Admission Orders for Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus (HBV) Transmission

The guidelines in this 2-page document were developed to help hospitals establish policies and standing orders in their labor and delivery and newborn units.

During 2005, the Centers for Disease Control and Prevention (CDC) published updated recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in children which includes the recommendation to administer hepatitis B vaccine to ***all newborns before hospital discharge.*** *The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have all endorsed the birth dose recommendation. To obtain a copy, go to* www.cdc.gov/mmwr/PDF/rr/rr5416.pdf.

To protect infants from HBV infection, CDC recommends that all delivery hospitals institute standing orders or admission orders, and protocols to ensure healthcare professionals do the following:

1. *Administer hepatitis B vaccine to* ***all*** *newborns before they are discharged from the hospital.*
2. *Identify all infants born to mothers who are hepatitis B surface antigen (HBsAg) positive or to mothers with unknown HBsAg status. Administer appropriate immunoprophylaxis to these infants.*

Admission orders / procedures for birthing mothers

For pregnant women who have a HBsAg lab report included in their prenatal records, do the following:

1. Examine a copy of the *original* laboratory report of the pregnant woman's HBsAg[1] test result to verify that the correct test (i.e., HBsAg) was performed and to verify that the testing date was during *this* pregnancy not a previous one. *Do not rely on a handwritten or transcribed HBsAg test result!*
2. Place a copy of the original HBsAg lab report into (1) the pregnant woman's L&D record and (2) the infant's hospital record.
3. If the pregnant woman is HBsAg positive, alert the nursery staff that the newborn is high risk and will need postexposure prophylaxis —both HBIG and hepatitis B vaccine—within 12 hours of birth.
4. Perform a repeat blood test for HBsAg[1] if the pregnant woman was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., not in a long-term, mutually monogamous relationship; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drugs).
5. Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

For pregnant women who do not have an HBsAg lab report on their prenatal record, do the following:

1. Perform HBsAg[1] testing ASAP on women who do not have a copy of an original HBsAg laboratory report from the current pregnancy included in their prenatal record.
2. Instruct the lab to call L&D and the nursery units with the newly obtained HBsAg test result ASAP.

Admission orders / procedures for newborns

Hospital procedures to follow for ALL newborns

1. Review a copy of the mother's *original* HBsAg[1] lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
2. Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg status and the newborn's birth weight. If the newborn weighs less than 2kg, see the descriptions below and footnotes 2, 5, 6.

For newborns of HBsAg-negative mothers

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before hospital discharge to all newborns weighing 2 kg or more at birth.[2, 3, 4]
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, site of administration, and lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.

For newborns of mothers with unknown HBsAg status, do the following:

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.[3, 5] Do not wait for test results to return before giving this dose of vaccine.
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, site of administration, and lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.
4. Confirm that the laboratory has received blood for the mother's HBsAg[1] test.
5. Verify when the mother's HBsAg result will be available and that it will be reported to L&D and the newborn unit ASAP.
6. If the nursery does not receive the report of the mother's HBsAg test at the expected time, call the laboratory for the result.
7. If the laboratory test indicates the mother's HBsAg[1] test result is positive, do the following:
   a. Administer hepatitis B immune globulin (HBIG 0.5 mL, IM) to the newborn ASAP. (Hepatitis B vaccine should have been given within 12 hours of birth.)

(continued on next page)

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b. Document the HBIG dose appropriately in the newborn's medical record. There is little benefit in giving HBIG if more than 7 days have elapsed since birth.
c. Alert the mother's and newborn's physician(s) of the test result.
d. Follow the instructions below "For newborns of HBsAg-positive mothers," steps 3–7.

8. If the newborn must be discharged before the mother's HBsAg result is known:
   a. Document contact information for the parents (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed.
   b. Obtain the name, address, and phone number of the mother's and the newborn's healthcare providers.
   c. Notify the mother's and newborn's healthcare providers that the mother's HBsAg test result is pending.

For newborns of HBsAg-positive mothers

1. Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine[3, 6] (0.5 mL, IM) at separate injection sites within 12 hours of birth.
2. Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including date, time, site of administration, and lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.
4. Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
5. Obtain the name, address, and phone number of the newborn's primary care provider.
6. Notify the provider of the newborn's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination and postvaccination testing of the infant for HBsAg and antibody to HBsAg after completion of the hepatitis B vaccine series.
7. Provide advice to the mother. Tell her the following:
   a. That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
   b. That it is critical for her infant to complete the full hepatitis B vaccine series on the recommended schedule;
   c. That blood will need to be drawn from the infant after completion of at least 3 doses of the hepatitis B vaccine series at age 9–18 months (usually done at a well-child visit) to determine if the infant developed a protective immune response to vaccination or needs additional management;
   d. About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
   e. That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is eligible for antiviral treatment.

Footnotes

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was/is ordered. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs or HBsAb) and antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg at birth and whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge, whichever comes first. The mother's HBsAg test result must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the IAC website at www.immunize.org/vis or call your state health department.
4. According to the CDC recommendations, exceptions to administering the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. If a birth dose is not administered, a copy of the mother's negative HBsAg test result from the current pregnancy must be placed in the infant's medical record and the attending physician must write a specific order directing staff not to administer the birth dose in the hospital. Infants who do not receive the first dose of hepatitis B vaccine before hospital discharge should receive the first dose no later than age 2 months.
5. An infant weighing less than 2 kg whose mother's HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
6. An infant weighing less than 2 kg whose mother is HBsAg positive should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.

SAMPLE TEXT

Admission Order for Routine Newborn Hepatitis B Vaccination (to include in the standard admission orders)

☐ **Hepatitis B Vaccine (RECOMBIVAX HB or Engerix-B) IM**
ONE TIME, Intramuscular, Dose: 0.5 mL. Give within 12 hours of birth to all infants who weigh 2 kg (4.4 lb) or more. Bathe the newborn, washing the site well with soap and water, cleanse the injection site with alcohol prior to IM administration. *Obtain verbal consent from the parent prior to administration. Give the hepatitis B Vaccine Information Statement (VIS) to the parent and document the vaccine's administration in the hospital medical record. If the parent is unwilling to give verbal consent, notify physician by morning rounds or prior to 12 hours of age.*

Guidelines for Vaccinating Pregnant Women

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR DISEASE CONTROL & PREVENTION

Guidelines for Vaccinating Pregnant Women

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

October 1998
(Updated May 2007)

Vaccination of Pregnant Women

Risk for a developing fetus from vaccination of the mother during pregnancy primarily is theoretical. No evidence exists of risk from vaccinating pregnant women with inactivated virus or bacterial vaccines or toxoids. Live vaccines pose a theoretical risk to the fetus. 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."[1]

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 vaccination 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 versus benefits – i.e., the risk of the vaccination versus 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/CONDITIONAL RECOMMENDATION (SEE TEXT)
ROUTINE	Hepatitis A			(See page 1)
	Hepatitis B	X		
	Human Papillomavirus (HPV)			(See page 1)
	Influenza (Inactivated)	Recommended		
	Influenza (LAIV)*		X	
	Measles*		X	
	Meningococcal (MCV4)			(See page 2)
	Mumps*		X	
	Pneumococcal			(See page 2)
	Polio (IPV)			(See page 2)
	Rubella*		X	
	Tetanus-Diphtheria (Td)	X		
	Tetanus-Diphtheria-Pertussis (Tdap)			(See page 4)
	Varicella*		X	
TRAVEL & OTHER	Anthrax			(See page 5)
	BCG*		X	
	Japanese Encephalitis			(See page 5)
	Meningococcal (MPSV4)	X		
	Rabies	X		
	Typhoid (Parenteral & Oral*)			(See page 5)
	Vaccinia*		X	(See page 5)
	Yellow Fever*			(See page 6)
	Zoster*		X	

*Live attenuated vaccine

Passive Immunization during Pregnancy

"No known risk exists for the fetus from passive immunization of pregnant women with immune globulin preparations."[1]

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 pregnant women who may be at high risk for exposure to [hepatitis A virus]**.[2]

Hepatitis B

- **Pregnancy is not a contraindication to vaccination**. Limited data indicate no apparent risk for adverse events to developing fetuses when hepatitis B vaccine is administered to pregnant women. Current vaccines contain noninfectious HBsAg and should cause no risk to the fetus.[3]
- **Pregnant women who are identified as being at risk for HBV** infection during pregnancy (e.g., having more than one sex partner during the previous 6 months, been evaluated or treated for an STD, recent or current injection drug use, or having had an HBsAg-positive sex partner) **should be vaccinated**.[3]

Human Papillomavirus (HPV)

- **Quadrivalent HPV vaccine is not recommended for use in pregnancy**.[4]
- The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events to the developing fetus. However, data on vaccination during pregnancy are limited. Until additional information is available, initiation of the vaccine series should be delayed until after completion of the pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose regimen should be delayed until after completion of the pregnancy. If a vaccine dose has been administered during pregnancy, no intervention is needed.[4]
- A vaccine in pregnancy registry has been established; patients and health-care providers should report any exposure to . . . HPV vaccine during pregnancy (telephone: 800-986-8999).[4]

Influenza (Inactivated)

- Vaccination with inactivated influenza vaccine is recommended for the following persons who are at increased risk for severe complications from influenza: . . . Women who will be pregnant during the influenza season.[5]
- One study of influenza immunization of approximately 2,000 pregnant women demonstrated no adverse fetal effects associated with influenza vaccine; similar results were observed in a study of 252 pregnant women who received inactivated influenza vaccine within 6 months of delivery.[5]

Influenza (LAIV)	• Persons who 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.[6] • If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.[1]
Meningococcal (MCV4) (conjugate)	• MCV4 is safe and immunogenic among nonpregnant persons aged 11-55 years, but no data are available on the safety of MCV4 during pregnancy. **Women of childbearing age who become aware that they were pregnant at the time of MCV4 vaccination should contact their health-care provider or the vaccine manufacturer**.[7]
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.[6] • If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.[1]
Pneumococcal (PPV23) (polysaccharide)	• 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.[8]
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.[9]

Rubella

- **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.[6]
- If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after MMR . . . vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, MMR . . . vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.[1]
- 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.[10]
- 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.[10]

Tetanus & Diphtheria (Td) (See also Tdap)

- **Pregnant women should receive Td vaccine if indicated.** Previously vaccinated pregnant women who have not received a Td vaccination within the last 10 years should receive a booster dose.[1]
- Pregnant women who have not received three doses of a vaccine containing tetanus and diphtheria toxoids should complete a series of 3 vaccinations. Two doses of Td should be administered during pregnancy to ensure protection against maternal and neonatal tetanus. The preferred schedule in pregnant women is two doses of Td separated by 4 weeks, and a dose of Tdap 6 months after the second dose (post-partum). Health-care providers can choose to substitute a single dose of Tdap for a dose of Td during pregnancy.[11]
- 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.[12]

Tetanus, Diphtheria, & Pertussis (Tdap)

- **Pregnancy is not a contraindication for use of Tdap**. Data on safety, immunogenicity and the outcomes of pregnancy are not available for pregnant women who receive Tdap. When Tdap is administered during pregnancy, transplacental maternal antibodies might protect the infant against pertussis in early life. They also could interfere with the infant's immune response to infant doses of DTaP, and leave the infant less well protected against pertussis.[11]
- ACIP recommends Td when tetanus and diphtheria protection is required during pregnancy. **In some situations*, health-care providers can choose to administer Tdap instead of Td to add protection against pertussis**. When Td or Tdap is administered during pregnancy, the second or third trimester is preferred.[11]
- Providers who choose to administer Tdap to pregnant women should discuss the lack of data with the pregnant women and are encouraged to report Tdap administrations regardless of the trimester, to the appropriate manufacturer's pregnancy registry: for Boostrix® to GlaxoSmithKline Biologicals at 1-888-825-5249, or for Adacel®, to sanofi pasteur at 800-822-2463.[11]

* "Situations with increased risk for pertussis: Health-care providers can choose to administer Tdap instead of Td to protect against pertussis in pregnant adolescents for routine or "catch-up" vaccination because the incidence of pertussis is high among adolescents, in pregnant health-care personnel and child care providers to prevent transmission to infants younger than 12 months of age and to other vulnerable persons, and in pregnant women employed in an institution or living in a community with increased pertussis activity.[11]

Varicella

- 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.[13]
- 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.[13]
- If vaccination of an unknowingly pregnant woman occurs or if she becomes pregnant within 4 weeks after . . . varicella vaccination, she should be counseled about the theoretical basis of concern for the fetus; however, . . . varicella vaccination during pregnancy should not be regarded as a reason to terminate pregnancy.[1]
- VZIG [Varicella Zoster Immune Globulin] should be strongly considered for susceptible, pregnant women who have been exposed.[13]
- NOTE: The manufacturer and CDC have established a Varivax® Pregnancy Registry to monitor outcomes of women who received the vaccine 3 months before or any time during pregnancy. Call 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**.[14]

BCG

- Although no harmful effects to the fetus have been associated with BCG vaccine, **its use is not recommended during pregnancy**.[15]

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**.[16]
- 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.[16]

Meningococcal (MPSV4) (polysaccharide)

- Studies of vaccination with MPSV4 during pregnancy have not documented adverse effects among either pregnant women or newborns. On the basis of these data, **pregnancy should not preclude vaccination with MPSV4, if indicated**.[7]

