

NEEDLE TIPS

from the Immunization Action Coalition — www.immunize.org

Let's Review! Healthy Patients Age 65 and Older Need Two Pneumococcal Vaccines Spaced One Year Apart

Despite the fact that more than a year has elapsed since the Centers for Disease Control and Prevention (CDC) first published its recommendations for use of two different pneumococcal vaccines (Pneumovax [pneumococcal polysaccharide vaccine, PPSV23, Merck] and Prevnar [pneumococcal conjugate vaccine, PCV13, Pfizer] and Pneumovax [pneumococcal polysaccharide vaccine, PPSV23, Merck]) in healthy adults age 65 years and older, confusion abounds about the details of these recommendations.

The Immunization Action Coalition (IAC) receives frequent inquiries about the use of pneumococcal vaccines in older adults, including “Can I give the two vaccines at the same visit?” or “How many months should I wait between doses of the two vaccines?” IAC’s website for healthcare professionals, www.immunize.org, continues to receive large numbers of visitors to its feature section “Ask the Experts” (ATE) (www.immunize.org/askexperts), where CDC experts answer questions about vaccines. The pneumococcal section

of ATE has been visited at a rate nearly three times that of any other ATE section, with more than 20,000 visits in January alone.

Let’s review the details of these recommendations. In 2014, followed by an update in 2015, CDC published the following recommendations for the use of two pneumococcal vaccines in healthy adults age 65 years and older:¹

- Administer 1 dose of **Prevnar** (PCV13) to people age 65 years and older if they have not received a dose in the past.
 - One year later, administer 1 dose of **Pneumovax** (PPSV23).
- If your patient already received a dose of **Pneumovax** at age 65 or older:
 - You don’t need to repeat **Pneumovax**.
 - However, make sure that all your patients age 65 and older who have not yet had **Prevnar** receive one dose at least a year after the **Pneumovax** dose.

(For patients who received any pneumococcal vaccine doses prior to age 65, see footnote 2.)

In February, CDC published “Recommended Adult Immunization Schedule, U.S., 2016 (see www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf). The pneumococcal vaccine recommendations are fully documented in the schedule and its highly detailed footnotes.

Medicare Part B fully covers pneumococcal vaccines. Both Prevnar and Pneumovax are covered under Part B for Medicare recipients age 65

years and older, as long as recommended spacing intervals are honored between vaccine doses.

Please make sure your patients are vaccinated according to CDC recommendations with pneumococcal vaccines. And patients 65 and older may be behind on other routinely recommended vaccines. Remember to check your patient’s immunization status for zoster and Tdap, as well as annual influenza vaccine.

FOOTNOTES

1 The 2014 recommendations titled “Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years: Recommendations of ACIP” are available at www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm. The 2015 recommendations titled “Intervals Between PCV13 and PPSV23 Vaccines: Recommendations of ACIP” are available at www.cdc.gov/mmwr/preview/mmwrhtml/mm6434a4.htm.

2 For patients vaccinated prior to age 65 due to high-risk conditions:

- If your patient received a dose of **Prevnar** at an age younger than 65:
 - You do not need to repeat **Prevnar**.
 - Administer **Pneumovax** at age 65 years, allowing at least a 1-year interval between it and the earlier dose of **Prevnar**.
- If your patient received **Pneumovax** at an age younger than 65:
 - You need to administer another dose of **Pneumovax** at age 65 or later (and at least 5 years after the last dose), but first administer **Prevnar** if your patient hasn’t had a dose, and then administer **Pneumovax** one year after the **Prevnar** dose.

to ensure they receive the PCV13 dose first? Or should the provider not miss an opportunity to give the PPSV23 and refer patients elsewhere for PCV13 in a year?

The Advisory Committee on Immunization Practices (ACIP) recommends that pneumococcal vaccine-naïve people age 65 years and older should

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Ask the Experts

The Immunization Action Coalition extends thanks to our experts, medical officer Andrew T. Kroger, MD, MPH, and nurse educator Donna L. Weaver, RN, MN, both with the National Center for Immunization and Respiratory Diseases at the Centers for Disease Control and Prevention (CDC).

Pneumococcal vaccines

If a provider does not yet stock pneumococcal conjugate vaccine (PCV13, Prevnar 13, Pfizer) for adults age 65 years and older but stocks pneumococcal polysaccharide vaccine (PPSV23, Pneumovax 23, Merck), should that provider refer patients to another provider

Immunization questions?

