

# SAFETY OF VACCINES FOR PREGNANT WOMEN AND ROLE OF REGULATORY SYSTEM RELATED THE ISSUE

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A vaccine is the most cost-effective measure available to protect and promote public health and this principle applies to use for vaccination of pregnant women. Pregnant women and newborn infants are at increased risk of complications from certain vaccine-preventable diseases (e.g., influenza, pertussis). The pregnant women in the US are 4-fold greater risk for hospitalization because of A/H1N1 infection than the general population. Maternal vaccination is an effective approach to prevent certain infectious diseases because it directly protects the mother and indirectly protects her newborn through passive antibody transfer. Clinical investigation and definitions for the assessment of outcomes should help expedite a variety of aspects of vaccine development as well as regulatory decision making. The reduction of child mortality by two-thirds in between 1990-2015 is the millennium development goals. The vaccines Tdap and inactivated influenza are routinely recommended in the USA by the advisory committee on immunization practices (ACIP) to be administered during each pregnancy. The study proves the benefits for both mother and babies, it is expected that future maternal immunizations will have to also obtain a specific indication from the FDA to be administered in this population. In 2014, California experienced a pertussis epidemic with over 11000 reported cases. Young infants have the highest reported rates of illness, hospitalization and death from pertussis. Influenza immunization during pregnancy helps protect both mother and baby from influenza and its complications. Changes to the immune system, heart and lung during pregnancy make pregnant women more susceptible to severe influenza illness, pneumonia, and hospitalization. Collaboration for evaluation of safety profile recommended vaccines in pregnant women and in infants born to vaccinated mothers. Very important for success of immunization and safety of vaccines in pregnant women is the strengthening pharmacovigilance structure. The pharmacovigilance now is almost in every country as part of regulatory agencies or like center of pharmacovigilance, which is necessary to monitor maternal, fetal and newborn and child health.

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