoring the safety of vaccines administered during pregnancy. It will compare challenges posed by monitoring vaccines administered early versus later in pregnancy, and provide a variety of perspectives on how to confront common problems such as determining the timing of vaccine exposure in relation to gestational age, and developing outcome definitions that are applicable to a variety of resource and study settings.

This symposium is appropriate for researchers interested in understanding study design decisions using primary and secondary data sources to monitor safety outcomes relevant to vaccine exposure in pregnancy.

Description: Participants in this symposium will 1) learn routine methodologies used by manufacturers to monitor potential vaccine-related outcomes that occur in pregnancy, including passive surveillance and pregnancy registries; 2) discover observational safety study designs used to determine the risk of adverse pregnancy outcomes associated with vaccine exposure during pregnancy, including distributed research networks, active surveillance, and complementary cohort and case control studies such as those conducted by the Vaccines and Medications in Pregnancy Surveillance Systems (VAMPSS); 3) understand the unique opportunities and challenges of utilizing integrated electronic health networks (i.e., Vaccine Safety Datalink (VSD)) and administrative claims based systems (i.e., the Truven Health MarketScan Research Databases; Post-licensure Rapid Immunization Safety Monitoring System (PRISM)) to study vaccine safety outcomes during pregnancy; 4) appreciate efforts led by the Global Alignment of Immunization safety Assessment in pregnancy (GAIA) to develop unifying obstetric and neonatal outcome definitions, case reporting forms, and risk assessment tools.

Participants:

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