

It's All About the Footnotes: 2014 Vaccine Schedules

Stanley E. Grogg, DO

Dr Grogg is the American Osteopathic Association's liaison to the Advisory Committee on Immunization Practices.

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Dr Grogg is on the speakers' bureaus for and is the primary investigator representing Oklahoma State University-Center for Health Sciences for several vaccine research studies for GlaxoSmithKline; MedImmune LLC; Merck & Co, Inc; Novartis Corporation; Pfizer Inc; and Sanofi. He is a consultant for Merck & Co, Inc, on the topic of human papillomavirus and Novartis Corporation on the topic of meningitis.

Address correspondence to Stanley E. Grogg, DO, Associate Dean, Professor of Pediatrics, Oklahoma State University-Center for Health Sciences, 1111 W 17th St, Tulsa, OK 74107-1898.

E-mail: stanley.grogg@okstate.edu

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The Advisory Committee on Immunization Practices (ACIP), a committee of the Centers for Disease Control and Prevention (CDC), each year reviews the recommendations of its vaccine review work group for changes to the child and adolescent, adult, and catch-up vaccine schedules. This analysis occurred at the October 2013 ACIP Meeting. Comments are suggested by the ACIP committee, the liaisons representing the different stakeholders, such as the American Osteopathic Association (AOA), and public comments. The present article provides language from the ACIP as well as a rationale for the 2014 vaccine updated schedules. (The actual footnote changes are in **boldface and italics**. The rationale follows the footnote changes.)

Highlights of the Children and Adolescent 2014 Vaccination Schedule Recommended Footnote Changes

Hepatitis B (HepB) Vaccine in Newborns

Administer the HepB vaccine if the mother is hepatitis B surface antigen (HBsAg)-positive and “administer HBIG [hepatitis B immune globulin] for infants weighing $\geq 2,000$ grams as soon as possible, **but no later than age 7 days**.”¹

Rationale: The addition of the notation is to reinforce the need for early administration of HBIG for protection of the infants in born to HBsAg-positive mothers.

Rotavirus (RV) Vaccines

Administer a series of RV vaccine to all infants as follows:

1. If **Rotarix** is used, administer a 2-dose series at 2 and 4 months of age.
2. If **RotaTeq** is used, administer a 3-dose series at ages 2, 4, and 6 months.
3. If any dose in series was **RotaTeq** or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.¹

Rationale: The addition of the brand names (RV5 is RotaTeq by Merck & Co, Inc; RV1 is Rotarix by GlaxoSmithKline) of the vaccines helps to clarify the differences in dosing.

Pneumococcal Vaccine

Persons With High-Risk Conditions

PCV13 [pneumococcal conjugate vaccine] and PPSV23 [pneumococcal polysaccharide vaccine] (Minimum age: 2 years): All recommended PCV13 doses should be administered prior to 23-valent Pneumococcal if possible.¹

Rationale: In this footnote, PCV13 (Prevar13 by Pfizer Inc) was placed before PPSV23 (Pneumovax by Merck & Co, Inc) to stress that because of efficacy and the interactions of the 2 types of pneumococcal vaccines, PCV13 should be administered before PPSV23, if at all possible.

For children aged 24 through 71 months with *any of the following conditions: chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy); diabetes mellitus; cerebrospinal fluid leak; cochlear implant; sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; HIV infection, chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; solid organ transplantation; or congenital immunodeficiency:*

- i. *Administer 1 dose of PCV13 if 3 doses of PCV (PCV7 and/or PCV13) were received previously.*
- ii. *Administer 2 doses of PCV13 at least 8 weeks apart if fewer than 3 doses of PCV (PCV7 and/or PCV13) were received previously.*
- iii. *Administer 1 supplemental dose of PCV13 if 4 doses of PCV7 or other age-appropriate complete PCV7 schedule were received previously. (from 2010 [recommendations], table 11).*
- iv. *The minimum interval between doses of PCV (PCV7 or PCV13) is 8 weeks.*
- v. *For children previously unvaccinated with PPSV23, administer PPSV23 at least 8 weeks after the most recent dose of PCV13.*

For children aged 6 through 18 years who have cerebrospinal fluid leak; cochlear implant; sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiencies [sic]; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma.