- ▶ Email nipinfo@cdc.gov
- ▶ Call your state health department (phone numbers at www.immunize.org/coordinators)

Needle Tips

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receive PCV13 first, followed by PPSV23 one year later. If the provider is unwilling to stock PCV13, then patients should be referred elsewhere to get PCV13 first. The solution, of course, is to stock PCV13 and PPSV23, both of which are covered by Medicare Part B.

We have a healthy 66-year-old patient who received a dose of PPSV23 in January then received a dose of PCV13 five months later at a different facility. Should the PCV13 dose be repeated since it was given earlier than the 1-year interval recommended by ACIP?

ACIP recommends that healthy people age 65 years and older receive PCV13 first, then PPSV23 one year later. When PPSV23 has been given first, ACIP recommends an interval of one year before giving PCV13. What to do when doses of PPSV23 and PCV13 are given without the recommended minimum interval is not addressed in the ACIP recommendations. The CDC subject matter experts have advised that in such a case, the dose given second does not need to be repeated. This is an exception to the usual procedure for a minimum interval violation as described in ACIP's *General Recommendations on Immunization* (see www.cdc.gov/mmwr/pdf/rr/rr6002.pdf, page 5). There is no evidence to support that there are benefits to repeating the dose of PCV13. Information about the recommended intervals between pneumococcal vaccines can be found at www.cdc.gov/mmwr/pdf/wk/mm6434.pdf, pages 944-7.

Diabetes is an indication for giving PPSV23 to patients younger than age 65 years. Does this include both insulin- and non-insulin-dependent diabetes?

Any diagnosis of diabetes, whether type 1 or type 2, is an indication for PPSV23. However, gestational diabetes does not qualify as an indication for PPSV23.

For adults without high-risk conditions, a 1-year interval is recommended between PCV13 and PPSV23 vaccines. What is the definition of a year? Does it need to be exactly one year? We have provided PCV13 to some individuals during flu season this year and told them to get the PPSV23 next year when they get their flu shot. What if they received their flu shot in November this year, but return for their flu shot in October next year? What you describe is an excellent strategy for administration of PCV13 and PPSV23 to people age 65 years and older. ACIP does not define "one year" but this is

IAC's "Ask the Experts" team from the Centers for Disease Control and Prevention



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assumed to be one calendar year. Receiving PPSV23 a few days or weeks earlier than one calendar year after PCV13 is not a medical problem. However, it could be a problem for reimbursement since Medicare will only pay for both vaccines if they are given at least 11 months apart. Private insurance may have similar rules. Here is the wording from the Centers for Medicare and Medicaid (CMS):

"An initial pneumococcal vaccine may be administered to all Medicare beneficiaries who have never received a pneumococcal vaccine under Medicare Part B. A different, second pneumococcal vaccine may be administered 1 year after the first vaccine was administered (i.e., 11 full months have passed following the month in which the last pneumococcal vaccine was administered)."

Why is there no recommendation for patients older than 65 years to get a booster dose of PPSV23 if they first received it at age 65 years or older? It seems to me that their protection against pneumococcal disease would benefit from a booster dose of PPSV23 five or ten years after the first dose.

People age 65 and older should be given a second dose of PPSV23 if they received the first dose 5 or more years previously and were younger than 65 years at the time of the first vaccination. Protection from a single dose of PPSV23 at age 65 years or older is believed to persist for 5-10 years. The benefit and safety of a second dose given after age 65 years is uncertain. Until such data are available, ACIP recommends only a single dose at age 65 years or older.

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I have a patient who takes adalimumab (Humira) for rheumatoid arthritis. Does a person who takes adalimumab meet the definition of immunosuppression for the purposes of PCV13 vaccination?

Adalimumab is a potent anti-inflammatory drug that blocks the activity of tumor necrosis factor (TNF). Adalimumab is considered immunosuppressive because serious infections have been reported in people taking the drug, including tuberculosis and infections caused by viruses, fungi, or bacteria. Consequently, a person taking adalimumab or other drugs that affect TNF activity (such as infliximab [Remicade], certolizumab pegol [Cimzia], golimumab [Simponi], or etanercept [Enbrel]) should be considered to have immunosuppression and receive PCV13.

A healthy child received only one dose of PCV at age 10 months. She is now 6 years old. Our state requires one dose of PCV13 after the first birthday for school attendance. Her physician says because she is older than 59 months, she does not need another dose of PCV13. What should we do in this situation?