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**.[17]
- **If the risk of exposure to rabies is substantial, preexposure prophylaxis might also be indicated during pregnancy**.[17]

Typhoid

- No data have been reported on the use of any of the three typhoid vaccines among pregnant women.[18]

Vaccinia (Smallpox)

- Live-viral vaccines are contraindicated during pregnancy; therefore, **vaccinia vaccine should not be administered to pregnant women for routine nonemergency indications**.[19]
- 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.[19]
- **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.[19]
- 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.[19]

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**.[20]
- . . . infection of the fetus with YF17D apparently occurs at a low rate . . . and has not been associated with congenital anomalies.[20]
- 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.[20]
- 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.[20]
- 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: 404-498-1600) at CDC should be contacted.[20]

Zoster (Shingles)

The ACIP has not yet issued recommendations on zoster vaccine. The manufacturer recommends not administering the vaccine during pregnancy:

- Contraindications: **Zostavax should not be administered to individuals . . . who are or may be pregnant**.[21]
- It is . . . not known whether Zostavax can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, naturally occurring VZV infection is known to sometimes cause fetal harm. Therefore, **Zostavax should not be administered to pregnant females**; furthermore, pregnancy should be avoided for three months following vaccination.[21]

Prenatal Serologic Screening

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

Rubella: "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."[10]

Hepatitis B: "All pregnant women should be routinely tested for HBsAg during an early prenatal visit (e.g., first trimester) in each pregnancy, even if they have been previously vaccinated or tested." "Women who are HBsAg positive should be referred to an appropriate case-management program to ensure that their infants receive timely postexposure prophylaxis and followup." "Women who are HBsAg positive should be provided with or referred for appropriate counseling and medical management." "When HBsAg testing of pregnant women is not feasible (i.e., in remote areas without access to a laboratory), all infants should receive hepatitis B vaccine $\leq$12 hours of birth and should complete the hepatitis B vaccine series according to a recommended schedule for infants born to HBsAg-positive mothers."[3] For more information, see Reference 3, p. 13.

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, with the exception of smallpox vaccine."[1]

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."[13]

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21. Zostavax (Package Insert). Whitehouse Station, NJ: Merck & Co. Inc.; 2006. Available at http://www.merck.com/product/usa/pi_circulars/z/zostavax/zostavax_pi.pdf.

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 http://www.cdc.gov/nip/publications/ACIP-list.htm. Or call the National Immunization Program's Information Center at (404) 639-8226.

- The American College of Obstetricians and Gynecologists (ACOG) **Technical Bulletin Number 160**, October 1991. This publication is available from the American College of Obstetricians and Gynecologists, Attn: Resource Center, 409 12th Street SW, Washington, DC 20024-2188.

- 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.

Delivery Hospital Policies and Procedures to Prevent Perinatal Hepatitis B Virus Transmission

At time of admission for delivery

- Review hepatitis B surface antigen (HBsAg) status of all pregnant women.
- Record maternal HBsAg test results on both labor and delivery record and on infant's delivery summary sheet.
- Perform HBsAg testing as soon as possible on women who
  - do not have a documented HBsAg test result;
  - were at risk for hepatitis B virus (HBV) infection during pregnancy (e.g., >1 sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner); or
  - had clinical hepatitis since previous testing.

After delivery

HBsAg-positive mothers and their infants

- Administer single-antigen hepatitis B vaccine and hepatitis B immune globulin (HBIG) to all infants born to HBsAg-positive mothers ≤12 hours after birth and record date and time of administration of HBIG and hepatitis B vaccine in infant's medical record.
- Provide information regarding hepatitis B to HBsAg-positive mothers, including
  - advice that they may breast feed their infants upon delivery;
  - modes of HBV transmission;
  - need for vaccination of their susceptible household, sexual, and needle-sharing contacts;
  - need for substance abuse treatment, if appropriate; and
  - need for medical management and possible treatment for chronic hepatitis B.

Mothers with unknown HBsAg status and their infants

- Administer single-antigen hepatitis B vaccine (without HBIG) to all infants born to mothers with unknown HBsAg status ≤12 hours after birth and record date and time of administration of hepatitis B vaccine on infant's medical record.
- Alert infant's pediatric health-care provider if an infant is discharged before the mother's HBsAg test result is available; if the mother is determined to be HBsAg positive, HBIG should be administered to the infant as soon as possible, but no later than age 7 days.

All mothers and their infants

- Administer a dose of single-antigen hepatitis B vaccine to all infants weighing ≥2,000 g.
- Ensure that all mothers have been tested for HBsAg prenatally or at the time of admission for delivery, and document test results.

At time infant is discharged

- Provide infant's immunization record to mother and remind her to take it to the infant's first visit to a pediatric health-care provider.

Source: CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: immunization of infants, children, and adolescents. *MMWR* 2005 (RR-16).

PROTECT
yourself & your growing family

Like most moms-to-be, you want to give your baby a healthy start in life.

Shots (also called immunizations) are a safe way to protect you and your baby from some harmful diseases.

Get up-to-date on the shots you need for a healthy pregnancy and baby.

Want to learn more?

For more information, talk with your doctor or local health department. Or, visit or call:

www.PregnancyShotsCA.org
www.GetImmunizedCA.org
(800) CDC-INFO/ (800) 232-4636

California Department of Public Health
Immunization Branch
850 Marina Bay Parkway
Richmond, CA 94804

Arnold Schwarzenegger, Governor—State of California
Kimberly Belshé, Secretary—Health and Human Services Agency
Mark B Horton, MD, MSPH, Director—Department of Public Health

IMM-887 (3/08)

IMMUNIZATIONS for a Healthy Pregnancy

Give your baby a healthy start

Thinking of having a baby?

Get shots before you get pregnant

It is best when shots are given before a woman becomes pregnant.

Whether it is your first baby, or you are planning to have another child, get up-to-date on your shots to protect you and your family. Talk with your doctor about which shots are right for you.

Pregnancy Planning Immunization Checklist

- ✓ MMR (measles, mumps, rubella)
- ✓ Tdap (tetanus, diphtheria, and whooping cough)
- ✓ Flu (influenza)
- ✓ Chickenpox
- ✓ Hepatitis B

Let your doctor know if you find out that you were pregnant at the time you got shots.

When you are pregnant...

You need a flu shot!

During pregnancy, the flu can cause serious health problems for you and your baby.

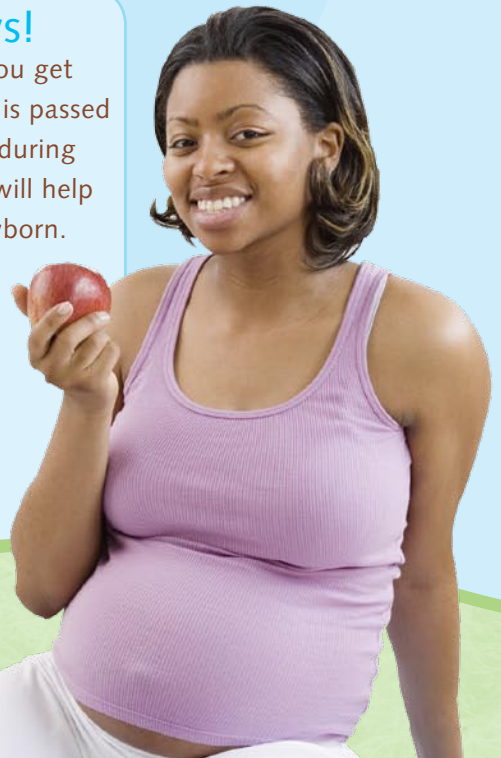
A flu shot is a safe and easy way to protect both you and your baby from the influenza virus.

Traveling out of the United States?

Talk with your doctor about shots to protect you from diseases that are still common in other parts of the world.

Good News!

The protection you get from some shots is passed on to your baby during pregnancy. This will help protect your newborn.



After your baby is born...

Get caught up

After you give birth, get any immunizations you may have missed. Some shots are even given in the hospital before you leave.

Stop flu and whooping cough!

Babies can get very sick from the flu and whooping cough, but are too young to be immunized.

To protect your new baby, flu and whooping cough shots are needed for anyone who:

- lives with your baby, or
- takes care of your baby.

Prevent germs from spreading

Remind people who are around your new baby to wash their hands often and cover their mouths when they cough.

Good News!

Getting shots while you are breastfeeding is safe for you and your baby.

Protect Your Baby for Life

Hepatitis B and Your Baby

Why should pregnant women be concerned about Hepatitis B?

Hepatitis B is a contagious liver disease that can be easily passed from a pregnant woman to her baby at birth. Fortunately, there is a vaccine to prevent babies from getting Hepatitis B.

How is Hepatitis B spread?

Hepatitis B is spread when blood, semen, or other body fluids from a person with the Hepatitis B virus enter the body of someone who is not infected. The virus is very infectious and is easily spread to others. This can happen through:

- An infected mother passing it to her baby at birth
- Sex with an infected person
- Direct contact with blood from an infected person, even in tiny amounts too small to see

What is Hepatitis B?

"Hepatitis" means inflammation of the liver. Hepatitis B is a liver disease that results from infection with the Hepatitis B virus. Some people are able to fight the infection and clear the Hepatitis B virus. For others, the virus remains in their body and becomes a chronic, or lifelong, illness. Over time, Hepatitis B can cause serious health problems.

How serious is Hepatitis B?

As many as1 in 4 people with Hepatitis B develop serious liver problems including liver damage, liver failure, and even liver cancer. Every year, approximately 3,000 people in the United States die from Hepatitis B-related liver disease.

Prevent Hepatitis B.
Get your baby vaccinated.

How common is Hepatitis B?

It is estimated that 350 million people worldwide and 1.2 million people in the United States are infected with Hepatitis B. For every 1,000 pregnant women that give birth each year, 1 to 2 of them have Hepatitis B.

Are babies at risk for Hepatitis B?

Yes. When a pregnant woman has Hepatitis B it can be spread easily to her baby. Babies and young children can also get Hepatitis B from close contact with family members or others who might be infected. Infants who become infected with Hepatitis B have a 90% chance of developing a lifelong, chronic infection.

Are pregnant women tested for Hepatitis B?

Yes. Many women do not know they are infected, since people with Hepatitis B often have no symptoms. As a result, all pregnant women are given a blood test for Hepatitis B as part of their prenatal care. The test is usually performed during the first prenatal visit. If a woman has not received prenatal care, then she will be tested at the hospital before she delivers her baby.

Why are women tested for Hepatitis B?

Pregnant women are routinely tested for Hepatitis B, along with other diseases. These tests are done to find health problems that can be prevented or treated in both a woman and her baby.

Can Hepatitis B be prevented?

Yes. A vaccine for Hepatitis B has been used for about 30 years. The vaccine has been recommended for infants beginning in 1991. Since then, experts believe that the vaccine has prevented more than half a million children in the United States from getting Hepatitis B.

When does my baby get the first dose of the Hepatitis B vaccine?

CDC recommends that the first dose of vaccine be given to your baby before leaving the hospital.

How many Hepatitis B doses does my baby need?

The vaccine is given as 3 or 4 shots, depending upon the brand of vaccine used. After the first shot is given in the hospital, the next shot is usually given at 1-2 months of age. The last shot is given between 6 months and 18 months of age. Ask your doctor when your baby needs to come back for the next shot in the series.

CDC recommends that babies get the first dose of the Hepatitis B vaccine before leaving the hospital.

Why are these shots important?

Vaccines are one of the most important and effective ways to prevent diseases. Millions of babies have received Hepatitis B shots in the U.S. Experts believe that this vaccine has helped to reduce the number of children getting Hepatitis B by more than 90% over the last 20 years.

For more information

Talk to your health professional, call your health department, or visit www.cdc.gov/hepatitis.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
Division of Viral Hepatitis

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www.cdc.gov/hepatitis

October 2010

Protect Your Baby for Life

When a Pregnant Woman Has Hepatitis B

Why should pregnant women be concerned about Hepatitis B?

Hepatitis B is a serious liver disease that can be easily passed to others. It is important for a woman to find out if she has Hepatitis B, so she can get medical care. It is also possible for a pregnant woman with Hepatitis B to pass the virus to her baby at birth. Fortunately, there is a vaccine to prevent babies from getting Hepatitis B.

What is Hepatitis B?

"Hepatitis" means inflammation of the liver. Hepatitis B is a contagious liver disease that results from infection with the Hepatitis B virus. When a person becomes infected, the Hepatitis B virus can stay in the person's body for the rest of his or her life and cause serious liver problems.

Can Hepatitis B be spread to babies?

Yes. The Hepatitis B virus can be spread to a baby during childbirth. This can happen during a vaginal delivery or a c-section.

How else is Hepatitis B spread?

Hepatitis B can also be spread when blood, semen, or other bodily fluids from a person with the virus enter the body of someone who is not infected. The virus is very infectious and is passed easily through breaks in the skin or in soft tissues such as the nose, mouth, and eyes.

This can happen through direct contact with blood from an infected person, even in tiny amounts too small to see. Hepatitis B can also be spread through sex with an infected person.

CDC recommends that babies get the HBIG shot and the first dose of Hepatitis B vaccine within 12 hours of being born.