For children aged 6 through 18 years who have chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma if treated with high-dose oral corticosteroid therapy); diabetes mellitus; alcoholism, chronic liver disease; or who have not received PPSV23, administer 1 dose of PPSV23. If PCV13 has been received previously, administer PPSV23 at least 8 weeks after the most recent dose of PCV13.

A single revaccination with PPSV23 should be administered after 5 years to children with sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiencies [sic]; HIV infection; chronic renal failure; nephrotic syndrome; diseases associated with treatment with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas and Hodgkin disease; generalized malignancy; solid organ transplantation; or multiple myeloma.¹

Rationale: These additions allow health care practitioners to differentiate between the use of pneumococcal vaccines for high-risk children aged 24 through 71 months and those aged 6 through 18 years. The paragraphs also differentiate the use of the pneumococcal vaccines in high-risk children and adolescents from those with immunodeficiencies.

Hepatitis A (HepA) Vaccine

Special Populations (Minimum Age: 12 Months)

Administer 2 doses of Hep A vaccine at least 6 months apart to previously unvaccinated persons who live in areas where vaccination programs target older children, or who are at increased risk for infection. *This includes persons traveling to or working in countries that have high or intermediate endemicity of Infection; men having sex with men; users of injection and non-injection illicit drugs; persons who work with HAV-infected primates or with HAV in a research laboratory setting; persons with clotting-factor disorders; persons with chronic liver disease.*¹

Rationale: This footnote clarifies the use of HepA for those traveling to endemic areas with hepatitis A and other high-risk conditions for contracting hepatitis A. The immunization is covered by Vaccines for Children funding if the patient qualifies.

Human Papillomavirus (HPV) Vaccine

Routine Vaccination

Administer the second dose 1 to 2 months after the first dose (minimum interval of 4 weeks), *administer the third dose at least 12 weeks after the second dose AND at least 24 weeks after the 1st dose.*¹

Rationale: The timing will be in weeks instead of months and defines the timing of the third dose of the HPV vaccine.

Meningococcal Vaccine

Vaccination of Persons With High-Risk Conditions and of Other Persons at Increased Risk of Disease

Children with anatomic or functional asplenia (including sickle cell disease):

- i. *For children younger than 19 months of age, administer a 4-dose infant series of MenHibrix or Menveo at 2, 4, 6, and 12 through 15 months of age.*
- ii. *For children aged 19 through 23 months who have not completed a series of MenHibrix or Menveo, administer 2 primary doses of Menveo at least 3 months apart.*

- iii. *For children aged 24 months and older who have not received a complete series of MenHibrix or Menveo or Menactra, administer 2 primary doses of either Menactra or Menveo. If Menactra is administered to a child with asplenia (including sickle cell disease), do not administer Menactra until 2 years of age and at least 4 weeks after the completion of all PCV13 doses.*

Children with persistent complement component deficiency:

- i. *For children younger than 19 months of age, administer a 4-dose infant series of either MenHibrix or Menveo at 2, 4, 6, and 12 through 15 months of age.*
- ii. *For children 7 through 23 months with persistent complement component deficiency who have not initiated vaccination, 2 options exist depending on age and vaccine brand:*
 - a. *For children who initiate vaccination at 7 months through 23 months of age, using Menveo, a two dose series should be administered with the second dose in the second year of life and at least 3 months after the first dose.*
 - b. *For children who initiate vaccination at 9 months through 23 months of age, using [Menactra], a two dose series of Menactra should be administered at least 3 months apart.*

For children aged 24 months and older, who have not received a complete series of MenHibrix, Menveo or Menactra, administer 2 primary doses of either Menactra or Menveo.