ACIP does not recommend routine PCV13 vaccination of healthy children 60 months of age or older. If there is a school requirement, the simplest solution is to give the child one dose of PCV13. However, health insurance may not pay for this dose. For more information on the ACIP recommendations for pneumococcal vaccination of children, go to www.cdc.gov/mmwr/pdf/rr/rr5911.pdf.

Hepatitis B vaccine

An 18-year-old with a documented hepatitis B series as a child was seen for a school-required titer of antibody to hepatitis B surface antigen (anti-HBs). She has juvenile rheumatoid arthritis and receives immunoglobulin (IG) infusions every month. Her last treatment with an IG infusion was three weeks prior to her blood draw. The anti-HBs titer was positive. Could the IG infusion from three weeks ago cause her anti-HBs to be false positive? If so, how long should she wait to have another anti-HBs drawn?

ACIP does not address this issue but it is not likely that standard IG (as opposed to hepatitis B immune globulin

[HBIG]) would cause a false positive anti-HBs. So if the anti-HBs was 10 mIU/mL or higher, the patient can be assumed to be immune to hepatitis B.

A physician ordered a 40-mcg dose of hepatitis B vaccine for a hemodialysis patient. The clinic does not stock the Recombivax HB 40-mcg/dose dialysis formulation (Merck) and would like to give 2 doses of Engerix-B 20-mcg/dose (GSK) for each dose in the series. Is this acceptable?

Yes. If given on the same day as separate injections in separate sites, two Engerix-B 20-mcg doses can be counted as the equivalent of one Recombivax HB 40-mcg dose. According to the package insert, Engerix-B is licensed for use in this manner. Vaccine package inserts for all vaccines are available at www.immunize.org/packageinserts.

Meningococcal ACWY vaccines

I have an HIV-positive 64-year-old patient who received meningococcal conjugate vaccine last week. Was this the correct vaccine for this patient or should he have gotten MPSV4 due to his age? Also, should this patient get another dose in 2 months?

Quadrivalent meningococcal conjugate vaccine (MenACWY [MCV4]: Menactra, Sanofi Pasteur; Menveo, GSK) was the correct vaccine in this situation. The 2013 ACIP recommendations on meningococcal vaccination recommend the use of meningococcal conjugate vaccine in adults age 56 years and older who (1) were vaccinated previously with MenACWY and now need revaccination, or (2) are recommended to receive multiple doses. ACIP does not consider HIV infection alone to be an indication for MenACWY vaccine. However, if the decision is made to vaccinate a person with HIV infection, the patient should receive 2 doses of MenACWY separated by 8–12 weeks. Both MenACWY vaccines are licensed for use in people through age 55 years, which means that the use of these vaccines in people age 56 and older is off-label but recommended by ACIP.

We have a 68-year-old who has been asplenic since 2009. She had one dose of meningococcal polysaccharide vaccine (MPSV4, Menomune, Sanofi Pasteur) in 2009, but no subsequent dose. She is now due for a booster. Should she receive 2 doses of MenACWY, 2 months apart, to catch up, or just one dose?

This situation is not addressed in the most recent ACIP guidelines for meningococcal conjugate vaccine. It is the CDC meningococcal subject matter expert's opinion that this patient should receive 2 doses of MenACWY separated by at least 8 weeks, followed by a booster dose of MenACWY every 5 years thereafter. The concern is that having had only MPSV4 previously, she may not have an adequate booster response to a single dose of MenACWY.

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Meningococcal B vaccines

I know the schedule for Trumenba (meningococcal serogroup B vaccine, Pfizer) is 0, 2, and 6 months. What are the MINIMUM intervals between doses of Trumenba and Bexsero (meningococcal serogroup B vaccine, GSK)? Our immunization information system needs to know the minimum intervals in order to assure that patients are appropriately vaccinated.

Neither ACIP nor the CDC meningococcal subject matter experts have addressed this issue. Given the lack of guidance, we must assume that the routine intervals are also the minimum intervals: for Trumenba, 8 weeks between doses 1 and 2, 4 months between doses 2 and 3, and 6 months between doses 1 and 3; for Bexsero, 4 weeks between doses 1 and 2. It is important to use these intervals when scheduling doses. However, if these intervals are violated, the doses still count and do not need to be repeated.

I have a patient who was given Trumenba in August. Two months later she was given a dose of Bexsero. How should I proceed with her MenB vaccination series? We stock both vaccines.

