

from Recommendations of the Advisory Committee on Immunization Practices (ACIP)



## GUIDELINES FOR VACCINATING PREGNANT WOMEN

OCTOBER 1998 (Updated June 2004)

#### **Vaccination of Pregnant Women**

"Risk to a developing fetus from vaccination of the mother during pregnancy is primarily theoretical. No evidence exists of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids. Benefits of vaccinating pregnant women usually outweigh potential risks when the likelihood of disease exposure is high, when infection would pose a risk to the mother or fetus, and when the vaccine is unlikely to cause harm." ACIP General Recommendations on Immunization, p. 18

Generally, live-virus vaccines are contraindicated for pregnant women because of the theoretical risk of transmission of the vaccine virus to the fetus. If a live-virus vaccine is inadvertently given to a pregnant woman, or if a woman becomes pregnant within 4 weeks after vaccination, she should be counseled about the potential effects on the fetus. But it is not ordinarily an indication to terminate the pregnancy.

Whether live or inactivated vaccines are used, vaccination of pregnant women should be considered on the basis of risks vs. benefits – i.e., the risk of the vaccination vs. the benefits of protection in a particular circumstance. The following table may be used as a general guide.

VACCINE		SHOULD BE CONSIDERED IF OTHERWISE INDICATED	CONTRAINDICATED DURING PREGNANCY	SPECIAL OR ABSENT RECOMMENDATION (SEE TEXT)
ROUTINE	Hepatitis A			(See page 1)
	Hepatitis B	<b>✓</b>		
	Influenza (inactivated)	<b>✓</b>		
	Influenza (LAIV)*		V	
	Measles*		V	
	Mumps*		V	
	Pneumococcal			(See page 3)
	Polio (IPV)			(See page 3)
	Rubella*		V	
	Tetanus/Diphtheria	V		
	Varicella*		<b>'</b>	
TRAVEL & OTHER	Anthrax			(See page 5)
	BCG*		<b>'</b>	
	Japanese Encephalitis			(See page 6)
	Meningococcal	V		
	Rabies	<b>✓</b>		
	Typhoid (Parenteral & Ty21a*)			(See page 6)
	Vaccinia*			(See page 7)
	Yellow Fever*			(See page 8)

<sup>\*</sup>Live, attenuated vaccine.

#### **Passive Immunization during Pregnancy**

"No known risk exists for the fetus from passive immunization of pregnant women with immune globulin preparations." ACIP *General Recommendations on Immunization*, p. 19



# Guidelines for Vaccinating Pregnant Women

Abstracted from recommendations of the Advisory Committee on Immunization Practices (ACIP)

#### HEPATITIS A

• "The safety of hepatitis A vaccination during pregnancy has not been determined; however, because hepatitis A vaccine is produced from inactivated [hepatitis A virus], the theoretical risk to the developing fetus is expected to be low. The risk associated with vaccination should be weighed against the risk for hepatitis A in women who may be at high risk for exposure to [hepatitis A virus]."

#### HEPATITIS B

- "On the basis of limited experience, there is no apparent risk of adverse effects to developing fetuses when hepatitis B vaccine is administered to pregnant women (CDC, unpublished data). The vaccine contains noninfectious HBsAg particles and should cause no risk to the fetus. [Hepatitis B virus] infection affecting a pregnant woman may result in severe disease for the mother and chronic infection for the newborn.

  Therefore, neither pregnancy nor lactation should be considered a contraindication to vaccination of women."
- "Hepatitis B vaccine is recommended for pregnant women at risk for hepatitis B virus infection . . ."<sup>3</sup>

### INFLUENZA (inactivated)

- "Because of the increased risk for influenza-related complications, women who will be pregnant during the influenza season should be vaccinated."
- "Vaccination can occur in any trimester."<sup>4</sup>
- "One study of influenza immunization of >2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine."