For children who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic, including countries in the African meningitis belt or to the Hajj, administer an age appropriate formulation and series of Menactra or Menveo for protection against serogroups A and W. Prior receipt of MenHibrix is not sufficient for children traveling to the meningitis belt or the Hajj. See MMWR [Morbidity and Mortality Weekly Report] 2013 62(RR02); 1-22, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>.

For children at risk during a community outbreak attributable to a vaccine serogroup administer or complete an age and formulation-appropriate series of MenHibrix, Menactra or Menveo.

For booster doses among persons with high-risk conditions refer to MMWR 2013 62(RR02); 1-22, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>.¹

Rationale: On the basis of the October 2013 ACIP recommendations, the information includes the details of the use of the MenACWY-CRM (Menveo, Novartis Vaccines) vaccine down to age 2 months for high-risk infants. In addition, the footnote updates the recommendations for MenHibrix, Menveo, and Menactra for children who have immunocompetencies and who are traveling to endemic areas of the world.

Catch-up Recommendations in Persons With High-Risk Conditions

If MenHibrix is administered, all 4 doses should be administered to achieve protection against Meningococcal disease.

If the first dose of MenHibrix is given at or after 12 months of life, 2 doses should be given at least 8 weeks apart to ensure protection against serogroups C and Y meningococcal disease.

For other catch-up recommendations in these persons, refer to MMWR 2013 62(RR02); 1-22, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6202a1.htm>.

For complete information on use of meningococcal vaccines, including issues related to vaccination of persons at increased risk of infection, see MMWR March 22, 2013 / 62(RR02);1-22, available at <http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>.¹

Rationale: By adding the URLs to the footnotes, the individual reviewing the meningitis vaccination indications can quickly access the website for more information on

the catch-up recommendations and use of the meningitis vaccines in patients with high-risk conditions.

Tetanus, Diphtheria, and Pertussis (Tdap) Vaccine

Persons aged **7 years and older** who are not fully immunized with the childhood DTaP [diphtheria, tetanus, pertussis] vaccine series, should receive Tdap vaccine as one (preferably the first) dose in the catch-up series; **if additional doses are needed at this age or older, use Td [diphtheria toxoids] vaccine instead of Tdap. For children 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose at age 11 through 12 years should not be administered. Td should be administered instead 10 years after the Tdap dose.**

Persons aged **11 years and older** who have not received Tdap vaccine should receive a dose followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter. **Repeat doses of Tdap are not recommended except for the pregnant adolescent, during every pregnancy.**¹

Rationale: The ACIP did not feel that it is cost effective to administer more than 1 dose of Tdap after age 7 years. The exception is that a dose of Tdap should be administered during each pregnancy to protect the fetus and mother.

An inadvertent dose of DTaP vaccine administered to children aged 7 through 10 years may count as part of the catch-up series. This dose may count as the adolescent Tdap dose, or the child can later receive a Tdap booster dose at age 11 through 12 years. **If pediatric DTaP is inadvertently administered to an adolescent aged 11 through 18 years, the dose should be counted as the adolescent Tdap booster.**¹

Rationale: This language helps to clarify that if an inadvertent dose of DTaP is given instead of a Tdap, there is no need to repeat the Tdap dose because the amount of diphtheria and pertussis is greater in the DTaP than the Tdap. Note that the reactions, especially local, may be

greater with the DTaP than the Tdap if the DTaP is administered after age 6 years.

Hemophilus influenzae Type B (Hib)

Conjugate Vaccine

Minimum age: 6 weeks for *PRP-T [ACT-Hib, DTaP-IPV/Hib (Pentacel) and Hib-MenCY (MenHibrix)], PRP-OMP [PedvaxHIB or Comvax]*. Minimum age: 12 months for *PRP-T [Hiberix]*.¹

Routine Vaccination

Administer a 2 or 3 dose Hib vaccine primary series and a booster dose (dose 3 or 4 depending on vaccine used in primary series) at age 12 through 15 months to all infants to complete a full Hib vaccine series.