How serious is Hepatitis B?

When babies become infected with Hepatitis B, they have a 90% chance of developing a lifelong, chronic infection. As many as 1 in 4 people with chronic Hepatitis B develop serious health problems. Hepatitis B can cause liver damage, liver disease, and liver cancer.

How common is Hepatitis B?

About 350 million people worldwide and 1.2 million people in the United States are infected with Hepatitis B.

Can doctors prevent a baby from getting Hepatitis B?

Yes. Babies born to women with Hepatitis B get two shots soon after birth. One is the first dose of the Hepatitis B vaccine and the other shot is called HBIG. The two shots help prevent the baby from getting Hepatitis B. The shots work best when they are given within 12 hours after being born.

What is HBIG?

HBIG is a medicine that gives a baby's body a "boost" or extra help to fight the virus as soon as he or she is born. The HBIG shot is only given to babies of mothers who have Hepatitis B.

How can I make sure my family is protected from Hepatitis B?

Get everyone tested for Hepatitis B
Your baby's father and everyone else who lives in your house should go to the doctor or clinic to be tested. Testing your family members helps to tell if they have Hepatitis B. If they do not have Hepatitis B, the doctor will talk to them about getting the Hepatitis B vaccine to protect them from getting the infection.

Cover cuts and sores
Since Hepatitis B is spread through blood, people with Hepatitis B should be careful not to expose other people to things that could have their blood on them. It is important not to share personal items such as razors, nail clippers, toothbrushes, or glucose monitors. Cuts and sores should be covered while they are healing.

Do not chew food for your baby
Tiny amounts of blood can sometimes be in a person's mouth. Do not pre-chew food before you feed it to your baby.

How many Hepatitis B shots does my baby need?

Your baby will get 3 or 4 shots, depending on which brand of vaccine is used. After the first dose is given in the hospital, the next dose is given at 1-2 months of age. The last dose is usually given by the time your baby is one year old. Ask your doctor or nurse when your baby needs to come back for each shot.

Does my baby need all the shots?

All the Hepatitis B shots are necessary to help keep your baby from getting Hepatitis B.

Prevent Hepatitis B.
Get your baby vaccinated.

How do I know my baby is protected?

After getting all the Hepatitis B shots, your doctor will test your baby's blood. The blood test tells you and your doctor that your baby is protected and does not have Hepatitis B. The blood test is usually done 1-2 months after the last shot. Be sure to bring your baby back to your doctor for this important blood test.

Hepatitis B is not spread by:

Breastfeeding
It is safe for you to breastfeed your baby. You cannot give your baby Hepatitis B from breast milk.

Cooking and eating
It is safe for you to prepare and eat meals with your family. Hepatitis B is not spread by sharing dishes, cooking or eating utensils, or drinking glasses.

Hugging and kissing
You can hug and kiss your baby, family members, or others close to you. You cannot give anyone Hepatitis B from hugging and kissing them. Also, Hepatitis B is not spread through sneezing or coughing.

For more information

Talk to your health professional, call your health department, or visit www.cdc.gov/hepatitis

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
Division of Viral Hepatitis

CDC
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www.cdc.gov/hepatitis

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IMMUNIZATION & Pregnancy

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Vaccines help keep a pregnant woman and her growing family healthy.

Before pregnancy

Before becoming pregnant, a woman should be up-to-date on routine adult vaccines. This will help protect her and her child. Live vaccines should be given a month or more before pregnancy. Inactivated vaccines can be given before or during pregnancy, if needed.

During pregnancy

Did you know that a mother's immunity is passed along to her baby during pregnancy? This will protect the baby from some diseases during the first few months of life until the baby can get vaccinated.

Flu Vaccine

It is safe, and very important, for a pregnant woman to receive the inactivated flu vaccine. A pregnant woman who gets the flu is at risk for serious complications and hospitalization. To learn more about preventing preventing the flu, visit the CDC website **http://www.cdc.gov/flu**.

Travel

Many vaccine-preventable diseases, rarely seen in the United States, are still common in other parts of the world. A pregnant woman planning international travel should talk to her health professional about vaccines. Information about travel vaccines can be found at CDC's traveler's health health website at **http://wwwnc.cdc.gov/travel/**

Childhood Vaccines

Pregnancy is a good time to learn about childhood vaccines. Parents-to-be can learn more about childhood vaccines from the CDC parents guide at **http://www.cdc.gov/vaccines/pubs/flyers-brochures.htm**. Also, the child and adolescent vaccination schedule can be downloaded and printed at **http://www.cdc.gov/vaccines/spec-grps/default.htm**.

After pregnancy

It is safe for a woman to receive vaccines right after giving birth, even while she is breastfeeding. A woman who has not received the new vaccine for the prevention of tetanus, diphtheria and pertussis (Tdap) should be vaccinated right after delivery. Vaccinating a new mother against pertussis (whooping cough) reduces the risk to her infant too. Guidelines can be found at **http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5704a1.htm?s_cid=rr5704a1_e**. Also, a woman who is not immune to measles, mumps and rubella and/or varicella (chicken pox) should be vaccinated before leaving the hospital. If inactivated influenza vaccine was not given during pregnancy, a woman should receive it now because it will protect her infant. LAIV may be an option.

Visit CDC's website at http://www.cdc.gov for more information. Or get an answer to your specific question by e-mailing cdcinfo@cdc.gov or calling 800-CDC-INFO (232-4636) · 24/7 · English or Spanish

CS124445 01/20/09

Immunization Coding

for Obstetrician–Gynecologists 2011

THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS
Women's Health Care Physicians

All diagnosis codes referred to in *Immunization Coding for Obstetrician–Gynecologists* were excerpted from the *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM), October 2009 Revision, published by the United States Government under the auspices of the ICD-9-CM Coordination and Maintenance Committee.

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Suggestions and comments are welcome. Address your comments to the following:

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Contents

Introduction

Immunization is coming to the forefront for obstetric–gynecologic practices. Therefore, the American College of Obstetricians and Gynecologists (the College) and its Working Group on Immunization recognized a need for a coding guide solely focused on immunization. Correct coding enables a physician's office immunization program to be profitable and to satisfy payer scrutiny. Codes condense a large amount of information into a short code description. Proper coding means being sure that the code selected is appropriate as follows:

- The code represents the most accurate description of "what" was performed and "why" it was performed consistent with coding conventions and guidelines
- The code is supported by documentation in the medical record

The *Current Procedural Terminology* (CPT) coding guidelines state that the code selected must be the most accurate description of the service provided and be consistent with coding conventions and guidelines. Individuals responsible for coding should carefully review their coding books, including any coding guidelines, notes, instructions, or other explanatory statements. These may be printed under subsections, headings, subheadings, or before and after codes. The physician also should know the bundling and unbundling rules used by CPT, commercial payers, and Centers for Medicare & Medicaid Services.

Reimbursement for Vaccinations

Physicians should strive to make their vaccination services at least marginally profitable. In order to accomplish this, a clinical practice must investigate whether their third-party payers cover these services, and if so, whether the payment is allowed for vaccine drugs and administration. The practice then can determine if the services are profitable.

Medicare

Medicare Part B currently covers preventive vaccine costs for three conditions:

1. Influenza (once per influenza season). Use CPT codes 90656, 90658, or 90660. They may be linked to diagnosis code V04.81. Payment is 100% of the Medicare allowable reimbursement.
2. Pneumococcal polysaccharide (once per lifetime). Use CPT codes 90669 or 90732 linked to diagnosis code V03.82. Payment is 100% of the Medicare allowable reimbursement.
3. Hepatitis B (for those in medium-risk to high-risk categories). Use CPT codes 90740–90747 linked to diagnosis code V05.3. The Part B deductible and 80% coinsurance apply.

Medicare typically pays for only one flu vaccination per year. If more than one vaccination is medically necessary (eg, multiple doses are required), then Medicare will pay for those additional vaccinations. If Medicare beneficiaries need to receive both a seasonal flu and an H1N1 vaccination, then Medicare will pay for both. If the vaccine is provided free to the health care provider, Medicare will reimburse only for the administration costs. If a patient receives both the influenza shot and a pneumococcal pneumonia virus vaccine during the same visit, use diagnosis code V06.6.

The pneumococcal vaccine is paid once per patient in most cases. However, Medicare will reimburse for revaccination if the patient is considered to be at the highest level of risk of a serious pneumococcal infection and for patients likely to have a rapid decrease in pneumococcal antibody levels. At least 5 years must have passed since the most recent dose of this vaccine.

Hepatitis B vaccinations are reimbursed only for Medicare beneficiaries considered to be at highest risk and those most likely to have rapid decreases in antibody levels. Medicare defines highest risk as patients with functional or anatomic asplenia, human immunodeficiency virus (HIV) infection, leukemia, lymphoma, Hodgkin disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression.

Medicare Part B does not cover other immunizations unless they are directly related to the treatment of an injury or direct exposure to a disease or condition (eg, tetanus or exposure to rabies). *The International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnosis code attached to the vaccine must define the disease or condition.

The prescription drug plan Medicare Part D, however, does cover other preventive vaccines. If the patient has Medicare Part D coverage, it is likely that they have preventive coverage for most vaccines. Travel vaccine coverage will depend on the Part D plan. In states that license pharmacists to provide vaccines, physicians can ask the patient to purchase the covered vaccine at the pharmacy and bring it into the office for administration. Alternatively, the physician can supply the vaccine, administer it in the office and ask the patient for full payment at the time of the service. The patient can then be given a claim form to submit to her Part D plan for reimbursement of her costs.

Medicaid

Medicaid reimburses for routine immunizations for covered individuals up to 21 years of age. For individuals younger than 21 years, there are two different programs that provide these services.

Patients 19–20 years old receive routine immunizations as part of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program. Physicians can bill Medicaid for the vaccines and the administration as a fee-for-service. This public program for low-income and medically indigent individuals is administered on a state-by-state basis. Thus, the extent of immunization coverage for adults varies state by state.

Patients 18 years or younger receive vaccinations through the state's Vaccines for Children (VFC) Program. This program is described in the next section.

Vaccines for Children Program

When the Centers for Disease Control and Prevention (CDC) investigated the U.S. measles

epidemic of 1989–1991, it found that more than one half of the children who had measles had not been immunized, even though many had seen a health care provider. In response, Congress created the VFC Program in 1993.

The VFC Program provides free vaccines to doctors who serve eligible children. It is administered at the national level by the CDC through the National Immunization Program. The CDC contracts with vaccine manufacturers to buy vaccines at reduced rates. Eligible children are those who meet the following criteria:

- Are eligible for Medicaid
- Are 18 years or younger
- Have no health insurance
- Are Native American or Alaskan Native
- Have health insurance but no immunization coverage. In these cases, these children must go to a Federally Qualified Health Center or Rural Health Clinic to receive their immunizations.

Vaccinations are provided for these diseases:

- Diphtheria
- Haemophilus influenza type b
- Hepatitis A
- Hepatitis B
- Human papillomavirus
- Influenza
- Measles
- Meningococcal disease
- Mumps
- Pertussis (whooping cough)
- Pneumococcal disease
- Polio
- Rotavirus
- Rubella
- Tetanus
- Varicella

Any physician or physician practice can become a VFC provider. First, contact your State and/or Territory VFC Program Coordinator. A Provider Enrollment Package will be mailed to you. After submission of this packet, your office will have a site visit. During this visit, a representative from the program will review the administrative requirements of the program and the proper storage and handling of vaccines with physicians and staff.

Because VFC vaccines are provided free of charge to the practice, your office cannot charge the patient for the vaccine product. However, you may charge an administrative fee to offset your costs of doing business. Each state sets a maximum fee that physicians can charge for administering a VFC vaccine. If the patient has no health insurance, a VFC provider cannot refuse to administer a recommended vaccine because a patient is unable to pay the administration fee. However, the health care provider can accept whatever the patient can afford to pay. The administration fee for Medicaid patients is billed to the Medicaid plan. For more information on the VFC program, visit the CDC web site: http://www.cdc.gov/vaccines/programs/vfc/default.htm.

Commercial Plans

Patients are enrolled in a variety of private or employer provided commercial health insurance programs. Coverage for immunizations will vary from plan to plan. Some plans may offer no coverage for preventive medicine services. For patients covered by these plans, it is important to inform them that they will have to bear the costs of immunizations "out-of-pocket." For patients who have coverage, it is very important to track payments to verify that the reimbursement received covers the cost of the vaccine product and other associated costs. Clinical practices must contact their patients' insurance plans to verify coverage for preventive and medically indicated vaccines and their administration.

Third-party payers may or may not reimburse for vaccinations provided at the time of a covered evaluation and management (E/M) service. Some third-party payers will disallow the vaccine administration codes at the time of an E/M service unless the E/M service is documented as separate and significant. (See section on "Coding Examples" for additional information on when it is appropriate to bill an E/M service with vaccine administration).

The Initial Reproductive Health Visit

The American College of Obstetricians and Gynecologists recommends that a girl's first visit to the obstetrician–gynecologist take place between the

ages of 13 years and 15 years. This visit is designed to provide health guidance, appropriate screening, and preventive health services. It is an excellent opportunity to discuss on-going immunization status as well as the new recommendations for the human papillomavirus vaccine, tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap), and meningococcal vaccine. The CPT code 99384 is used for a preventive visit for a new patient, aged 12–17 years. The CPT code 99394 is used for a preventive visit for an established patient in the same age range.

