Summary of Topic:
The Centers for Disease Control and Prevention (CDC) recommends routinely administering influenza vaccine and tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine (Tdap) to pregnant women. Our goal is to review how CDC monitors the safety of maternal influenza and Tdap vaccines in pregnant women and their exposed infants.

Description of Session:
On the Double: Monitoring the Safety of Influenza Vaccine and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine (Tdap) in Pregnant Women and their Infants at CDC

Administering vaccines to pregnant women has potential to protect mothers and their infants from vaccine-preventable diseases. The Advisory Committee on Immunization Practices (ACIP) recommends routinely administering two vaccines to pregnant women: influenza vaccine and Tdap. Since 2004, inactivated influenza vaccine (IIV) has been recommended in any trimester for women who are or will be pregnant during the influenza season to protect the mother from severe influenza; in 2017 ACIP included recombinant influenza vaccine (RIV) as an option for use in pregnant women (1). Since 2012, Tdap has been recommended during every pregnancy between 27-36 weeks gestational age to protect young infants from pertussis, via maternal transplacental pertussis antibody transfer (2). While available data support the safety of maternal influenza and Tdap vaccines, pre-licensure studies excluded pregnant women. Monitoring the safety of influenza and Tdap vaccines in pregnant women and their exposed infants is of value to healthcare providers and the public.

The Centers for Disease Control and Prevention (CDC), in collaboration with partners, conducts post-licensure vaccine safety monitoring for U.S.-licensed vaccines. Vaccine safety surveillance and research is conducted through three systems: the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), and the Clinical Immunization Safety Assessment (CISA) Project. During recent years, these systems have been adapted to monitor maternal vaccine safety, assessing health outcomes in pregnant women and their exposed infants. Numerous maternal vaccine safety studies have been implemented. The systems work together to provide timely safety data to the public about maternal vaccine safety for influenza vaccine and Tdap. They are also ready to monitor new maternal vaccines in development, when they become available. In this session, we will provide an overview of each vaccine safety monitoring system, describe studies completed, and highlight studies in progress that are expected to further the evidence base for maternal vaccine safety for influenza vaccine and Tdap. It is targeted to healthcare and public health professionals who want to better understand CDC’s methods for monitoring the safety of vaccines in U.S. pregnant women.

Opening Remarks: CDC maternal vaccine safety monitoring overview --- Karen R. Broder, MD, Pediatric Medical Officer and Oidda Museru, RN, MPH, Nurse Epidemiologist, Immunization Safety Office (ISO)/CDC (5 minutes)
Vaccine Adverse Event Reporting System (VAERS): Enhanced surveillance for maternal influenza and Tdap vaccine safety -- Pedro Moro, MD, MPH, Epidemiologist, ISO/CDC (15 minutes)

Vaccine Safety Datalink (VSD): Epidemiologic studies for maternal influenza and Tdap vaccine safety -- Lakshmi Sukumaran, MD, MPH, Pediatric Medical Officer, ISO/CDC (15 minutes)

Clinical Immunization Safety Assessment (CISA) Project: Clinical research studies in pregnant women receiving influenza or Tdap vaccines – Karen R. Broder, MD (10 minutes)

Discussion: (15 minutes) - Oidda Museru and speaker panel

References

ACIP Influenza Vaccine recommendations 2017-18 season (MMWR 2017)

ACIP Tdap recommendations for pregnant women (MMWR 2013)