



**FDA** Update

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Vaccines For Use in  
Pregnancy to Protect  
Young Infants  
from Disease

# Presentation Outline

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Introduction

Role of the FDA

Vaccines for Use in Pregnancy

Nonclinical Development

Clinical Trial Considerations

Advisory Committee

Conclusions

# Vaccines for Use During Pregnancy

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The goal of vaccinating pregnant women is to protect the mother and/or her child from infectious diseases



# Introduction

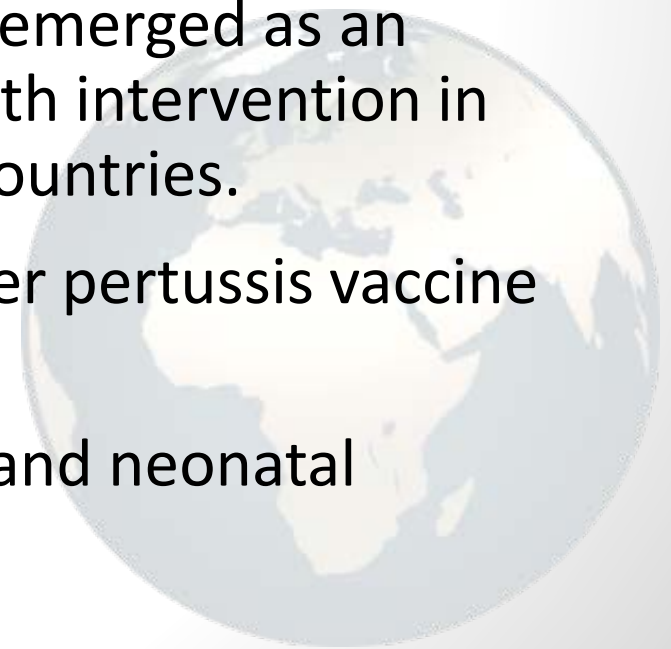
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- Immunization during pregnancy has the potential to protect the mother and the infant against vaccine-preventable diseases.
- Newborn infants are at high-risk for significant illness and death from certain infectious diseases because their immune 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.

# Global Public Health Strategy

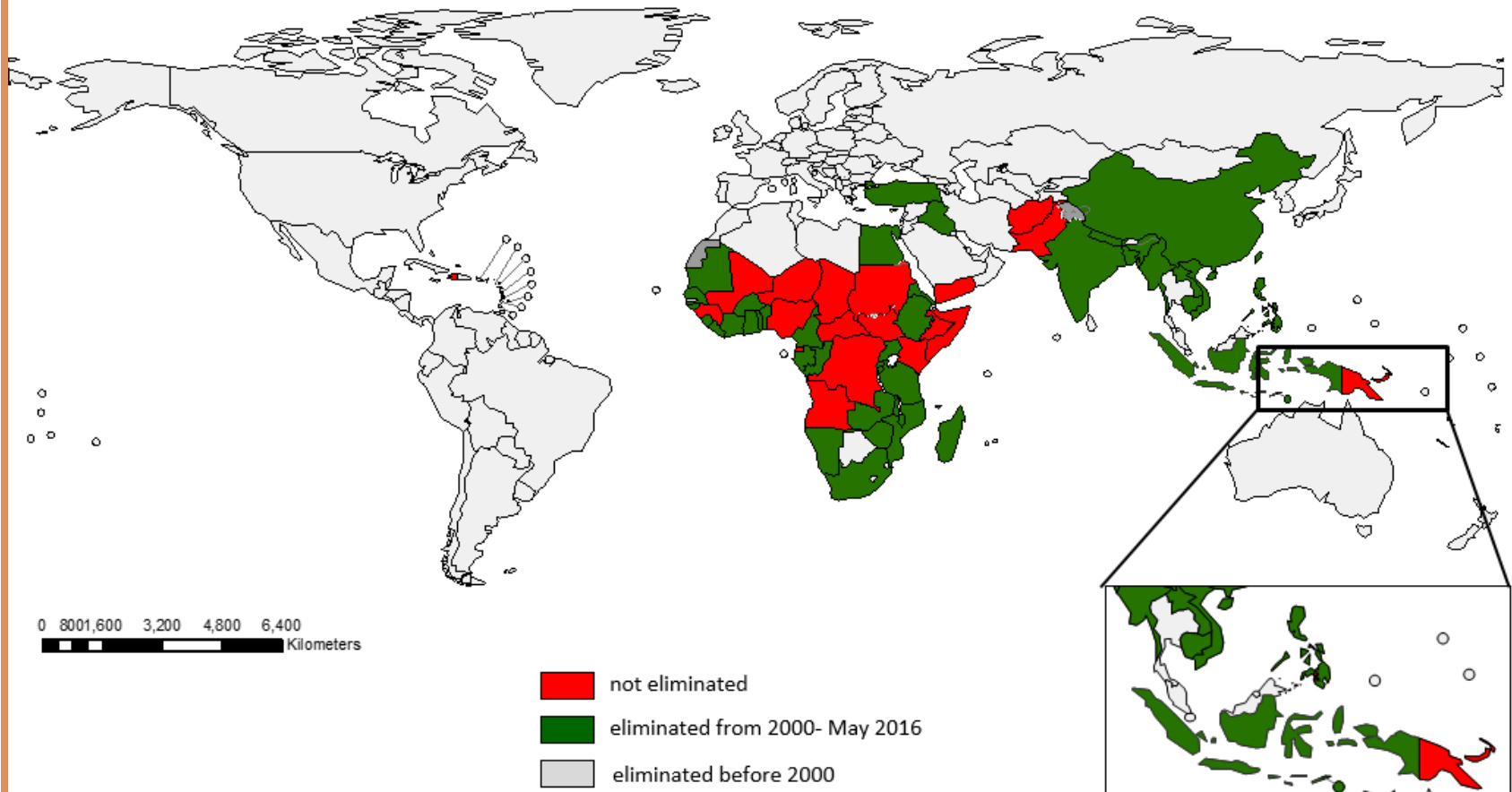
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- There has been renewed interest in immunization during pregnancy by the scientific and public health community.
- Worldwide, almost 700,000 children less than one month of age die each year due to infectious diseases, such as pneumonia or sepsis.
- 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