It may be appropriate to offer and administer indicated vaccines during these initial reproductive health visits. If these services are performed, the physician should also code for the appropriate vaccine administration code(s) and the appropriate vaccine product code(s) as well as the preventive service.

Coding for Vaccinations*

ICD-9-CM Diagnosis Codes for Vaccination Services

Diagnosis codes for vaccinations usually are from the V code category (Supplementary Classification of Factors Influencing Health Status and Contact with Health Services) of ICD-9-CM. If a patient is being seen for a specific disease or symptom, report both the code for the disease or symptom and a code for the vaccination.

Diagnosis codes used for vaccinations are categorized as follows:

- Persons with potential health hazards related to communicable diseases, including patients who have been exposed to or had contact with someone with a communicable disease
- Persons with need for isolation, other potential health hazards and prophylactic measures, including prophylactic administration of vaccines
- Persons encountering health services in other circumstances, including encounters during which a planned vaccination was not carried out

The diagnosis codes most likely to be reported when vaccinations are administered are listed as follows.

Persons with Potential Health Hazards Related to Communicable Diseases

Excludes: family history of infectious and parasitic diseases (V18.8)

personal history of infectious and parasitic diseases (V12.0)

V01 Contact with or exposure to communicable diseases

- V01.1 Tuberculosis
  Conditions classifiable to 010–018
- V01.4 Rubella
  Conditions classifiable to 056
- V01.5 Rabies
  Conditions classifiable to 071
- V01.7 Other viral diseases
  Conditions classifiable to 042–078, and V08, except as above
  - V01.71 Varicella
  - V01.79 Other viral diseases
- V01.8 Other communicable diseases
  Conditions classifiable to 001–136, except as above
  - V01.84 Meningococcus
- V01.9 Unspecified communicable diseases

V03 Need for prophylactic vaccination and inoculation against bacterial diseases

Excludes: vaccination not carried out (V64.00–V64.09)

vaccines against combinations of diseases (V06.0–V06.9)

- V03.2 Tuberculosis [BCG]
- V03.7 Tetanus toxoid alone
- V03.8 Other specified vaccinations against single bacterial diseases
  - V03.81 Hemophilus influenza, type B [Hib]
  - V03.82 Streptococcus pneumoniae [pneumococcus]
  - V03.89 Other specified vaccination
  - V03.9 Unspecified single bacterial disease

*Note: Obstetrician–gynecologists and their staff should always use the term "coding" in preference to "reimbursement" regarding services rendered. Coding is the action undertaken to secure reimbursement. The intent is to report the services provided using the correct codes; the appropriate reimbursement will follow. If the claim is inappropriately denied, the physician has support for his or her appeal when correct codes were reported.

V04 Need for prophylactic vaccination and inoculation against certain viral diseases

Excludes: vaccines against combinations of diseases (V06.0–V06.9)

V04.0 Poliomyelitis

V04.2 Measles alone

V04.3 Rubella alone

V04.5 Rabies

V04.6 Mumps alone

V04.7 Common cold

V04.8 Other viral diseases

V04.81 Influenza (includes H1N1)

V04.82 Respiratory syncytial virus (RSV)

V04.89 Other viral diseases

V05 Need for other prophylactic vaccination and inoculation against single diseases

Excludes: vaccines against combinations of diseases (V06.0–V06.9)

V05.3 Viral hepatitis

V05.4 Varicella

Chicken pox

V05.8 Other specified disease

V05.9 Unspecified single disease

V06 Need for prophylactic vaccination and inoculation against combinations of diseases

Note: Use additional single vaccination codes from categories V03–V05 to identify any vaccinations not included in a combination code.

V06.1 Diphtheria-tetanus-pertussis, combined [DTP] [DTaP]

V06.3 Diphtheria-tetanus-pertussis with poliomyelitis [DTP + polio]

V06.4 Measles-mumps-rubella [MMR]

V06.5 Tetanus-diphtheria [Td] [DT]

V06.6 Streptococcus pneumoniae [pneumococcus] and influenza

V06.8 Other combinations

Excludes: multiple single vaccination codes (V03.0–V05.9)

Persons with Need for Isolation, Other Potential Health Hazards and Prophylactic Measures

V07 Need for isolation and other prophylactic measures

Excludes: prophylactic organ removal (V50.41–V50.49)

V07.2 Prophylactic immunotherapy

Administration of:

immune sera [gamma globulin]

RhoGAM

Persons Encountering Health Services in Other Circumstances

V64 Persons encountering health services for specific procedures, not carried out

V64.0 Vaccination not carried out

V64.00 Vaccination not carried out, unspecified reason

V64.01 Vaccination not carried out because of acute illness

V64.02 Vaccination not carried out because of chronic illness or condition

V64.03 Vaccination not carried out because of immune compromised state

V64.04 Vaccination not carried out because of allergy to vaccine or component

V64.05 Vaccination not carried out because of caregiver refusal

Guardian refusal

Parent refusal

V64.06 Vaccination not carried out because of patient refusal

V64.07 Vaccination not carried out for religious reasons

V64.08 Vaccination not carried out because patient had disease being vaccinated against

V64.09 Vaccination not carried out for other reason

CPT and Medicare Coding for Vaccinations

Vaccination Procedures

A vaccination procedure has two components: 1) the administration of the vaccine and 2) the vaccine (drug) itself. The administration may be performed by either the physician or qualified nonphysician provider. When both the vaccine drug and the administration are provided by the physician office, report a code for the vaccine and a code for administration of the vaccine.

Table 1. CPT Codes for Vaccine Administration (Single or Combination Vaccine/Toxoid)

Code	Method	Route of Administration	Type of Service	Reporting Rules
90465	Injection	Percutaneous, intradermal, subcutaneous, or intramuscular	Primary	Report only one primary vaccine administration per day. Report for administration of first vaccine if more than one was provided. Physician also provides counseling. Patient is younger than 8 years.
+90466	Injection	Percutaneous, intradermal, subcutaneous, or intramuscular	Additional	Report for secondary or subsequent vaccine administration per day. Physician also provides counseling. Patient is younger than 8 years. Report only with code 90465 or code 90467.
90467	Intranasal or oral	Intranasal or oral	Primary	Report only one primary vaccine administration per day. Report for administration of first vaccine if more than one was provided. Physician also provides counseling. Patient is younger than 8 years.
+90468	Intranasal or oral	Intranasal or oral	Additional	Report for secondary or subsequent vaccine administration. Physician also provides counseling. Patient is younger than 8 years. Report only with code 90465 or code 90467.
90471	Injection	Percutaneous, intradermal, subcutaneous, or intramuscular	Primary	Report only one primary vaccine administration per encounter. Physician also provides counseling.
+90472	Injection	Percutaneous, intradermal, subcutaneous, or intramuscular	Additional	Report for secondary or subsequent vaccine administration. Physician also provides counseling. Report only with code 90471 or code 90473.
90473	Intranasal	Intranasal or oral	Primary or oral	Report only one primary vaccine administration per encounter. Physician also provides counseling.
+90474	Intranasal or oral	Intranasal or oral	Additional	Report for secondary or subsequent vaccine administration. Physician also provides counseling. Report only with code 90471 or code 90473.

Codes for Administration of the Vaccine

The administration codes specify the method and route of administration (see Table 1 for CPT codes). Medicare and CPT both use the same set of codes to report administration of most vaccines.

Medicare requires special Healthcare Common Procedure Coding System (HCPCS) codes for the administration of influenza, pneumoccocal, or hepatitis B vaccines (see Table 2). Note that some commercial carriers also accept these HCPCS codes. A summary of these codes follows.

G codes are temporary codes used to identify professional health care services that would be reported using a CPT code if one existed or to provide more information. Report the G code for administration and the applicable CPT code for the vaccine.

Table 2. Medicare's HCPCS Codes for Vaccine Administration

Code	Vaccine	Specific Method	Type of Service
G0008	Influenza	Injection	Primary
G0009	Pneumoccocal	Injection	Primary
G0010	Hepatitis B	Injection	Primary

There are no specific HCPCS codes for administration of other vaccines. In these cases, Medicare accepts the appropriate CPT code for the vaccine administration.

Codes for the Vaccine Drug Product

Both CPT and Medicare use CPT codes 90476–90749 to report the vaccine drugs (see Table 3, Table 4, and Table 5). Beginning in 2006, CPT has included symbol ✓ in front of a code number to indicate

Table 3. Vaccines Commonly Administered to Adolescents and Adults

(Report Both an Administration Code and a Vaccine Code)

Vaccine	Code for Vaccine Product	Administration Codes	
		CPT	Medicare
Hepatitis A, adult, IM	90632	90471–90472	90471–90472
Hepatitis A, adolescent, 2-dose schedule, IM	90633	90471–90472	90471–90472
Hepatitis B, adolescent, 2-dose schedule, IM	90743	90471–90472	G0010
Hepatitis B, pediatric/adolescent, 3-dose schedule, IM	90744	90471–90472	G0010
Hepatitis B, adult, IM	90746	90471–90472	G0010
Hepatitis B, dialysis or immunosuppressed patient, 3-dose schedule, IM	90740	90471–90472	G0010
Hepatitis B, dialysis or immunosuppressed patient, 4-dose schedule, IM	90747	90471–90472	G0010
HepA-HepB, adult, IM	90636	90471–90472	90471–90472
HPV virus, types 6, 11, 16, 18 (quadrivalent), 3-dose schedule, IM	90649	90471–90472	90471–90472
HPV virus types 16, 18 (bivalent), 3-dose schedule, IM	90650	90471–90472	90471–90472
Influenza virus, split, preservative free, patient 3 years of age and older, IM	90656	90471–90472	G0008
Influenza virus, split, patient 3 years of age and older, IM	90658	90471–90472	G0008
Influenza virus, live, intranasal	90660	90473–90474	G0008
Meningococcal polysaccharide, sub	90733	90471–90472	90471–90472
Meningococcal conjugate, serogroups A,C,Y and W-135 (tetravalent), IM	90734	90471–90472	90471–90472
Pneumococcal polysaccharide, 23-valent, patient 2 years of age or older, sub or IM	90732	90471–90472	G0009
Tetanus toxoid adsorbed, IM	90703	90471–90472	90471–90472
Tetanus and diphtheria toxoids (Td) adsorbed, preservative free, patient 7 years of age or older, IM	90714	90471–90472	90471–90472
Tetanus and diphtheria toxoids (Td) adsorbed, patient 7 years of age or older, IM	90718	90471–90472	90471–90472
Tetanus, diphtheria toxoids and acellular pertussis (Tdap), patient 7 years of age or older, IM	90715	90471–90472	90471–90472
Zoster (shingles), live, sub injection	90736	90471–90472	90471–90472

Abbreviation: HPV, human papillomavirus; IM, intramuscular; sub, subcutaneous.
*Medicare code for vaccine product: G9142

that this vaccine was not approved by the U.S. Food and Drug Administration (FDA) at the time the CPT book was published. Once the vaccine has FDA approval, the code is considered active. The changes in vaccine status are posted at www.ama-assn.org/ama/pub/category/10902.html.

Table 3, Table 4, and Table 5 summarize coding for vaccines and their administration under both CPT and Medicare rules, assuming that you are not immunizing patients who are younger than 8 years. If you are immunizing patients younger than 8 years and providing physician counseling, then you

Table 4. Vaccines Commonly Administered to Children

(Report Both an Administration Code and a Vaccine Code)

Vaccine	Code for Vaccine Product	Administration Codes (CPT and Medicare)
Diphtheria, tetanus toxoids, acellular pertussis, and haemophilus influenza B (DtaP-Hib), IM	90721	90471–90472
Diphtheria, tetanus toxoids, acellular pertussis, haemophilus influenza Type B and poliovirus, inactivated (DTaP-Hib-IPV), IM	90698	90471–90472
Diphtheria, tetanus toxoids, acellular pertussis, hepatitis B, and poliovirus, inactivated (DtaP-HepB-IPV), IM	90723	90471–90472
Diphtheria, tetanus toxoids, and acelluar pertussis (DTaP), patient younger than 7 years, IM	90700	90471–90472
Diphtheria and tetanus toxoids (DT), patient younger than 7 years, IM	90702	90471–90472
Hepatitis B and haemophilus influenza B, (HepB-Hib), IM	90748	90471–90472
Haemophilus influenza B, PRP-OMP conjugate, (Hib), 3-dose schedule, IM	90647	90471–90472
Haemophilus influenza B, PRP-T conjugate, (Hib), 4-dose schedule, IM	90648	90471–90472
Influenza virus, split, preservative free, patient 6–35 months of age, IM	90655	90471–90472
Influenza virus, split, patient 6–35 months of age, IM	90657	90471–90472
Measles, mumps and rubella virus (MMR), live, sub	90707	90471–90472
Measles, mumps, rubella and varicella (MMRV), live, sub	90710	90471–90472
Pneumococcal conjugate, polyvalent, patient younger than 5 years, IM	90669	90471–90472
Poliovirus, inactivate (IPV), sub or IM	90713	90471–90472
Rotavirus, pentavalent, live, 3-dose schedule, oral	90680	90473–90474
Varicella virus, live, sub	90716	90471–90472

Abbreviation: IM, intramuscular; sub, subcutaneous.