The ACIP meningococcal serogroup B vaccine recommendations (www.cdc.gov/mmwr/pdf/wk/mm6441.pdf, pages 1171–6) state that the same vaccine must be used for all doses in the MenB series. So the clinician needs to complete a series with one or the other vaccine. If a person has already received 1 dose of Bexsero and one of Trumenba, then pick a brand and finish a recommended schedule with that brand. Ignore the extra dose of the other product. The next dose in the series (either Trumenba or Bexsero) should be separated from the previous dose of Bexsero by at least 1 month.

My 8-year-old patient had a bone marrow transplant and has just finished the post-transplant re-vaccination process. Should I offer her vaccination with a MenB vaccine now or wait two years until she is 10 years old?

Neither brand of meningococcal B vaccine is approved by FDA or recommended by ACIP for people younger than age 10 years. You should defer meningococcal B vaccination until she is 10 years of age.

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DTaP/Tdap vaccines

Can Quadracel (DTaP-IPV, Sanofi Pasteur) be used to complete a series with vaccines other than Daptacel (DTaP, Sanofi Pasteur) or Pentacel (DTaP-IPV-Hib, Sanofi Pasteur)?

ACIP recommends the same brand of DTaP be used for all doses but that a different brand can be used if necessary. So Quadracel can be used in a series with another brand of DTaP if necessary. CDC published a short *MMWR* article about Quadracel on Sept. 4, 2015 (www.cdc.gov/mmwr/pdf/wk/mm6434.pdf, pages 948–9).

There is a debate within my clinical department about not allowing influenza vaccine to be given with DTaP and PCV13. Are there data that state these should not be given concomitantly?

A CDC study has shown a small increased risk for febrile seizures during the 24 hours after a child receives the inactivated influenza vaccine at the same time as the PCV13 vaccine or DTaP vaccine. However, the risk of febrile seizure with any combination of these vaccines is small and ACIP recommends giving these vaccines at the same visit if indicated. See www.cdc.gov/vaccinesafety/concerns/febrile-seizures.html for more information.

One of our staff inadvertently gave Tdap to an infant instead of DTaP. Now what should be done?

If Tdap was inadvertently administered to a child younger than 7 years of age, it should not be counted as either the first, second, or third dose of DTaP. The dose should be repeated with DTaP. Continue vaccinating on schedule. If the dose of Tdap was administered for the fourth or fifth DTaP dose, the Tdap dose can be counted as valid. Please remind your staff to always check the vaccine vial at least three times before administering any vaccine.

We would like to avoid stocking both Tdap and Td vaccines. Is CDC likely to recommend that Tdap completely replace Td in the immunization schedule in the near future?

Currently, ACIP recommends giving only 1 dose of Tdap to adolescents and adults who have not previously received the vaccine, with the exception of pregnant women, who should be vaccinated during each pregnancy. ACIP is unlikely to recommend routine Tdap revaccination for groups other than pregnant women. Vaccine providers will need to continue to stock Td vaccine in order to administer it to patients who need to complete the full primary 3-dose tetanus and diphtheria series and also to administer 10-year booster doses of Td throughout the lifetime of those who have completed the primary series. Note that if a person who previously received Tdap needs a booster dose of Td (as a routine booster dose or for wound management), it is acceptable to administer Tdap if Td is not available.

Zoster vaccine

I know that ACIP only recommends zoster vaccine for adults age 60 years and older, although it is licensed for use in those 50 years and older. If I choose to vaccinate patients age 50–59 years, are there any criteria as to which patients in this age group might benefit most from zoster vaccination?

For vaccination providers who choose to use zoster vaccine among certain patients age 50 through 59 years despite the absence of an ACIP recommendation, factors that might be considered include particularly poor anticipated tolerance of herpes zoster or postherpetic neuralgia symptoms (e.g., attributable to preexisting chronic pain, severe depression, or other comorbid conditions; or inability to tolerate treatment medications because of hypersensitivity or interactions with other chronic medications). More information on this issue is available at www.cdc.gov/mmwr/pdf/wk/mm6044.pdf, page 1528.

We have an 18-year-old male patient with a history of chickenpox disease. He now has shingles. We are unsure what to advise for future vaccination. Should we administer zoster vaccine?

ACIP does not recommend zoster vaccination for people younger than age 60 years regardless of their history of shingles. Zoster vaccine is licensed by FDA for people age 50 years and older so a clinician may choose to vaccinate a person 50–59 years of age. Insurance may not pay for a dose of zoster vaccine given to a person younger than age 60 years.