#### INFLUENZA (LAIV)

• "The following populations should not be vaccinated with LAIV . . . pregnant women. (These persons should receive inactivated influenza vaccine.)" 5

#### **MEASLES**

- "Measles-mumps rubella (MMR) vaccine and its component vaccines should not be administered to women known to be pregnant. Because a risk to the fetus from administration of these live virus vaccines cannot be excluded for theoretical reasons, women should be counseled to avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines or MMR or other rubella-containing vaccines."
- "If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled regarding the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy." 3

#### **MUMPS**

- "Measles-mumps rubella (MMR) vaccine and its component vaccines should not be administered to women known to be pregnant. Because a risk to the fetus from administration of these live virus vaccines cannot be excluded for theoretical reasons, women should be counseled to avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines or MMR or other rubella-containing vaccines."
- "If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled regarding the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy." 3

#### PNEUMOCOCCAL (PPV23)

• "The safety of pneumococcal polysaccharide vaccine during the first trimester of pregnancy has not been evaluated, although no adverse consequences have been reported among newborns whose mothers were inadvertently vaccinated during pregnancy."

#### POLIO (IPV)

"Although no adverse effects of IPV have been documented among pregnant women or their fetuses, vaccination of pregnant women should be avoided on theoretical grounds. However, if a pregnant woman is at increased risk for infection and requires immediate protection against polio, IPV can be administered in accordance with the recommended schedules for adults."

#### RUBFLLA

- "Measles-mumps rubella (MMR) vaccine and its component vaccines should not be administered to women known to be pregnant. Because a risk to the fetus from administration of these live virus vaccines cannot be excluded for theoretical reasons, women should be counseled to avoid becoming pregnant for 28 days after vaccination with measles or mumps vaccines or MMR or other rubella-containing vaccines."
- "If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled regarding the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy." 3
- "Rubella-susceptible women who are not vaccinated because they state they are or may be pregnant should be counseled about the potential risk for CRS and the importance of being vaccinated as soon as they are no longer pregnant."
- A registry of susceptible women vaccinated with rubella vaccine between 3 months before and 3 months after conception the "Vaccine in Pregnancy (VIP) Registry" was kept between 1971 and 1989. No evidence of CRS occurred in the offspring of the 226 women who received the current RA 27/3 rubella vaccine and continued their pregnancy to term.<sup>9</sup>

#### TETANUS & DIPHTHERIA

- "Td toxoid is indicated routinely for pregnant women. Previously vaccinated pregnant women who have not received a Td vaccination within the last 10 years should receive a booster dose."
- "Pregnant women who are not immunized or only partially immunized against tetanus should complete the primary series." 3
- "Although no evidence exists that tetanus and diphtheria toxoids are teratogenic, waiting until the second trimester of pregnancy to administer Td is a reasonable precaution for minimizing any concern about the theoretical possibility of such reactions." 10

#### VARICFLLA

- "The effects of the varicella virus vaccine on the fetus are unknown; therefore, **pregnant women should not be vaccinated**. Nonpregnant women who are vaccinated should avoid becoming pregnant for 1 month following each injection. For susceptible persons, having a pregnant household member is not a contraindication to vaccination."
- "Because the virulence of the attenuated virus used in the vaccine is less than that of the wild-type virus, the risk to the fetus, if any, should be even lower."<sup>11</sup>
- "If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after . . . varicella vaccination, she should be counseled regarding the theoretical basis of concern for the fetus; however, . . . varicella vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy." 3
- "VZIG [Varicella Zoster Immune Globulin] should be strongly considered for susceptible, pregnant women who have been exposed."<sup>11</sup>
- The manufacturer & CDC have established a VARIVAX® Pregnancy Registry to monitor outcomes of women who got the vaccine 3 months before or any time during pregnancy. Call **1-800-986-8999**.

#### **ANTHRAX**

• "No studies have been published regarding use of anthrax vaccine among pregnant women. Pregnant women should be vaccinated against anthrax only if the potential benefits of vaccination outweigh the potential risks to the fetus." 12

BCG

• "Although no harmful effects to the fetus have been associated with BCG vaccine, its use is not recommended during pregnancy." 13

#### JAPANESE ENCEPHALITIS

- "No specific information is available on the safety of JE vaccine in pregnancy. Vaccination poses an unknown but theoretical risk to the developing fetus, and the vaccine should not be routinely administered during pregnancy."<sup>14</sup>
- "Pregnant women who must travel to an area where risk of JE is high should be vaccinated when the theoretical risks of immunization are outweighed by the risk of infection to the mother and developing fetus." <sup>14</sup>

#### MENINGOCOCCAL

- Studies have shown the vaccine to be both safe and
  efficacious when given to pregnant women. While high
  antibody levels were found in umbilical cord blood
  following vaccination during pregnancy, antibody levels
  in the infants decreased during the first few months after
  birth. Subsequent response to meningococcal
  vaccination was not affected.
- "Based on data from studies involving use of meningococcal vaccines administered during pregnancy, altering meningococcal vaccination recommendations during pregnancy is unnecessary."