The primary series with *ActHIB, MenHibrix or Pentacel* consists of 3 doses and should be administered at 2, 4, and 6 months of age. The primary series with *PedvaxHIB or Comvax* consists of 2 doses and should be administered at 2 and 4 months of age; a dose at age 6 months is not indicated.

One booster dose (dose 3 or 4 depending on vaccine used in primary series) of any Hib vaccine should be administered at age 12 through 15 months. An exception is Hiberix vaccine. Hiberix should only be used for the booster (final) dose, in children aged 12 months through 4 years, who have received at least 1 prior dose of Hib.¹

Rationale: Adding the brand names to the various Hib vaccines should help clarify for health care practitioners the types of Hib vaccines that are available and their dosage and timing of administration.

Catch-up Vaccination

If dose 1 was administered at ages 12 through 14 months, administer a *second (and final)* dose at least 8 weeks after dose 1.

If the first dose was administered at age 7 through 11 months, administer the second dose at least 4 weeks later and a *third (and final)* dose at age 12 through 15 months, regardless of Hib vaccine (PRP-T or PRP-OMP) used for first dose.

*For catch-up issues related to MenHibrix, see meningococcal vaccine footnotes and also MMWR March 22, 2013 / 62(RR02); 1-22, available at <http://www.cdc.gov/mmwr/pdf/rr/rr6202.pdf>.*¹

Rationale: This additional language helps to clarify how to administer the different brands of Hib vaccines and timing for catch-up vaccinations.

High-Risk Conditions

Children aged 12 through 59 months who are at increased risk for Hib disease including those with: anatomic or functional asplenia (including sickle cell disease), human immunodeficiency virus (HIV) infection, immunoglobulin deficiency, early component complement deficiency, or chemotherapy recipients, who have received either no doses or only one dose of Hib vaccine before 12 months of age should receive two additional doses of Hib vaccine 8 weeks apart; children who received two or more doses of Hib vaccine before 12 months of age should receive one additional dose.

Recipients of hematopoietic stem cell transplant (HSCT) should be revaccinated with a 3-dose regimen of Hib vaccine starting 6 months after successful transplant, regardless of vaccination history; doses should be administered at least 4 weeks apart.

For patients <60 months of age undergoing chemotherapy or radiation treatment who received Hib vaccine dose(s) within 14 days of starting therapy or during therapy, repeat the dose(s) at least 3 months following therapy completion.

A single dose of any licensed Hib conjugate vaccine should be administered to unimmunized older children (≥15 months) and adolescents undergoing an elective splenectomy; vaccine should be administered at least 14 days before procedure.*

Hib vaccine is not routinely recommended for patients older than 5 years of age. However one dose of Hib vaccine should be administered to unimmunized persons aged 5 years or older who have anatomic or functional asplenia (including sickle cell disease) and*

unvaccinated persons 5 through 18 years of age with human immunodeficiency virus (HIV) infection.

** Patients who have not received a primary series and booster dose or at least 1 dose of Hib vaccine after 14 months of age are considered unimmunized.¹*

Rationale: The addition of these paragraphs helps health care practitioners differentiate the use of the Hib vaccine for high-risk conditions.

Influenza Vaccine

For contraindications to the use of live attenuated influenza vaccine (LAIV), “see *MMWR* 2013; 62 (No. RR-7):1-43, available at <http://www.cdc.gov/mmwr/pdf/rr/rr6207.pdf>.”¹

Rationale: By adding the URL to the footnotes, vaccine administrators can directly access the website for the contraindications for LAIV.