Table 5. Vaccines Commonly Administered for Travel

(Report Both An Administration Code and a Vaccine Code)

Vaccine	Code for Vaccine Product	Administration Codes (CPT and Medicare)
Japanese encephalitis, sub	90735	90471–90472
Rabies, IM	90675	90471–90472
Typhoid, live, oral	90690	N/A
Typhoid, Vi capsular polysaccharide, IM	90691	90471–90472
Yellow fever, sub	90717	90471–90472

Abbreviation: IM, intramuscular; sub, subcutaneous.

would use codes 90465 and 90466 instead of codes 90471 and 90472 for injectable vaccines and codes 90467 and 90468 instead of codes 90473 and 90474 for intranasal or oral vaccines.

Administration codes:

90471 Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); one vaccine (single or combination vaccine/toxoid)

+90472 Each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure.)

90473 Immunization administration by intranasal or oral route; one vaccine (single or combination vaccine/toxoid)

+90474 Each additional vaccine (single or combination vaccine/toxoid) (List separately in addition to code for primary procedure.)

Coding Examples

Case 1

A 72-year-old woman comes in for her annual check-up. She also requests a flu vaccine. The patient has Medicare. The appropriate physical examination is performed and a Pap smear specimen is collected.

Comment:

Medicare allows coverage for a pelvic examination every 2 years; for certain high-risk patients, it is covered annually. Collection of a Pap specimen is also a reimbursable service at the time of these encounters. Other services (eg, vaccines) also may be performed during these encounters and should be coded and billed separately. Medicare requires specific HCPCS codes for these services. The appropriate procedure codes and ICD-9-CM linkages are listed as follows.

G0101 Medicare pelvic exam
V72.31 Routine gyn exam

Q0091 Collection of Pap smear
V72.31 Routine gyn exam

90658 Influenza vaccine (product), IM use
V04.81 Need for prophylactic vaccination—influenza

G0008 Influenza vaccine administration
V04.81 Need for prophylactic vaccination—influenza

Case 2

A 12-year-old new patient is brought to your office by her mother. The patient and her mother want to talk about a variety of topics, including reproductive health, birth control options, and vaccinations. The patient is not sexually active and declines a pelvic examination and collection of a Pap smear specimen. The appropriate history is obtained. A physical examination limited to the head, chest, abdomen, and extremities is performed. Questions are answered and the appropriate counseling is given. The physician then administers an influenza vaccine, a Tdap vaccine, and the first of the series of three HPV vaccines.

Comment:

This is an example of the initial reproductive health visit recommended by the College. This encounter should be coded using the preventive medicine codes. The comprehensive nature of preventive medicine codes reflects an age and gender appropriate history and/or examination and is not synonymous with the comprehensive examination required in other E/M codes. There are no CPT guidelines stating what is included in a preventive visit; it will vary with the needs of each patient. In

this case, a pelvic and breast examination were not necessary. Nevertheless, this encounter is reported as a preventive visit. Other services may be provided at the time of these encounters and should be coded and billed separately. The appropriate procedure codes and ICD-9-CM linkages are listed as follows.

99384 Initial comprehensive preventive medicine adolescent (12–17 years)
V70.0 Routine general medical examination

90649 HPV vaccine (quadrivalent) (drug), IM
or
90650 HPV virus (bivalent) (drug) IM
V04.89 Need for prophylactic vaccination—other viral illnesses

90471 Vaccine administration
V04.89 Need for prophylactic vaccination—other viral illnesses

90658 Influenza vaccine (drug), IM
V04.81 Need for prophylactic vaccination—influenza

+90472 Vaccine administration—additional vaccine
V04.81 Need for prophylactic vaccination—influenza

90715 Tdap vaccine (drug), IM
V06.1 Need for prophylactic vaccination—Tdap

+90472 Vaccine administration—additional vaccine
V06.1 Need for prophylactic vaccination—Tdap

NOTE: Some third-party payers deny payment for the vaccine administration codes (90471, +90472) provided on the same day as an E/M service. It is important to track and appeal such denials because they are in conflict with CPT coding guidelines and standard payment conventions.

Case 3

A 34-year-old established patient requests assistance in obtaining her hepatitis B vaccine. Her insurance plan requires her to obtain her vaccine product from her local pharmacy. She brings the appropriately stored vaccine to the office. The office nurse sees the patient, checks her blood pressure, obtains appropriate informed consent documents, and administers the hepatitis B vaccine.

Comment:

This example describes a situation where the only service provided in the office is the vaccine administration. The services provided by the nurse are integral to the vaccine administration code. A separate E/M service was not provided in this situation. Because the patient brought the vaccine product with her, it is not appropriate to bill for the vaccine product. The appropriate procedure code and ICD-9-CM linkage is listed as follows.

90471 Vaccine administration
V05.3 Need for prophylactic vaccination—viral hepatitis

Case 4

A 21-year-old established patient comes in for her wellness examination. She has questions about the HPV vaccine. In addition to the usual age appropriate history, counseling, comprehensive physical examination, and Pap test, the patient is given information regarding the requested vaccine. Her questions are answered and she requests that the first of the series of three vaccinations be given.

Comment:

This example illustrates the additional counseling that will be necessary as new vaccinations become available. The additional work involved with this counseling is integral to the preventive medicine visit and not reported separately. The appropriate procedure codes and ICD-9-CM linkages are listed as follows.

99395 Periodic comprehensive preventive medicine 18–39 years
V72.31 Gyn exam with Pap

90649 HPV vaccine (quadrivalent) (drug)
or
90650 HPV virus (bivalent) (drug), IM
V04.89 Need for prophylactic vaccination—viral disease

90471 Vaccine administration
V04.89 Need for prophylactic vaccination—viral disease

Case 5

The 21-year-old established patient mentioned in Case 4 returns to the clinic in 1 month for the second of her series of three HPV vaccines. She also

reports dysuria. The office nurse checks her blood pressure, completes the appropriate vaccine informed consent documents, and orders a urinalysis. The urinalysis result is normal. The nurse administers the HPV vaccine, documents the encounter in the medical record, and asks the patient to make a follow-up appointment with her physician to further assess her report of dysuria.

Comment:

This example illustrates an encounter where the nurse provides a separate E/M service distinct from the vaccine administration service. Some vaccines require a multidose regimen. It is appropriate to use the same vaccine product code for each of the three injections. The appropriate procedure codes and ICD-9-CM linkages are listed as follows. Modifier 25 is appended to the E/M encounter to signify the distinct and separate service.

99211–25	Office outpatient visit (nursing encounter)
788.1	Dysuria
81000	Urinalysis
788.1	Dysuria
90649	HPV vaccine (quadrivalent) (drug)
or	
90650	HPV virus (bivalent) (drug), IM
V04.89	Need for prophylactic vaccination—other viral illnesses
90471	Vaccine administration
V04.89	Need for prophylactic vaccination—other viral illnesses

Case 6

A 28-year-old new patient presents with severe dysmenorrhea. She also requests an influenza vaccine. A detailed history is taken and a detailed physical examination is performed. The medical decision making is of low complexity. The patient is given information regarding the influenza vaccine and the vaccine is administered by the office nurse.

Comment:

Many times patients will request vaccine services at the time of a problem-oriented visit. It is appropriate to code and bill for the vaccine administration and vaccine product as well as a code for the E/M service. If counseling is extensive and accounts for more than 50% of the total time spent with the patient, it may be appropriate to code based on time rather than the usual key components of history, physical examination, and medical decision making.

99203–25	Office outpatient visit-new patient
625.3	Dysmenorrhea
90658	Influenza vaccine (drug), IM
V04.81	Need for prophylactic vaccination—influenza
90471	Vaccine administration
V04.81	Need for prophylactic vaccination—influenza

Case 7

A 25-year-old nulligravid patient is receiving prenatal care in the office. At 12 weeks of gestation, she requests an influenza vaccination.

Comment:

Pregnant patients will request, and in some instances require, vaccinations during their pregnancies. Vaccination services performed during pregnancy should be billed separately at the time of the service. You might also add a secondary ICD-9-CM code to indicate any condition that makes the patient high risk for influenza. This will facilitate payment from plans that only cover vaccinations for patients identified as "high-risk patients." A separate E/M service should not be reported because the office visit is part of the global obstetric package.

90656	Preservative-free influenza vaccine (drug), IM
V04.81	Need for prophylactic vaccination—influenza
V22.2	Pregnancy (single) (uterine) (without sickness)
90471	Vaccine administration
V04.81	Need for prophylactic vaccination—influenza
V22.2	Pregnancy (single) (uterine) (without sickness)

Case 8

The patient referenced in Case 7 is now at 28 weeks of gestation. She is Rh negative and is administered antenatal Rh immune globulin.

Comment:

It is appropriate to code and bill for the Rh immune globulin administration outside the global obstetric

package. Some payers may require the use of special HCPCS codes ("J" codes) to identify the Rh immune globulin product. Also, note that the CPT codes for administration of immune globulins are different than those used for administration of vaccines.

90384 or J2790	Rho(D) immune globulin (RhIg), full dose (drug), IM
V07.2	Prophylactic administration of RhoGAM
96372	Immune globulin administration, subcutaneous or IM
V07.2	Prophylactic administration of RhoGAM

Case 9

The patient referenced in Case 7 and Case 8 is now 6 weeks postpartum. On her antenatal screening, her Rubella titer was negative. She is given a measles, mumps, and rubella vaccination. It also is noted that the patient has not received a pertussis immunization. The Advisory Committee on Immunization Practices recommends that individuals in close contact with infants should receive a pertussis immunization to prevent the spread of pertussis to the infant. The patient is given a Tdap vaccine.

Comment:

The postpartum visit will, often times, require vaccination services. Again, these services should be coded and billed outside the global obstetric package. A separate E/M service should not be reported because the 6-week postpartum visit is part of the global obstetric package.

90707	MMR vaccine (drug), subcutaneous
V06.4	Need for prophylactic vaccination—MMR
90471	Vaccine administration
V06.4	Need for prophylactic vaccination—MMR
90715	Tdap vaccine (drug), IM
V06.1	Need for prophylactic vaccination—Tdap
+90472	Vaccine administration—additional vaccine
V06.1	Need for prophylactic vaccination—Tdap

Coding Resources

Most ob-gyns will have the most current edition of *The Essential Guide to Coding in Obstetrics and Gynecology* in their offices. They may also be familiar with these coding tools:

- *Healthcare Common Procedure Coding System* (HCPCS)—a coding system established in 1978 as a way to standardize identification of medical services, supplies, and equipment. There are two sets of codes. The first, or Level I of the HCPCS comprises *Current Procedural Terminology* (CPT), a numeric coding system maintained by the American Medical Association (AMA). The second, or Level II, is a code set for medical services not included in Level I, such as durable medical equipment, prosthetics, orthotics, and supplies.

- American Medical Association's *Current Procedural Terminology* (CPT)—the most widely accepted medical nomenclature used to report medical procedures and services under public and private health insurance programs. It was developed by the American Medical Association in 1966. Each year, an annual publication is prepared that makes changes corresponding with significant updates in medical technology and practice.

- *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM)—is based on the World Health Organization's Ninth Revision, International Classification of Diseases (ICD-9). ICD-9-CM is the official system of assigning codes to diagnoses and procedures associated with hospital utilization in the United States. The ICD-9 is used to code and classify mortality data from death certificates.

A number of resources have been developed to assist physicians with selecting the correct codes and interacting with third-party payers. In addition to these publications, coding workshops, coding webcasts, and a web site for questions and information is provided at www.acog.org. Publications listed as follows can be ordered through the Publications and Educational Materials catalog, online at acog.org/bookstore, or from the distribution center (1-800-762-2264).

- *ICD-9-CM Abridged, Diagnostic Coding in Obstetrics and Gynecology*—this book provides all the ICD-9-CM diagnosis codes most commonly reported by obstetrician–gynecologists in the same format as the complete ICD-9-CM book. This version also includes guides to assist with diagnostic reporting of pregnancy termination, follow-up visits for Pap tests, and obstetric ultrasound examinations. This book is revised annually.

- *Ob/Gyn Coding Manual: Components of Correct Procedural Coding* with CD-ROM—this 400+ page book provides important information to assist physicians in correct coding for surgical procedures commonly performed by obstetrician–gynecologists. Each code is listed with services that are part of the procedure's global surgical package, information about whether Medicare will reimburse for an assistant or co-surgeons for the procedure, and other coding hints. In addition, it includes information about the included and/or excluded services according to both Medicare's Correct Coding Initiative and ACOG's Committee on Coding to note when these opinions differ. This information may be useful in preparing appeals to third-party payers, made simpler with the included CD. Also included are sections on reproductive medicine, modifiers, relative value units, and bundling issues. This book and CD are revised annually.

- *Frequently Asked Questions in Obstetric and Gynecologic Coding*—this book includes more than 100 often asked coding questions received from ACOG Fellows throughout the past few years. ACOG's Committee on Coding and Nomenclature developed the answers. Subjects include gynecologic surgery, emergency medicine services, laboratory services, modifiers, infertility, laparoscopy and hysteroscopy, Medicare, obstetrics, and ultrasound examinations. Revised every odd year.

