Vaccines For Use in Pregnancy to Protect Young Infants from Disease
Vaccines for Use During Pregnancy

The goal of vaccinating pregnant women is to protect the mother and/or her child from infectious diseases.
Immunization during pregnancy has the potential to protect the mother and the infant against vaccine-preventable diseases.

Newborn infants are at high-risk for significant illness and death from certain infectious diseases because their immune system has not fully developed.

One aim of vaccinating pregnant women is to increase the amount of maternal antibody (proteins that fight disease) transferred to infants, potentially protecting them from infectious disease.
There has been renewed interest in immunization during pregnancy by the scientific and public health community.

Worldwide, almost 700,000 children less than one month of age die each year due to infectious diseases, such as pneumonia or sepsis.

Immunization during pregnancy has emerged as an important and successful public health intervention in both industrialized and developing countries.

- CDC recommendation to administer pertussis vaccine during pregnancy
- Worldwide reduction in maternal and neonatal tetanus
39 Countries eliminated MNT between 2000 & May 2016
*(Plus Ethiopia except Somali region and 16 regions out of 17 in Philippines) leaving 20 countries yet to eliminate MNT

Source: WHO/UNICEF Database
Date of slide: 19 May 2016
Map production: Immunization, Vaccines and Biologicals, (IVB), World Health Organization
National and Global Stakeholders

- World Health Organization
- Department of Health and Human Services
- Academic Institutions
- National Regulators
- Bill and Melinda Gates Foundation
- Local Health Providers
- Non-Profit Organizations
Role of the FDA

- Engage in discussions with national and international stakeholders
- Define regulatory pathways for development and licensure of vaccines for use in pregnancy and license new vaccines
- Provide advice to regulated industry
- Obtain input from Advisory Committee
Selected Vaccines that may be considered for Use in Pregnancy

<table>
<thead>
<tr>
<th>Vaccines licensed for Adolescents &amp; Adults</th>
<th>Vaccines in Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Tdap</td>
<td>• Respiratory Syncytial Virus</td>
</tr>
<tr>
<td>• Influenza</td>
<td>• Group B Streptococcus</td>
</tr>
<tr>
<td></td>
<td>• Cytomegalovirus</td>
</tr>
</tbody>
</table>
Selected Licensed Vaccines Used in Pregnancy

- Several licensed vaccines may be used during pregnancy to prevent disease in the mother, unless specifically contraindicated.
  - Tdap
  - Influenza

- Vaccines recommended for pregnant women were first licensed and approved for use based on safety and effectiveness data in non-pregnant women.

- These vaccines were then recommended by public health policy makers for pregnant women based on their perceived benefit and minimal risk for the mother and infant.

- Currently, no vaccine is approved specifically for use during pregnancy to protect the infant.
Vaccines in Development

What is needed to approve a vaccine for use in pregnancy to protect the infant?

- Demonstration that the vaccine is
  - Safe
  - Effective
    - Shows protection in infants
- Clinical development program specifically designed for pregnant women and the infant
Nonclinical Development

• Description of manufacturing process of the vaccine

• Appropriate product characterization to determine acceptability of candidate vaccines for clinical studies

• Toxicology Studies in Animals
  • Reproductive and developmental toxicology
Clinical Development

Non-pregnant Women of Childbearing Potential

- Up to 50 subjects
- Phase 1: Safety
- Phase 2: Safety & Immuno-genicity

Pregnant Women

- Up to 50 subjects
- Phase 1: Safety
- Phase 2: Safety & Immuno-genicity
- Phase 3: Effective-ness & Safety

Post-Licensure study

Ongoing Safety Oversight
Vaccines for Use in Pregnancy to protect infants from disease

Safety Evaluation

• Potential adverse events in the mother
• Potential complications
  • Specific to Pregnancy
  • Obstetric complications
• Infant outcomes data
  • Follow-up of infant
Vaccines for Use in Pregnancy: Clinical Trial Considerations

• For diseases with low incidence, it may not be feasible to directly measure a vaccine’s effectiveness in preventing disease in newborn infants in clinical trials.
• For vaccines already recommended for use in pregnancy controlled clinical trials present challenges.
• FDA acknowledges that alternative clinical trial designs may be needed to determine the effectiveness of vaccines used during pregnancy to protect the infant.
• FDA has the expertise to provide advice and facilitate such studies.
Advisory Committee

- The FDA convened the Vaccines and Related Biological Products Advisory Committee in November 2015 to publicly discuss clinical trial considerations for vaccines for use during pregnancy.
- The Committee acknowledged that development of vaccines for use during pregnancy is possible with consideration of unique scientific, clinical, and regulatory considerations.
  - Manufacturers should seek FDA guidance on clinical development programs for vaccines to be administered during pregnancy to prevent infant diseases.
Further Information

- Vaccines and Related Biological Products Advisory Committee- November 13, 2015: “Clinical development and requirements for licensure of vaccines intended for use during pregnancy to prevent disease in the infant”
  - FDA briefing document
  - Transcript
  - Presentations

- http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/ucm427602.htm
Conclusion

- Progress has been made over the last decade in advancing research and programs aimed at immunization during pregnancy.
- FDA is engaged in dialogue with national and global stakeholders to address barriers to implementation.
- Vaccines to be used during pregnancy specifically intended to protect the infant are in development.
- FDA is in communication with manufacturers to agree on the unique requirements for clinical trials involving pregnant women.
Contact the FDA

By phone, toll-free:
1-800-835-4709
(or 240-402-8010)

E-mail:
ocod@fda.hhs.gov

http://www.fda.gov/BiologicsBloodVaccines/default.htm

http://twitter.com/#!/FDACBER
Thank you