My patient is a 66-year-old male with a condition that requires treatment with intravenous immune globulin (IVIG) once a month. Can he receive zoster vaccine?

Yes. The concern about interference by circulating antibody (from the IVIG) with varicella vaccine does not apply to zoster vaccine. The amount of antigen in zoster vaccine is high enough to offset any effect of circulating antibody. Also, studies of zoster vaccine were performed on patients who had circulating antibody (because they had varicella earlier in life) or who had received antibody-containing blood products and there was no appreciable effect on efficacy. Some patients who receive IVIG are immunosuppressed. Since immunosuppression is a contraindication to zoster vaccine, it is important to screen to ensure a patient is not immunosuppressed when administering zoster vaccine.

Before administering zoster vaccine is it necessary to ask if the person has ever had chickenpox or shingles?

No. All people age 60 years or older, whether they have a history of chickenpox or shingles or not, should be given zoster vaccine unless they have a medical contraindication to vaccination.

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For patients age 60 or older who don't remember having chickenpox in the past, should we test them for varicella immunity before giving zoster vaccine?

No. Simply vaccinate them with zoster vaccine according to the ACIP recommendations.

We weren't familiar with the recommendation (not to test) and tested a 60-year-old for varicella antibody because she said she never had chickenpox. Her result was negative. Should this patient receive zoster vaccine or varicella vaccine?

In this situation, since you've tested the patient and the results were negative, the patient should receive varicella vaccine. A person age 60 years or older who has no medical contraindications is eligible for zoster vaccine, regardless of their memory of having had chickenpox. However, if an adult age 60 years or older is tested for varicella immunity for whatever reason, and the test is negative, he/she should be given 2 doses of varicella vaccine at least 4 weeks apart, not zoster vaccine. It is important to note that at the current time, zoster vaccine is not recommended for individuals whose varicella immunity is based on vaccination. See www.cdc.gov/vaccines/vpd-vac/shingles/hcp-vaccination.htm for more information.

General vaccine questions

We have a question concerning delaying vaccinations for an infant born to a heroin-addicted mother. We had a foster parent come into our health department requesting only certain vaccines for a 3-month-old, stating that the private physician recommends delaying the schedule due to the possible residual effects of the heroin. The baby appeared to be healthy.

Heroin use or addiction of the mother is not a reason to delay vaccination of an otherwise healthy infant.

What is the provider's liability when using standing order protocols?

While you did not say this explicitly, we assume the concern is about a vaccine injury in a person who was vaccinated using a standing order. Of course, as long as the person is properly screened for contraindications and precautions, an injury from a vaccine is very unlikely. In the event that an injury does occur, the National Vaccine Injury Compensation Program (VICP) provides liability protection for the vaccinator and the clinician who signed the standing order for any vaccine that is covered by the vaccine injury compensation program (all vaccines that are routinely administered to children are covered by the program for all ages of patients). More information about the VICP is available on their website at www.hrsa.gov/vaccine-compensation/index.html.

Ask the Experts

About IAC's Question of the Week

Each week, *IAC Express* highlights a new, topical, or important-to-reiterate Q&A. This feature is a cooperative venture between IAC and CDC. William L. Atkinson, MD, MPH, IAC's associate director for immunization education, chooses a new Q&A to feature every week from a set of Q&As prepared by experts at CDC's National Center for Immunization and Respiratory Diseases.

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To find the healthcare settings listed by state, visit www.immunize.org/honor-roll/influenza-mandates/honorees.asp

To read position statements supporting mandatory HCP vaccination from leading healthcare organizations and professional medical societies or to apply, visit www.immunize.org/honor-roll/influenza-mandates

The protective cap on a single-dose vial was removed but the vaccine was not needed. No needle punctured the rubber seal. According to CDC's Vaccine Storage & Handling Toolkit, the vial without the cap should be discarded at the end of workday. If no needle punctured the seal, what is the reasoning for discarding the vaccine?

Removing the protective cap increases the likelihood the septum or stopper could be punctured.

The puncture may not be visible. It is important to ensure that the rubber seal on single-dose vials is not punctured because single-dose vials do not contain a preservative. Once the protective cap has been removed, the vaccine should be discarded at the end of the workday because it may not be possible to determine if the rubber seal has been punctured. CDC's Vaccine Storage & Handling Toolkit is available at www.cdc.gov/vaccines/recs/storage/toolkit.