- *The Essential Guide to Coding in Obstetrics and Gynecology*—this publication includes information from ACOG's coding workshop syllabus and other ACOG coding resources not in workbook format. The book covers coding diagnoses and procedures, E/M Services, gynecologic surgery, obstetric services, ultrasound procedures, infusions, injections, immunizations, vaccinations, services to Medicare patients, and preventive care. Other chapters discuss use of modifiers and dealing with third-party payers. Revised every even year.

- *Procedural Coding in Obstetrics and Gynecology*—this booklet provides an introduction to the basics of CPT, Fourth Edition, procedure coding and to the new codes for the current year. In addition, chapters are devoted to ultrasound examinations and clarifying the sometimes confusing issue of modifiers. Revised every odd year.

Summary of Maternal Immunization Recommendations

Resources for health care professionals

Vaccines help keep your pregnant patients and their growing families healthy.

Last Updated December 2018

Vaccine*	Indicated During Every Pregnacy	May Be Given During Pregnancy in Certain Populations	Contraindicated During Pregnancy	Can Be Initiated Postpartum or When Breastfeeding or Both
Inactivated influenza	X†,1,2			X‡
Tetanus toxoid, reduced diptheria toxoid and acellular pertussis (Tdap)	X†,3,4			X‡
Pneumococcal vaccines		X§,5,6		X§,5,6
Meningococcal conjugate (MenACWY) and Meningococcal serogroup B		X‖,7		X‖,7
Hepatitis A		X¶,8		X¶,8
Hepatitis B		X#,9,10		X#,9,10
Human papillomavirus (HPV)**				X**,11,12
Measles, mumps, and rubella			X††,13,14	X††
Varicella			X††,13,15,16	X††

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*An "X" indicates that the vaccine can be given in this window. See the corresponding numbered footnote for details.

† Inactivated influenza vaccination can be given in any trimester and should be given with each influenza season as soon as the vaccine is available. The Tdap vaccine is given at 27–36 weeks of gestation in each pregnancy, preferably as early in the 27–36-week window as possible. The Tdap vaccine should be given during each pregnancy in order to boost the maternal immune response and maximize the passive antibody transfer to the newborn. Women who did not receive Tdap during pregnancy (and have never received the Tdap vaccine) should be immunized once in the immediate postpartum period.[1–3]

‡ Vaccination during every pregnancy is preferred over vaccination during the postpartum period to ensure antibody transfer to the newborn.[3,4]

§ There are two pneumococcal vaccines: 1) the 23-valent pneumococcal polysaccharide vaccine (PPSV23) is recommended in reproductive-age women who have heart disease,lung disease, sickle cell disease, and diabetes as well as other chronic illnesses; 2) the 13-valent pneumococcal vaccine (PCV13) is recommended for reproductive-aged women with certain immunocompromised conditions, including human immunodeficiency virus (HIV) infection and asplenia. The PCV13 vaccine should be deferred in pregnant women, unless the woman is at increased risk of pneumococcal disease and after consultation with her health care provider the benefits of vaccination are considered to outweigh the potential risks.[5,6]

‖ Quadrivalent conjugate meningococcal vaccine is routinely recommended for adolescents aged 11–18 years, along with individuals with HIV infection, complement component deficiency (including eculizumab use), functional or anatomic asplenia (including sickle cell disease), exposure during a meningococcal disease outbreak, travel to endemic or hyperendemic areas, or work as a microbiologist routinely exposed to *Neisseria meningitidis*. If indicated, pregnancy should not preclude vaccination. The serogroup B vaccine should be deferred in pregnant women, unless the woman is at increased risk of serogroup B meningococcal disease[7] and, after consultation with her health care provider, the benefits of vaccination are considered to outweigh the potential risks.[7]

¶ Pregnant women with any of the conditions that increase the risk of either acquiring or having a severe outcome from hepatitis A infection (eg, having chronic liver disease, clotting-factor disorders, traveling, using injection and noninjection drugs, and working with nonhuman primates) should be vaccinated during pregnancy if not previously vaccinated. Pregnant women at risk of hepatitis A infection during pregnancy should also be counseled concerning all options to prevent hepatitis A infection. Any woman who wants to be protected from hepatitis A or has an indication for use may receive the vaccine during pregnancy or during the postpartum period.[8]

Hepatitis B vaccination is recommended for women who are identified as being at risk of hepatitis B infection during pregnancy (eg, women who have household contacts or sex partners who are hepatitis B surface antigen–positive; have more than one sex partner during the previous 6 months; have been evaluated or treated for a sexually transmitted infection; are current or recent injection-drug users; have chronic liver disease; have HIV infection; or have traveled to certain countries). Any woman who wants to be protected from hepatitis B or has an indication for use may receive the vaccine during pregnancy and the postpartum period. Pregnant women at risk of hepatitis B infection during pregnancy should be counseled concerning other methods to prevent hepatitis B infection.[1,9]

** The HPV vaccination in pregnancy is not recommended, however, inadvertent HPV vaccination during pregnancy is not associated with adverse events for the woman or her fetus. The HPV vaccine can be given to postpartum and breastfeeding women. The HPV vaccine should be administered to women through age 26 years who were not previously vaccinated. Vaccination timing and number of doses should follow Centers for Disease Control and Prevention and American College of Obstetricians and Gynecologists' guidance.[11,12]

†† Live attenuated vaccines including, measles–mumps–rubella, varicella, and live-attenuated influenza vaccine are contraindicated for pregnant women. If indicated (ie, among seronegative women), the measles–mumps–rubella vaccine and the varicella vaccine should be given during the postpartum period. Inadvertent administration during pregnancy has not been associated with congenital rubella or congenital varicella syndromes.[13–16]

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The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

CDC
Centers for Disease Control and Prevention

Unprotected People #72
Pertussis

Infant Dies after Contracting Pertussis from Adult Family Members

In December 2004, a 29-day-old infant died from pneumonia and respiratory failure, complications of pertussis. Several weeks before the infant's birth, her mother and maternal grandmother had developed prolonged paroxysmal cough with posttussive vomiting.

According to information published in MMWR on January 28, 2005, during 1996-2004, 35.1% of pertussis patients were 6 months of age or younger (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5403a3.htm). Infants this age are particularly vulnerable to the disease because they are too young to have received the 3-dose primary series of pertussis vaccine.

CDC describes pertussis as a highly communicable disease, transmitted from patients to close contacts by respiratory droplets. It can be severe in nonimmunized infants; healthcare workers should suspect pertussis in nonimmunized or partially immunized infants with respiratory distress.

The following case report is based on information from a medical school, hospital, and local and state public health agencies in West Virginia, as well as from NIP staff. Titled "Brief Report: Fatal Case of Pertussis in an Infant—West Virginia, 2004," it appeared in MMWR on January 28, 2005.

Brief Report: Fatal Case of Pertussis in an Infant—West Virginia, 2004

In December 2004, an infant aged 29 days in West Virginia died from pertussis after exposure to adult family members with probable undiagnosed pertussis. Pertussis (i.e., whooping cough) is a prolonged respiratory illness caused by the bacterium Bordetella pertussis and characterized by a violent cough, inspiratory whoop, and posttussive vomiting. The cough often lasts from several weeks to up to 3 months. However, adolescents and adults, even those previously vaccinated as children, often have disease not recognized as pertussis, leading to intrafamilial and nosocomial transmission. In the United States, children aged <6 months are at the highest risk for severe illness or death from pertussis because most infants do not complete their primary vaccination series until age 6 months. This report summarizes results of the West Virginia Department of Health and Human Resources (WVDHHR) case investigation, which underscore the critical need to prevent pertussis transmission to infants from adolescents and adults with undiagnosed disease.

On December 11, the infant was taken by her parents to a local emergency department (ED) with difficulty breathing. The infant had been coughing for approximately 5 days with increasing severity, resulting in posttussive vomiting and several choking episodes. At presentation, the infant was lethargic, and examination revealed tachycardia and mild fever (99.5 degrees F [37.5 degrees C]). Before intubation and oxygen supplementation, the infant had thick, foamy mucus coming from her mouth, appeared cyanotic, and had an O2 saturation of 70% by pulse oximetry. Seizure activity was noted during intubation. Laboratory results revealed severe leukocytosis (white blood cell count: 104,100/microliter; normal: 5,000-19,500 microliter), severe lymphocytosis (26,600/microliter; normal: 2,500-16,500/microliter), and a nasopharyngeal swab was positive for respiratory syncytial virus (RSV) by rapid immunoassay alone. A chest radiograph revealed right upper lobe and perihilar infiltrates, and an electrocardiogram indicated supraventricular tachycardia. Three hours after arrival at the ED, the infant was transferred to a pediatric intensive care unit (PICU) with diagnoses of pneumonia and respiratory failure.

On transfer to the PICU, the infant was placed on droplet precautions and contact isolation, treated for

(continued on next page)

suspected sepsis, and started on azithromycin for presumed B. pertussis infection on the basis of clinical signs. The infant's ventilator course was characterized by hypoxemia (admission PaO2/FiO2 ratio: 172) and increasing hypercarbia. Sequential cardiac ultrasounds demonstrated increasing pulmonary hypertension (right ventricular pressure: 2/3 systemic). Nineteen hours after admission, oxygenation worsened precipitously (PaO2/FiO2 ratio: 52-60) and failed to improve with nitric oxide administration or high-frequency ventilation. A double-volume exchange transfusion was performed, but the infant failed to improve and died approximately 30 hours after admission to the PICU.

A specimen obtained from the infant's nasopharynx after admission to the PICU was reported at the time of the infant's death to be positive for B. pertussis DNA and negative for B. parapertussis DNA by polymerase chain reaction (PCR); however, no specimen was submitted for culture. Results were negative by both rapid immunoassay and culture for RSV, influenza A and B, and parainfluenza viruses 1, 2, and 3, and negative by culture for adenovirus. The diagnosis of confirmed pertussis was based on history, clinical findings, and a positive PCR test. The infant might have had a coinfection with RSV based on the positive RSV rapid immunoassay at the ED; this result was not confirmed by a repeat RSV rapid immunoassay or by culture at the PICU.

The infant was born at 36 weeks' gestation (birth weight: 2,665 g) by normal, uncomplicated, vaginal delivery. The infant's mother, aged 20 years, had a prolonged paroxysmal cough with posttussive vomiting and whoop that began approximately 3 weeks before the infant's delivery. The cough was still present at the time of the infant's death. The mother received guaifenesin/dextromethorphan cough syrup after delivery. The infant's maternal grandmother, aged 58 years, had a prolonged paroxysmal cough illness (onset date: approximately 2 weeks before the infant's mother's illness) with posttussive vomiting; she had received azithromycin after a diagnosis of sinusitis. Two weeks before the infant's illness, the infant's father, aged 22 years, had onset of a paroxysmal cough illness of >3 weeks' duration.

A day after the infant's death, a case investigation identified four additional close contacts (two cousins, a paternal grandmother, and a great-grandmother) of the infant with cough illness (duration: 3-8 days) at the time of the infant's death. The birth hospital and the ED had no droplet precautions in place while the infant and the infant's symptomatic family members were in the facilities; 30 birth hospital and 11 ED employees were identified as potential contacts. The local health department and the ED provided erythromycin to 24 recent (i.e., during the preceding 3 weeks) contacts of the infant and symptomatic family members. Of nine nasopharyngeal swabs submitted for culture, all were negative for pertussis (all household members swabbed had been symptomatic for >3 weeks); no PCR testing for pertussis was performed. Pertussis alerts were issued to the public, healthcare providers, schools, and a large retail store where the infant's father worked.

This case underscores the need to protect infants from pertussis transmission. The healthcare community can limit the spread of pertussis by (1) educating caretakers and the public about preventing exposure of infants to any person with a cough illness, (2) educating healthcare providers to consider pertussis in adolescents and adults with a cough illness and to ask these patients to wear a mask or isolate themselves from other patients, and (3) encouraging confirmation of pertussis by culture of nasopharyngeal secretions. Healthcare providers must be encouraged to observe droplet precautions while attending to patients with respiratory illnesses. No U.S.-licensed pertussis vaccine for persons aged ≥7 years is available; however, in 2004, two pharmaceutical companies submitted biologics license applications to the Food and Drug Administration for two tetanus toxoid and reduced diphtheria toxoid and acellular pertussis vaccine adsorbed (Tdap) products, one for persons aged 10–18 years and the other for persons aged 11–64 years.