For the 2014-2015 season, follow dosing guidelines in the 2014 ACIP influenza vaccine recommendations.¹

Rationale: Because of the different types of influenza vaccines (eg, intradermal, intramuscular, high dose, nasal) and the development of additional new vaccines, follow the ACIP guidelines for administration of the particular vaccination.

Next Steps

The ACIP and CDC submitted finalized guidelines to the American Academy of Pediatrics, American Academy of Family Physicians, and American Congress of Obstetricians and Gynecologists. The CDC will publish the guidelines on its website in January 2014, and *Pediatrics* and *American Family Physician* will publish them in February 2014.

Highlights of the 2014 Adult Vaccine Schedule Recommended Footnotes Changes

Influenza Vaccine

Annual vaccination against influenza is recommended for all persons aged 6 months and older.

Persons aged 6 months and older, including pregnant women *and persons with hives only allergy to eggs*, can receive the inactivated influenza vaccine (IIV).

An age-appropriate IIV vaccine formulation should be used.

Adults 18-49 years of age can receive the recombinant influenza vaccine (RIV) (FluBlok). RIV does not contain egg protein.

Healthy, nonpregnant persons aged 2-49 years without high-risk medical conditions can receive either intranasally administered live, attenuated influenza vaccine (LAIV) (FluMist), or IIV. Healthcare personnel who care for severely immunocompromised persons (i.e., those who require care in a protected environment) should receive IIV or *RIV* rather than LAIV.

The intramuscularly or intradermally administered IIV are options for adults aged 18-64 years.

Adults aged 65 years and older can receive the standard dose IIV or the high-dose IIV (Fluzone High-Dose).²

Rationale: This language helps to explain the use of the IIV in patients with mild egg allergy and the use of RIV (FluBlok) for patients with more severe egg allergy without the need for an allergist consultation. The footnotes also expound on the non-bias of the ACIP as to which approved influenza vaccine should be administered.

Td/Tdap Vaccine

Administer one dose of Tdap vaccine to pregnant women during each pregnancy (preferred during 27-36 weeks' gestation), regardless of *time interval* since prior Td or Tdap vaccination.

Persons aged 11 years and older who have not received Tdap vaccine or for whom vaccine status is unknown should receive a dose of Tdap followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter. Tdap can be administered regardless of interval since the most recent tetanus or diphtheria-toxoid containing vaccine.

Repeat doses of Tdap are not recommended except during every pregnancy.²

Rationale: These footnotes help to clarify the use of Tdap in adolescents and emphasize the use of Tdap during pregnancy.

Varicella Vaccine

Evidence of immunity to varicella in adults *being considered for vaccination* includes any of the following:

1. documentation of 2 doses of varicella vaccine at least 4 weeks apart
2. U.S.-born before 1980 except health-care personnel, and pregnant women
3. history of varicella based on diagnosis or verification of varicella disease by a health-care provider
4. history of herpes zoster based on diagnosis or verification of herpes zoster disease by a health-care provider
5. laboratory evidence of immunity or laboratory confirmation of disease²

Rationale: This footnote details the evidence of immunity, which includes a health care provider's diagnosis, which is not the case for the diagnosis of measles and mumps.

HPV Vaccine

A complete series for either HPV4 or HPV2 consists of 3 doses. The second dose should be administered 4-8 weeks after the first dose; the third dose should be administered at least 12 weeks after the second dose and at least 6 months (24 weeks) after the first dose.²

Rationale: This change in the footnote harmonizes language similar to the pediatric schedule about intervals between first and second, second and third, and first and third doses.

Herpes Zoster Vaccine

A single dose of zoster vaccine is recommended for adults aged 60 years and older regardless of whether they report a prior episode of herpes zoster. Although the vaccine is licensed by the Food and Drug Administration (FDA) for use among and can be administered to persons aged 50 years and older, ACIP recommends that vaccination begins at age 60 years.