#### RABIES

- "Because of the potential consequences of inadequately treated rabies exposure, and because there is no indication that fetal abnormalities have been associated with rabies vaccination, **pregnancy is not considered a contraindication to postexposure prophylaxis.**" <sup>16</sup>
- "If the risk of exposure to rabies is substantial, preexposure prophylaxis might also be indicated during pregnancy."

#### TYPHOID

• "No data have been reported on the use of any of the three typhoid vaccines among pregnant women." <sup>17</sup>

#### VACCINIA (SMALLPOX)

- "Live-viral vaccines are contraindicated during pregnancy; therefore, vaccinia vaccine should not be administered to pregnant women for routine nonemergency indications." 18
- "However, vaccinia vaccine is not known to cause congenital malformations. Although <50 cases of fetal vaccinia infection have been reported, vaccinia virus has been reported to cause fetal infection on rare occasions, almost always after primary vaccination of the mother."
- "Pregnant women who have had a definite exposure to smallpox virus (i.e., face-to-face, household, or close-proximity contact with a smallpox patient) and are, therefore, at high risk for contracting the disease, should . . . be vaccinated. Smallpox infection among pregnant women has been reported to result in a more severe infection than among nonpregnant women. Therefore the risks to the mother and fetus from experiencing clinical smallpox substantially outweigh any potential risks regarding vaccination. In addition, vaccinia virus has not been documented to be teratogenic, and the incidence of fetal vaccinia is low." 18
- "When the level of exposure risk is undetermined, the decision to vaccinate should be made after assessment by the clinician and the patient of the potential risks versus the benefits of smallpox vaccination." <sup>18</sup>

#### YELLOW FEVER

- "The safety of yellow fever vaccination during pregnancy has not been established, and the vaccine should be administered only if travel to an endemic area is unavoidable and if an increased risk for exposure exists." 19
- "... infection of the fetus with YF17D apparently occurs at a low rate ... and has not been associated with congenital anomalies." <sup>19</sup>
- "If international travel requirements are the only reason to vaccinate a pregnant woman, rather than an increased risk of infection, efforts should be made to obtain a waiver letter from the traveler's physician." <sup>19</sup>
- "Pregnant women who must travel to areas where the risk of yellow fever is high should be vaccinated and, despite the apparent safety of this vaccine, infants born to these women should be monitored closely for evidence of congenital infection and other possible adverse effects resulting from yellow fever vaccination" 19
- "If vaccination of a pregnant woman is deemed necessary, serologic testing to document an immune response to the vaccine can be considered, because the seroconversion rate for pregnant women in a developing nation has been reported to be substantially lower than that observed for other healthy adults and children. To discuss the need for serologic testing, the appropriate state health department or the Division of Vector-Borne Infectious Diseases (telephone: 970-221-6400) or the Division of Global Migration and Quarantine (telephone: 404-639-1600) at CDC should be contacted." 19

- 1. Centers for Disease Control & Prevention. Prevention of Hepatitis A Through Active or Passive Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 48 (No. RR-12): 24, 1999.
- 2. Centers for Disease Control & Prevention. Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 40 (No. RR-13): 4, 1991.
- 3. Centers for Disease Control & Prevention. General Recommendations on Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 51 (No. RR-2): 18-19, 2002.
- 4. Centers for Disease Control & Prevention. Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 53 (No. RR-6): 10, 2004.
- 5. Centers for Disease Control & Prevention. Using Live, Attenuated Influenza Vaccine for Prevention and Control of Influenza: Supplemental Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 52 (No. RR-13): 5, 2003.
- 6. Centers for Disease Control & Prevention. Notice to Readers: Revised ACIP Recommendation for Avoiding Pregnancy After Receiving a Rubella-Containing Vaccine. *MMWR* 50 (No. 49): 1117, 2001.
- 7. Centers for Disease Control & Prevention. Prevention of Pneumococcal Disease: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 46 (No. RR-8): 6, 1997.
- 8. Centers for Disease Control & Prevention. Poliomyelitis Prevention in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 49 (No. RR-5): 14, 2000.
- 9. Centers for Disease Control & Prevention. Measles, Mumps, and Rubella Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and Control of Mumps: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 47 (No. RR-8): 32-33, 1998.
- 10. Centers for Disease Control & Prevention. Diphtheria, Tetanus, and Pertussis: Recommendations for Vaccine Use and Other Preventive Measures: Recommendations of the Immunization Practices Advisory Committee (ACIP). *MMWR* 40 (No. RR-10): 14, 1991.
- 11. Centers for Disease Control & Prevention. Prevention of Varicella: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 45 (No. RR-11): 19, 1996.
- 12. Centers for Disease Control & Prevention. Use of Anthrax Vaccine in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 49 (No. RR-15): 11, 2000.
- 13. Centers for Disease Control & Prevention. The Role of BCG Vaccine in the Prevention and Control of Tuberculosis in the United States: A Joint Statement by the Advisory Council for the Elimination of Tuberculosis and the Advisory Committee on Immunization Practices. *MMWR* 45 (No. RR-4): 13, 1996.
- 14. Centers for Disease Control & Prevention. Inactivated Japanese Encephalitis Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 42 (No. RR-1): 12-13, 1993.