Contemporary OB/GYN®

PATIENT HANDOUT

Pregnancy Vaccine Questionnaire

Questionnaire	Vaccine today	Refuse vaccine (patient initials)	VIS given
1. Do you have allergies to Eggs ____ Yeast ____ Neomycin ____			
2. Have you had a flu shot this year? Yes _____ No _____			
3. Have you had a pneumonia shot? Yes _____ No _____			
4. When was your last tetanus or whooping cough shot? Year _____			
5. Have you had the 3-shot hepatitis B series? Yes _____ No _____			
6. Have you had the 2-shot hepatitis A vaccine? Yes _____ No _____			
7. (For women 19 years of age and younger) Have you received the meningitis vaccine? Yes _____ No _____			

Patient's signature _____ Patient's name (printed) _____

Date _____ Witness' signature _____ Witness' name (printed) _____

Abbreviation: VIS, Vaccine Information Statement

Guiding Principles for Development of ACIP Recommendations for Vaccination during Pregnancy and Breastfeeding

April 2008

Advisory Committee on Immunization Practices
Workgroup on the Use of Vaccines during Pregnancy and Breastfeeding

Guiding principles for developing ACIP recommendations for vaccination during pregnancy and breastfeeding
April 10, 2008

Formulating policy to guide vaccination of women during pregnancy and breastfeeding is challenging because the evidence-base to guide decisions is extremely limited. In the past, ACIP has not provided guidance to workgroups on either the process to formulate policy for this population or the format and language for recommendations. As a result, workgroups have taken a variety of approaches to considering and presenting the issues, resulting in a diversity of recommendations that vary in clarity and underlying rationale. . The principles presented here provide guidance to help standardize both the process of policy formulation and the format and language of recommendations for pregnant and breastfeeding women. All ACIP statements about vaccines and other biologics for use in adolescents or adults should include a background section on vaccination during pregnancy and breastfeeding and provide explicit pregnancy and breastfeeding recommendations using standardized language as outlined below. To arrive at pregnancy and breastfeeding recommendations, ACIP workgroups or subject matter experts charged with developing vaccine statements should review the process suggestions outlined below. These suggestions, while similar to the process generally followed by workgroups, focus specifically on issues related to pregnancy, breastfeeding and decision making in the absence of a strong evidence-base.

1. This document and appendix provide a brief overview of specific issues related to vaccination during pregnancy and breastfeeding

2. Guidance for the pregnancy and breastfeeding **background** section
    a. Title: "Vaccination of women during pregnancy and breastfeeding"
    b. Scope: This section should address the following core topics with a narrow focus on the vaccine product/s in question
        i. Disease burden: pregnant women, fetus, newborns and young infants
        ii. Vaccination during pregnancy
            1. Objective and rationale: (clear statement of the primary objective(s): to protect mother and/or fetus and/or neonate and/or young infant)
            2. Immunogenicity data (mother; neonate and young infant if available)
            3. Efficacy data (mother; neonate and young infant if available)
            4. Safety data (mother; fetus, neonate and young infant if available)
            5. Pregnancy trimester-specific issues (safety, efficacy, other)
        iii. Vaccination during breastfeeding
            1. Objective and rationale: (clear statement of the primary objective(s): to protect mother and/or neonate and/or young infant and/or future offspring)
            2. Efficacy
            3. Safety
            4. Timing (eg, immediately post-partum or later in infancy; with respect to the infant/childhood vaccine series)

   iv. Cost-effectiveness (only if there are unique issues related to vaccine use during pregnancy/breastfeeding)
   v. Alternatives or adjuncts to vaccination during pregnancy
   vi. Logistics (eg, vaccination record) and coadministration with other vaccines
   vii. Areas for future research (could highlight important, feasible studies that would assist vaccine policy decisions)
c. Length: the section should be short for most vaccine products
d. Data sources: indicate types of studies including well controlled clinical trials, observational studies, reviews of published literature, and unpublished data

3. Guidance for the pregnancy/breastfeeding **recommendations**
   a. These recommendations should be integrated into the recommendations section of the document rather than presented separately (as suggested for the pregnancy/breastfeeding background). Explicit recommendations should be provided both for vaccination during pregnancy and during breastfeeding
   b. Recommendations should reference the pregnancy/breastfeeding background section for rationale and other details
   c. Pregnancy and breastfeeding recommendations should appear in the "special populations" section of the recommendations. If pregnancy or breastfeeding are deemed precautions or contraindications, recommendations should instead appear in the "precautions/contraindications" section, and the special populations section should refer readers to the precautions/ contraindications section.
   d. Recommendations should specify
      i. Precautions/contraindications for the pregnant and breastfeeding populations
      ii. Timing of vaccination
         1. During pregnancy: pregnancy trimester
         2. During breastfeeding: any specific time periods to aim for or avoid
      iii. Minimum time period between vaccination and becoming pregnant, if vaccination is a precaution or contraindication

4. Guidance on language to reduce unnecessary variation across statements
   a. Pregnancy/breastfeeding background section
      i. For each topic heading listed in 2b, lack of data should be stated explicitly where it applies.
      ii. For safety, absence of adequate study/surveillance/follow up should be distinguished clearly from absence of adverse events
   b. Recommendations section:
      i. General

      Distinguish clearly between contraindications and precautions. ACIP definitions are as follows:

      Contraindication: A condition in a recipient that increases the risk for a serious adverse reaction. *A vaccine will not be administered when a contraindication is present*

Precaution: A condition in a recipient that might increase the risk for a serious adverse reaction or that might compromise the ability of the vaccine to produce immunity. *Under usual circumstances, vaccination should be deferred. However, vaccination might be indicated because benefits outweigh risks*

In the context of pregnancy and breastfeeding, serious adverse reaction includes maternal, fetal or neonatal serious adverse events linked to the vaccine. Contraindication means that there is direct evidence or strong biologic plausibility and suggestive evidence that the risk of severe adverse event is elevated for at least one of these groups. Precaution means there is no supporting evidence but there is some biologic plausibility; precaution may also mean that there is a lack of data to support safety.

ii. Standard language: Choose which best applies and modify language only if necessary
    1. Pregnancy recommendations
        1. "Vaccination of pregnant women is recommended; all pregnant women should be vaccinated"

        Illustrative examples: Inactivated influenza vaccine
        2. "Pregnancy is not a contraindication or precaution to vaccination; routine vaccination recommendations should be applied to pregnant women"

        Illustrative examples: Tetanus-diphtheria (Td), Hepatitis B, Meningococcal polysaccharide
        3. "Pregnancy is a precaution and under normal circumstances vaccination should be deferred; vaccine should only be given when benefits outweigh risks"

        Illustrative examples: Hepatitis A , IPV, or yellow fever (in case of travel to an area where exposure is likely); rabies (eg, after a possible exposure)
        4. "Pregnancy is a contraindication to vaccination; vaccine should not be administered to pregnant women. Vaccination with contraindicated vaccines during pregnancy is not ordinarily a reason for pregnancy termination"

        Illustrative examples: MMR, varicella, live-attenuated influenza vaccine
    2. Timing of vaccination during pregnancy
        1. "Vaccination can be given at any time during pregnancy"
        2. "Vaccination should be deferred until X trimester of pregnancy unless there is a specific indication for vaccination early in pregnancy that outweighs risks"
        3. "Vaccine should not be administered during X trimester of pregnancy"

4. *For vaccines where pregnancy is a contraindication*: "Women should avoid becoming pregnant until 28 days after vaccination"
    i. Note: 28 days is the time period that applies to most currently contraindicated vaccines; however if for a particular vaccine product there is evidence for a shorter or longer time period, the 28 days may be modified as needed.

3. Breastfeeding recommendations
    1. "Breastfeeding is not a contraindication or precaution to vaccination; routine vaccination recommendations should be applied"

    Illustrative examples: Current recommendations appear to place all vaccines except smallpox in this category (although the language is not clear)
    2. "Breastfeeding is a precaution and under usual circumstances vaccination should be deferred; vaccine should only be given when benefits outweigh risks"
    3. "Breastfeeding is a contraindication to vaccination; vaccine should not be administered to breastfeeding women."

    Illustrative example: smallpox vaccine

4. Timing of vaccination during breastfeeding
    1. "Vaccination is recommended before postpartum hospital discharge for all women whether or not they intend to breastfeed"
    2. "Vaccine may be administered at any time postpartum, for all women whether or not they intend to breastfeed"
    3. "Where possible, vaccination of breastfeeding women should be deferred until X period postpartum, unless benefits outweigh risks"
    4. "For breastfeeding women, vaccine should not be administered during X period postpartum"

5. Suggestions to aid policy decision-making in the absence of adequate data
    a. Review any unpublished or pre-licensure data available (eg, from accidental vaccinations of pregnant women)
    b. Assess whether there will be adequate data in the future and on what timeline
    c. Review the decisions of other professional organizations/ other countries and the underlying rationale
    d. Review "ACIP precedents" with regards to vaccination during pregnancy and breastfeeding
        i. Vaccination during breastfeeding is contraindicated only for smallpox vaccine
        ii. Live vaccines pose theoretical concern more often than inactivated vaccines

iii. When risk of maternal infection is high and risk of a poor outcome is high, vaccination is recommended (eg, rabies, yellow fever)
iv. In the absence of adequate safety and efficacy data, direct protection of mother provides a stronger basis than indirect protection of neonate/ young infant for a recommendation of vaccination during pregnancy
v. There is more comfort with second and third trimester vaccination than first trimester (not based on safety data, but based on public perception)

e. Evaluate safety checks in place in case the pregnancy/breastfeeding recommendations for the product in question result in unintended adverse consequences
    i. Is post-licensure data on safety (passive, or active, or special studies) likely to detect important adverse events?
    ii. Are there registries or other sources that would allow for detection of safety or efficacy concerns?
    iii. If there are concerns about maternal antibody inhibition of infant response to a similar vaccine or fetal antigen tolerance with subsequent diminished postnatal responsiveness, is any system in place to monitor those outcomes?
    iv. Are there any sentinel events of concern that warrant particular attention?

6. Suggestions on how to standardize the gathering of expert opinion
    i. Areas of expertise that should be represented in workgroup deliberations:
        1. Disease burden (all relevant populations (eg, pregnant women, neonates, young infants)
        2. Vaccine product: efficacy, safety for pregnant women, fetus, newborn/infant as relevant
        3. Maternal/neonatal immunology if concerns about maternal antibody inhibition of infant immune response to same or related vaccine are relevant
        4. Consider: target population representation (eg, pregnant woman; a representative of infants who have been affected by the disease in question)
        5. Scientific leader from obstetric clinical community
        6. Scientific leader from pediatric clinical community
        7. Consider: inclusion of someone with expertise in health law
    ii. Strategies for obtaining input
        1. If some members are particularly vocal or stifling of free conversation, consider solicitation of written input through a standard set of key questions from all members
        2. Consider pulling in additional targeted experts if a particular issue stands out as complex or controversial
    iii. Suggestion of procedures to follow when expert opinion cannot reach consensus
        1. Present pros and cons as options to the full ACIP, with a summary of supporting evidence, and let them vote

2. Allow the workgroup to draft a dissenting opinion and present both positions to ACIP before they vote

Appendix: Brief overview of issues related to vaccination during pregnancy and breastfeeding

1. Vaccination during pregnancy
    a. Vulnerable populations
        i. Pregnant women
            1. Altered immune response
            2. Increased risk of some infections
            3. Increased risk of severe outcomes (maternal, fetal or both) of some infections
        ii. Fetus, newborn, young infant
            1. Immature immune response
            2. Increased risk of some infections
            3. Increased risk of severe outcomes of some infections
            4. Infection sequelae can result in lifelong disability
    b. The promise of vaccination during pregnancy (any or all of the below)
        i. Protection of mother
        ii. Protection of fetus
        iii. Protection of neonate
        iv. Protection of young infant
        v. In the US there are approximately 4 million live births each year
        vi. In the US >98% of women have at least 1 prenatal visit, providing a health care opportunity for vaccination
    c. Concerns about vaccination of pregnant women
        i. Lack of data to make evidence-based decisions
            1. No or limited well-controlled trials to establish efficacy of vaccines in pregnant women or their offspring
            2. No or limited post-licensure studies of efficacy or safety (eg, from registries, VAERS, Vaccine Safety Datalink)
            3. No or limited animal data
            4. No or limited data on burden of illness
                - Key aspects of interest: incidence, severity, sequelae, time period of most vulnerability to infection
                - Key target populations: pregnant woman, fetus, newborn, young infant
        ii. Theoretical concerns about efficacy (woman, fetus, newborn)
            1. Will altered immune status of pregnant woman reduce response to vaccine?
            2. Will sufficient maternal antibody be transferred to fetus to confer protection (to fetus, newborn)?
            3. Will half life of maternal antibody be sufficient to protect fetus/newborn during relevant period of vulnerability?
        iii. Theoretical concerns about safety (woman, fetus, newborn)
            1. Vaccine type
                - Live vaccines (eg, viral antigen) historically have been viewed as more risky than inactivated and toxoid vaccines

i. There is evidence of fetal vaccinia infection following smallpox vaccination during pregnancy
ii. There is no direct evidence of any live vaccine resulting in a fetal or neonatal serious adverse event

- Even more limited data on newer vaccine types
  i. Unclear that generalizations about live vs. inactivated vaccines can be applied to new or future vaccine antigen types and technologies
  ii. Unclear that generalizations about live parenteral vaccines can be applied to live mucosal vaccines