Persons aged 60 years and older with chronic medical conditions may be vaccinated unless their condition constitutes a contraindication, such as pregnancy or severe immunodeficiency.²

Rationale: The statement about health care practitioners not being a specific indication for vaccination will be deleted. On the basis of the unknown longevity of the herpes zoster vaccine, only those aged 60 years or older should be given the zoster vaccine, even though the FDA approved the vaccine for individuals aged 50 years or older.

Pneumococcal Vaccine

When PCV13 is also indicated, PCV13 should be given first. When indicated, PPSV23 vaccine should be administered to patients who are uncertain of their vaccination status and there is no record of vaccination.²

Rationale: This footnote emphasizes the need to administer PCV13 before a PPSV23 vaccine, if possible. If the PCV13 is being administered after a PPSV23, there should be a year interval between vaccinations. If the PPSV23 is administered after the PCV13, the interval is 2 months.

Meningococcal Vaccine

Administer 2 doses of **quadrivalent** meningococcal conjugate vaccine (MCV4) at least 2 months apart to adults of all ages with functional asplenia or persistent complement component deficiencies.²

Rationale: This footnote emphasizes the need for use of a quadrivalent meningitis vaccine in adult patients with high risk.

HIV infection is not an indication for routine MCV4 vaccination. If an HIV infected person of any age is vaccinated, 2 doses of MCV4 vaccine should be administered at least 2 months apart.

Administer a single dose of meningococcal vaccine to microbiologists routinely exposed to isolates of *Neisseria meningitidis*, military recruits, **persons at risk during an outbreak attributable to a vaccine serogroup**, and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic.

MCV4 is preferred for adults with any of the preceding indications who are aged 55 years and younger as well as for adults aged 56 years and older who a) were vaccinated previously with MCV4 and are recommended for revaccination or b) for whom multiple doses are anticipated. Meningococcal polysaccharide vaccine (MPSV4 = Menomune by Sanofi) is preferred for adults age 56 years and older who have not received MCV4 previously and who require a single dose only (e.g., travelers).

Revaccination with MCV4 every 5 years is recommended for adults previously vaccinated with MCV4 or MPSV4 who remain at increased risk for infection (e.g., adults with anatomic or functional asplenia, persistent complement component deficiencies, or microbiologists).²

Rationale: This footnote explains the issue of HIV-infected persons and the use of the MCV4 vaccine and redefines the use of the MCV4 for those at risk during an outbreak and with other high-risk conditions.

Hib Vaccine

1 dose of Hib vaccine should be administered to persons who have functional or anatomic asplenia, sickle cell disease, or are undergoing elective splenectomy, if they have not previously received

Hib vaccine. Hib vaccination 14 or more days before splenectomy is suggested. Recipients of hematopoietic stem cell transplant (HSCT) should be vaccinated with a 3-dose regimen 6 months after successful transplant, regardless of vaccination history; at least 4 weeks should separate doses.

Hib vaccine is not recommended for adults with HIV infection since their risk of Hib infection is low.²

Rationale: Because adults are not typically at risk for Hib infection, these footnotes add the need for Hib vaccine for individuals with certain high-risk conditions but does not include HIV-infected individuals.

Next Steps

The 2014 adult schedule recommendations were reviewed by the American Academy of Family Physicians, the American College of Physicians, the American Congress of Obstetricians and Gynecologists, and the American College of Nurse Midwives. It has been submitted to the CDC's *MMWR* and will be published in *Annals of Internal Medicine* and *MMWR* in early February 2014.

Conclusion

The footnotes of the vaccination schedule are very important and define the ACIP-recommended timing and use of preventive vaccinations. The 2014 vaccination schedule recommendations include the new ACIP-approved meningococcal vaccinations, add the Hib vaccine to the adult schedule, and clarify the use and timing of vaccinations in various situations. Health care practitioners must stay abreast of approved preventive immunizations to provide patients with correct and updated advice. (doi:10.7556/jaoa.2014.017)

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