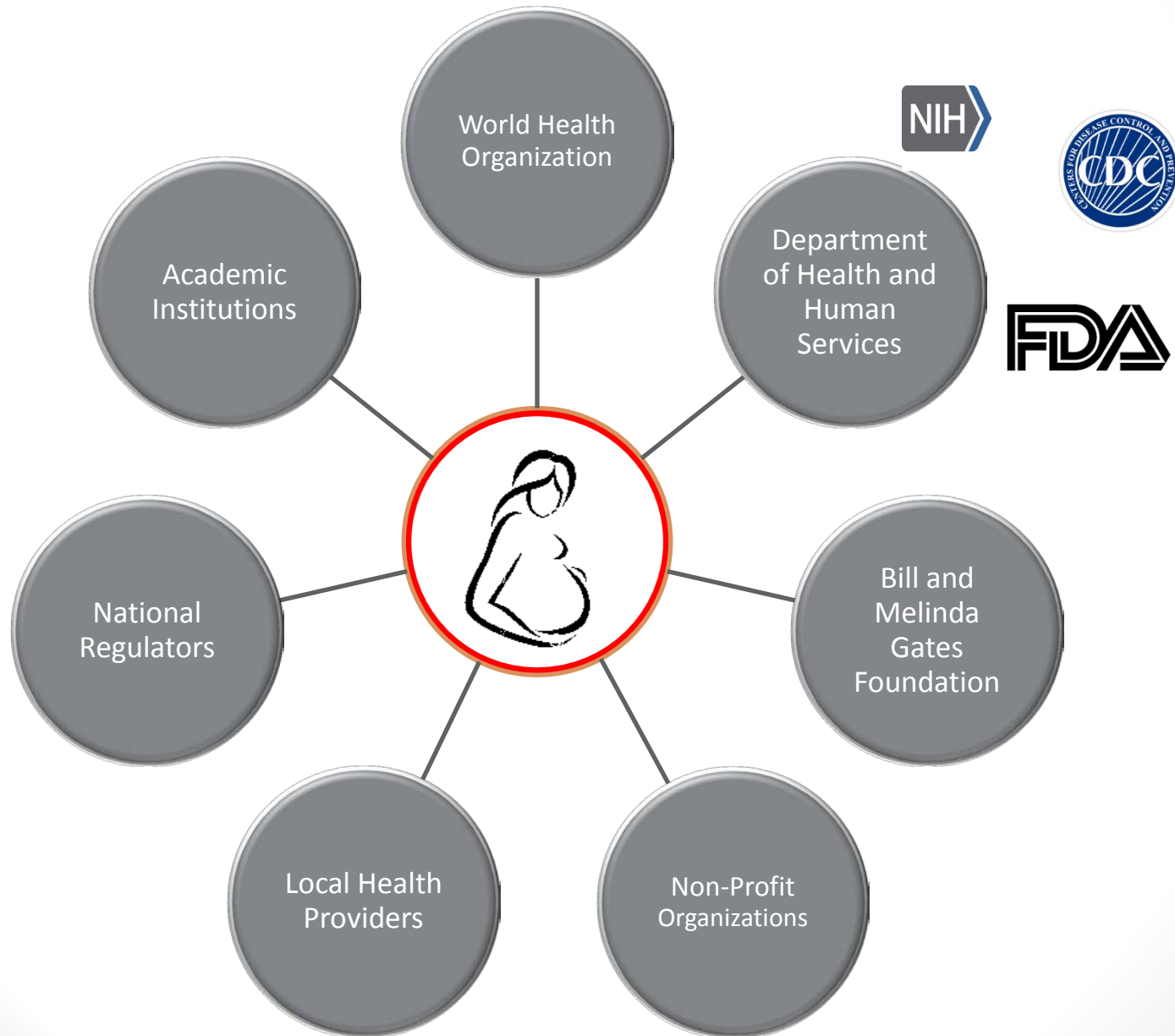


Source: WHO/UNICEF Database  
Date of slide : 19 May 2016  
Map production: Immunization Vaccines and  
Biologicals, (IVB), World Health Organization

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# National and Global Stakeholders



# Role of the FDA

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**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

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## Vaccines licensed for Adolescents & Adults

- Tdap
- Influenza

## Vaccines in Development

- Respiratory Syncytial Virus
- Group B Streptococcus
- Cytomegalovirus

# Selected Licensed Vaccines Used in Pregnancy

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- 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

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**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

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- 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



Up to 500 subjects



Phase 1

Phase 2

Safety

Safety & Immunogenicity

## Pregnant Women



Up to 50 subjects



Up to 500 subjects



Thousands of subjects



Phase 1

Phase 2

Phase 3

Safety

Safety & Immunogenicity

Effectiveness & Safety

Post-Licensure study

Ongoing Safety Oversight

# Vaccines for Use in Pregnancy to protect infants from disease

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## 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

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- 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

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- 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

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- 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

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- 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

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



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



E-mail:  
[ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov)



<http://twitter.com/#!/FDACBER>

Thank you