2. Additives/adjuvants/preservatives (eg, thimerosal)
   - Limited or no safety data on exposure of pregnant women, fetus and newborn to these
3. Timing of vaccination
   - Safety risks may vary with time period of vaccination during pregnancy (eg, early pregnancy vs. late pregnancy; immediately post-partum vs. later)

iv. Concerns about impaired newborn/infant immune response to childhood series

1. Primary concern is inhibition of newborn or infant response to active vaccination due to high concentratons of passively acquired maternal antibodies
2. Evidence that transplacental transfer of maternal antibody can interfere with infant response to childhood vaccine series
   - naturally-acquired or vaccine-induced maternal measles antibody interferes with infant response to measles vaccine
3. Theoretic concern that vaccination during pregnancy could similarly impair response to routine childhood series
   - Extent of inhibition depends on multiple factors (eg, type of maternal and infant vaccine antigen, concentration and avidity of maternal antibody, timing and doses in infant series)
   - Priming of the infant immune system can occur despite presence of maternal antibody
4. In addition to concerns about maternal antibody inhibition of infant postnatal responses to infant immunization series, there are also theoretical concerns that the fetus could develop antigen tolerance *in utero* which may result in diminished postnatal responsiveness to the infant immunization series.

v. Lack of harmonization with FDA labeled indications *(see Table for a description of FDA pregnancy categories)*

1. Label subject to federal regulations
   - 21 CFR 201.56 (General) and 201.57 (Specific)
2. One currently licensed vaccine (HPV) is pregnancy category B
3. One currently licensed vaccine (anthrax) is pregnancy category D
4. All other licensed vaccines are currently labeled as category C

vi. Public perception/risk communication
    1. Temporal association between vaccine and adverse pregnancy events
    2. Principle of avoiding <u>any</u> unnecessary exposures during pregnancy
vii. Legal liability
    1. National Childhood Vaccine Injury Act
        - If covered vaccine properly prepared and accompanied by proper directions and warnings, manufacturer cannot be held liable for injuries.
        - Law clearly covers vaccine directly administered to child
        - Statute is silent on *in utero* transmission (eg, adverse effect in fetus whose mother is vaccinated); case law is unclear
viii. Logistical concerns
    1. Most obstetric offices do not have the infrastructure (eg, proper storage refrigerator, tracking of administration documentation required by law) to administer vaccines and obstetric providers often do not view vaccination as their primary responsibility
    2. There is no good vaccine record keeping system for adult vaccination (eg, to avoid problem of repeat vaccination)
    3. Providers who care for pregnant women are often most concerned about the woman and fetus and may be less educated/aware about infectious risks to the neonate and young infant
    4. Vaccine recommendations for pregnant women have a history of lack of clarity

d. Alternatives or supplements to vaccination during pregnancy: Depending on the infection, some or all of the below may be effective as adjuncts or as alternatives
    i. Routine infection control (eg, hand hygiene, respiratory etiquette)
    ii. Vaccination of household contacts of newborns/pregnant women ("cocoon strategy" for pertussis and influenza) but limited data on efficacy
    iii. Postpartum vaccination (See section 2 below)
        1. Eg, rubella and Tdap vaccination recommendation
        2. Avoids safety concerns of vaccination during pregnancy
        3. Only confers fetal protection in subsequent pregnancies (assuming maternal antibody levels persist at adequate concentrations)
        4. Only confers maternal protection after the time of vaccination (eg, misses vulnerable time window of that pregnancy and early postpartum period)

2. Vaccination during breastfeeding
    i. Objectives
        1. Protect mother from vaccine-preventable diseases
        2. Indirect protection of neonate/ infant by preventing infection in mother ("cocoon strategy"; see 1d)
        3. Confer protection in subsequent pregnancies (eg, rubella)
        4. Transfer of protective antibody to neonate/ infant
            - Antibody in human milk is >90% secretory IgA
            - Offers surface protection in the mouth

- Unclear whether offers additional protection (eg, against respiratory infection)
- Transfer of circulatory IgG to infant has not been documented

ii. Concerns

1. Interruption of breastfeeding (which has known, important benefits)
2. Interference of antibody transferred via human milk with neonate/infant direct response to childhood series
    - A particular issue for orally administered vaccines
    - Evidence from rotavirus and poliovirus vaccines suggest this may be overcome by administering >1 dose
3. Transmission of vaccine virus in the case of live vaccines
    - Evidence from smallpox, MMRV, MMR
4. Consistency with FDA labels
    - Majority of labels state "Because many drugs are excreted in human milk, caution should be exercised when administering vaccine to a nursing woman"

Table. Food and Drug Administration pregnancy categories*. Regulation requires that each product be classified under one of five pregnancy categories (A, B, C, D, or X), on the basis of risk of reproductive and developmental adverse effects or, for certain categories, on the basis of such risk weighed against potential benefit.

Pregnancy category A	Adequate and well controlled studies in women fail to demonstrate a risk to the fetus in the first trimester (and there is no evidence of a risk in later trimester), and the possibility of fetal harm appears remote.
Pregnancy category B	Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women OR Animal studies have shown an adverse effect, but adequate and well-controlled studies in pregnant women have failed to demonstrate a risk to the fetus during the first trimester (and there is no evidence of risk in later trimesters)
Pregnancy category C	Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks OR Animal reproduction studies have not been conducted and there are no adequate and well-controlled studies in humans
Pregnancy category D	There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.
Pregnancy category X	Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

*Note: As of January, 2008, FDA is in the process of developing a new pregnancy labeling system. This new system is under consideration and has not yet been instituted.

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This document can be found on the CDC website at:
http://www.cdc.gov/vaccines/recs/acip/downloads/preg-principles05-01-08.pdf

Prenatal Care Provider Policies and Procedures to Prevent Perinatal Hepatitis B Virus Transmission

Prenatal care providers should test every woman for hepatitis B surface antigen (HBsAg) during an early prenatal visit (e.g., in the first trimester), even if a woman has been previously vaccinated or tested.

In addition, prenatal care settings should incorporate each of the following actions into their policies and protocols:

For a pregnant woman with a *positive* HBsAg test result

- Report the positive test result to the health department.
- Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg status to the hospital where the delivery is planned and to the health-care provider who will care for the newborn.
- Attach an alert notice or sticker to the woman's medical record to remind the delivery hospital/nursery that the infant will need hepatitis B vaccine and HBIG at birth.
- Educate the mother about the need for immunoprophylaxis of her infant at birth, and obtain consent for immunoprophylaxis before delivery. Consider printing additional reminder notices for mothers about the importance of immunoprophylaxis for infants and attaching the notices to the inside front or back cover of the medical record.
- Advise the mother that all household, sexual, and needle-sharing contacts should be tested for HBV infection and vaccinated if susceptible.
- Provide information to the mother about hepatitis B, including modes of transmission, prenatal concerns (e.g., infants born to HBsAg-positive mothers may be breastfed), medical evaluation and possible treatment of chronic hepatitis B, and substance abuse treatment (if appropriate).
- Refer the mother to a medical specialist for evaluation of chronic hepatitis B.

For a pregnant woman with a *negative* HBsAg test result

- Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg status to the hospital where the delivery is planned and to the health-care provider who will care for the newborn.
- Include information in prenatal care education about the rationale for and importance of newborn hepatitis B vaccination for all infants.
- Administer the hepatitis B vaccine series if the patient has a risk factor for HBV infection during pregnancy (e.g., injection-drug use, more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually-transmitted disease [STD]).
- Repeat HBsAg testing upon admission to labor and delivery for HBsAg-negative women who are at risk for HBV infection during pregnancy or who have had clinical hepatitis since previous testing.

Unprotected People #91
Human Papillomavirus (HPV)

Christine Baze's Story

PopSmear.org is a Boston-based non-profit organization whose purpose is to raise awareness and educate women about how to prevent cervical cancer and HPV. PopSmear.org was created in 2002 by Christine Baze, a Boston musician who is also a cervical cancer survivor. She was just 31 years old when she was diagnosed with cervical cancer. In recognition of her educational and outreach efforts, Ms. Magazine named Baze in their annual award: "50 women who made a difference."

Christine Baze gave IAC permission to share her personal story:

I'm supposed to be a rock star — that's what I thought until April 18th, 2000. I had just left my day job in January to pursue my passion: music. My band was doing well and I could not have been happier, but then there was blood. I called my gynecologist and he told me not to worry. So I didn't. I went on gigging and booking and writing songs—the best 3 months ever. I was so happy and felt so lucky. Little did I know it would not last.

In March, I went for my yearly Pap test. I've had yearly Paps since I was 18 years old, and always had normal results, until this one. I was told that I had some dysplastic cell growth on my cervix and that he needed to do a colposcopy to biopsy the cells. I barely knew where my cervix was and certainly didn't understand anything about cell mutation—that's when I was told it could turn into cancer many years down the road if not treated. Cancer? Me? He assured me that I did NOT have cancer and that we would meet the following week to review the results of this biopsy and schedule a LEEP procedure [loop electrosurgical excision procedures], a mild surgery that would scrape off the bad cells.

He was wrong. At 8:15 the morning of April 18th, I received a phone call confirming an appointment I did not have, with a doctor I did not know. Realizing I had not heard the news yet, the woman apologized on the other line, and stumbled over her words as she told me she was confirming an appointment with a gynecologic oncologist at a local cancer center. That's how I found out I had cancer.

It all happened very quickly after that. I was diagnosed with invasive cervical cancer with extensive lymphatic invasion. I had a radical hysterectomy 10 days after my diagnosis, a laparoscopic procedure a month later to move my ovaries out of the "frying zone," 5 weeks of daily pelvic radiation concurrent with 4 rounds of chemotherapy, followed by 3 rounds of internal radiation (brachytherapy). They gave me everything they had in order to save me. Within 4 months I was done with everything. Everything other than the deep dark depression, that is.

Everyone knows that treatment is hard, and everyone sees the toll it takes on your body. But for me, I think the depression that followed was almost worse. Once my body was no longer being assaulted, my mind started to digest all that had happened, and it wasn't pretty. I felt like I lost everything. And through it all, the one thing that always centered me, that always made me happy, was gone. The music was gone. I couldn't play, sing, or write. I had no desire for the thing I loved the most. I didn't know who I was anymore.

I decided to attack with full force: Individual therapy, group therapy, anti-depressant, acupuncture, yoga, journaling, Reiki, and more. I did anything I could to fight off the depression, and eventually it started to work. Time, absolutely was a huge part of it. Time, and the fact that I just refused to quit. I had worked way too hard to stay alive, and I wanted my life back.

(continued on next page)

By the fall of 2001, I finally got back to my day job, felt strong physically and emotionally, but still hadn't found the music. I sort of felt like that side of me was gone, it left with my uterus and was never returning. But then I saw the movie "Harold and Maude." Maude is an older woman who embraces everything there is to embrace in life. Every sensation—touch, taste, smell—she lives in the moment and teaches this young boy Harold how to do the same. I was completely inspired by Maude's spirit and enthusiasm, as well as the Cat Stevens soundtrack. I heard the song "trouble" and was drawn back to the piano—I felt like the song had been written for me, that it was the story of the last year and a half of my life. This is when I returned to the piano.

Since then, my life has brought me all kinds of new and wonderful experiences. I decided I wanted to give back to the cancer community by raising money and awareness so other women don't have to go through what I did. I decided to do a benefit concert and call it "PopSmear." I was going to do it in my back yard, but soon it spiraled into a great big event. Jim's Big Ego, The Mudhens, and Catie Curtis all agreed to perform. Amy Brooks from WBOS emceed the night. We sold out the Paradise Rock Club in Boston and raised $10,000 for the cause! It was truly one of the best nights of my life as a person, as a musician, and as a cancer survivor.

In 2003, I decided to take it on the road, created The Yellow Umbrella Tour, and went to six cities. Ms. Magazine named me one of the "50 women who made a difference in 2003." I've done the Tour every year since, and we have hit 86 cities, raising awareness and educating women about cervical cancer, HPV, and the modern technologies available to help women feel confident in maintaining their cervical health.

It is so important that women understand that cervical cancer is caused by HPV—a virus—and that there are new, fantastic technologies to help prevent it. Now there is an HPV vaccine to prevent the majority of cases of cervical cancer (for girls and women 9-26), there is an HPV test that can be done at the same time as your Pap (for women 30+), and there is a better Pap (a liquid Pap, for all women). These technologies were not available for me, but they are available today, and can totally PREVENT cervical cancer. My case is the perfect example that the standard Pap is NOT enough, because even though I had my annual gyn visit every year, the Pap test missed the cell changes year after year (squamous cell cancers take 5-10 years to develop). The Pap can be wrong up to 50% of the time. But the liquid Pap in combination with the HPV test is almost 100% accurate. And the HPV test is the ONLY way you can know if you are carrying the virus BEFORE it becomes invasive, which is why it is so important to know your HPV status. It's amazing and every woman should know about it.

So my message is clear:

- Every woman (9-26) should get the HPV vaccine.
- Every woman (18+) should get screened with the liquid Pap.
- Every woman (30+) should be screened with the HPV test along with the liquid Pap

Ladies: Don't blow off your annual gyn visit. Go in and have a conversation with your doctor. Learn the facts about cervical health, be proactive and empowered. Protect yourself with the vaccine, and then continue screening with the best — a liquid Pap and HPV test.

I feel so fortunate to be given this opportunity to share my story, share my music, and make a difference. I'm grateful to all the sponsors, volunteers, friends, and family for their support and love. When people believe in what they are doing, wonderful things can happen, and this is a wonderful thing.

Thanks for the support.

Christine Baze

For more information about Christine and her organization PopSmear, go to www.popsmear.org/