- 15. Centers for Disease Control & Prevention. Control and Prevention of Meningococcal Disease and Control and Prevention of Serogroup C Meningococcal Disease: Evaluation and Management of Suspected Outbreaks: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 46 (No. RR-5): 5, 1997.
- 16. Centers for Disease Control & Prevention. Human Rabies Prevention—United States, 1999: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 48 (No. RR-1): 17, 1999.
- 17. Centers for Disease Control & Prevention. Typhoid Immunization: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 43 (No. RR-14): 7, 1994.
- 18. Centers for Disease Control & Prevention. Vaccinia (Smallpox) Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 50 (No. RR-10): 12 & 19, 2001.
- 19. Centers for Disease Control & Prevention. Yellow Fever Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2002. *MMWR* 51 (No. RR-17): 7, 2002.

#### **Prenatal Screening for Vaccine-Preventable Diseases**

The ACIP currently recommends prenatal screening for rubella and hepatitis B:

"Prenatal serologic screening . . . is indicated for all pregnant women who lack acceptable evidence of rubella immunity. Upon completion or termination of their pregnancies, women who do not have serologic evidence of rubella immunity or documentation of rubella vaccination should be vaccinated with MMR before discharge from the hospital, birthing center, or abortion clinic." ACIP, *Measles, Mumps, and Rubella — Vaccine Use and Strategies for Elimination of Measles, Rubella, and Congenital Rubella Syndrome and Control of Mumps,* p. 18.

"All pregnant women should be routinely tested for HBsAg during an early prenatal visit in each pregnancy. . . . HBsAg-positive mothers identified during screening may have HBV-related acute or chronic liver disease and should be evaluated by their physicians." ACIP, *Protection Against Viral Hepatitis*, p. 14.

#### Vaccinating Women who are Breastfeeding

"Neither inactivated nor live vaccines administered to a lactating woman affect the safety of breast-feeding for mothers or infants. Breast-feeding does not adversely affect immunization and is not a contraindication for any vaccine." ACIP, *General Recommendations on Immunization*, p. 18.

The following applies to varicella vaccine, which was licensed after the ACIP General Recommendations were published: "Whether attenuated vaccine VZV is excreted in human milk and, if so, whether the infant could be infected are not known. Most live vaccines have not been demonstrated to be secreted in breast milk. Attenuated rubella vaccine virus has been detected in breast milk but has produced only asymptomatic infection in the nursing infant. Therefore, varicella vaccine may be considered for a nursing mother." ACIP, Prevention of Varicella, pp. 19-20.

#### For More Information

More detailed information about vaccination of pregnant women can be found in:

**ACIP statements** for specific diseases.

The ACIP's *Update on Adult Immunization* (MMWR Vol. 40, No. RR-12, November 15, 1991). See especially p.9 and Appendix 5, pp.82-88.

Current ACIP recommendations can be found on the National Immunization Program's website at <a href="http://www.cdc.gov/nip/publications/ACIP-list.htm">http://www.cdc.gov/nip/publications/ACIP-list.htm</a>. Or call the National Immunization Program's Information Center at (404) 639-8226.

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The American College of Physicians' *Guide for Adult Immunization*, Third Edition, pp. 25-29. Customer Service for the American College of Physicians can be contacted at (215) 351-2600 or (800) 523-1546.