

# NEEDLE TIPS

from the Immunization Action Coalition — [www.immunize.org](http://www.immunize.org)

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## New ACIP recommendations for HPV, influenza, MenB, typhoid, and yellow fever vaccines. Make sure you're up to date!

An abundance of new guidance has recently been issued for the use of vaccines by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) in 2015 and more will be published soon. The guidance covers the use of 9-valent human papillomavirus vaccine (9vHPV, Gardasil 9, Merck); meningococcal serotype B vaccines (MenB: Bexsero, GlaxoSmithKline; Trumenba, Pfizer); influenza vaccines, typhoid vaccines (Typhim Vi, Sanofi Pasteur; Vivotif, PaxVax) and yellow fever vaccine (YF, YF-VAX, Sanofi-Pasteur).

The following provides a brief summary of the recent changes voted upon at the February ACIP meeting, as well as recommendations recently published in *Morbidity and Mortality Weekly Report (MMWR)*.

### Human papillomavirus vaccine

On March 27, *MMWR* published "Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the ACIP."

The new 9vHPV vaccine is recommended for use along with the other HPV vaccines already recommended for use by ACIP. The recommendations include HPV vaccination of all boys and

girls at age 11 or 12 years, with HPV vaccine use recommended for females through age 26 and for males through age 21, as well as for men through age 26 who are immunocompromised or who have sex with men. For females, the 2-valent (2vHPV, Cervarix, GlaxoSmithKline), 4-valent (4vHPV, Gardasil, Merck), or 9-valent (9vHPV) HPV vaccines may be used. For males, either 4vHPV or 9vHPV should be administered. Any recommended HPV vaccine, including 9vHPV, may be used to complete a previously begun HPV vaccine series. Updated ACIP HPV recommendations are available online at [www.cdc.gov/mmwr/pdf/wk/mm6411.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf), pages 300–304.

### Influenza vaccine

At its February meeting, ACIP voted to approve its annual influenza vaccine recommendations for the 2015–2016 influenza season. The committee reaffirmed the need for annual influenza vaccination for all people age 6 months and older. Based on new data, ACIP removed the previously recommended preference for the use of live attenuated influenza vaccine (LAIV, FluMist, AstraZeneca) in children age 2 through 8 years, noting

**Recommendations...** continued on page 5 ►

## 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).

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### HPV vaccine

#### Which types of HPV are most likely to cause disease?

Of the annual average of 26,900 HPV-related cancers in the United States, approximately 64% are attributable to HPV 16 or 18 (65% for females; 63% for males; approximately 21,300 cases annually), which are included in all three HPV vaccines. Approximately 10% are attributable to HPV types 31, 33, 45, 52, and 58 (14% for females; 4% for males; approximately 3,400 cases annually), which are included in the 9-valent HPV vaccine. HPV type 16, 18, 31, 33, 45, 52, or 58 account for about 81% of cervical cancers in the United States.

Approximately 50% of cervical precancers (CIN2 or greater) are caused by HPV 16 or 18 and 25% by HPV 31, 33, 45, 52, or 58. HPV 6 or 11 cause 90% of anogenital warts (condylomata) and most cases of recurrent respiratory papillomatosis.

More information about HPV and HPV-related cancers is available in the 2014 HPV ACIP statement at [www.cdc.gov/mmwr/pdf/rr/rr6305.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf).

### Are healthcare personnel at risk of occupational infection with HPV?

Occupational infection with HPV is possible. Some HPV-associated conditions (including anogenital and oral warts, anogenital intraepithelial neoplasias, and recurrent respiratory papillomatosis) are treated with laser or electrosurgical procedures that could produce airborne particles. These procedures should be performed in an appropriately ventilated room using standard precautions and local exhaust ventilation. Workers in HPV research laboratories who handle wild-type virus or "quasi virions" might be at risk of acquiring HPV from occupational exposures. In

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### Immunization questions?

- Email [nipinfo@cdc.gov](mailto:nipinfo@cdc.gov)
- Call your state health department (phone numbers at [www.immunize.org/coordinators](http://www.immunize.org/coordinators))

the laboratory setting, proper infection control should be instituted including, at minimum, bio-safety level 2. Whether HPV vaccination would be of benefit in these settings is unclear because no data exist on transmission risk or vaccine efficacy in this situation.

**Please summarize information about Merck's new 9-valent HPV vaccine (9vHPV, Gardasil 9).** 9vHPV contains the four HPV types in 4vHPV (Gardasil; 16, 18, 6, and 11) and 5 additional "high risk" types (31, 33, 45, 52, and 58). It was licensed by the U.S. Food and Drug Administration (FDA) on December 10, 2014. 9vHPV is approved for use in females 9 through 26 years and males 9 through 15 years (Merck has subsequently submitted clinical trial data to the FDA for males 16 through 26 years of age). 9vHPV has the same schedule as 4vHPV (three intramuscular doses spaced 0, 1, and 6 months apart). In a clinical trial comparing 9vHPV to 4vHPV, 9vHPV reduced the risk of disease caused by the 5 additional strains by 97%. ACIP states that clinicians can administer either 4vHPV or 9vHPV to males through age 26 years to complete the HPV vaccine series.

**With the availability of 9vHPV, has the ACIP changed its recommendations for HPV vaccines?**

The ACIP recommendations for HPV vaccination have not changed. ACIP recommends that routine HPV vaccination be initiated for females and males at age 11 or 12 years. The vaccination series can be started as early as age 9 years. Vaccination is also recommended for females aged 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. In addition, vaccination is recommended for men age 22 through age 26 years who 1) have sex with men or 2) are immunocompromised as a result of infection (including HIV), disease, or medication. Other males 22 through 26 years of age may be vaccinated at the clinician's discretion.

Vaccination of females is recommended with 2vHPV (Cervix, GlaxoSmithKline), 4vHPV (as long as this formulation is available), or 9vHPV. Vaccination of males is recommended with 4vHPV (as long as this formulation is available) or 9vHPV. Ideally, HPV vaccine should be administered before potential exposure to HPV through sexual contact.

All 3 HPV vaccines should be given as a 3-dose schedule, with the second dose given 1 to 2 months after the first dose and the third dose 6 months after the first dose.

The 2014 ACIP recommendations are available at [www.cdc.gov/mmwr/pdf/rr/rr6305.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf) (covers 2vHPV and 4vHPV), and the newly released 2015 ACIP recommendations (published March 27, 2015) are at [www.cdc.gov/mmwr/pdf/wk/mm6411.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf), pages 300–304 (covers 9vHPV).

**Can an HPV vaccine series begun with 2vHPV or 4vHPV be completed with 9vHPV?**

Yes. Any available HPV vaccine may be used to continue or complete the series for females. 9vHPV or 4vHPV may be used to continue or complete the series for males. However, receiving fewer than 3 doses of 4vHPV or 9vHPV may provide less protection against genital warts caused by HPV types 6 and 11 than the usual 3-dose series. There are no data on the efficacy of the 5 additional HPV types included in 9vHPV if the person receives fewer than 3 doses.

**Does ACIP recommend revaccination with 9vHPV for patients who previously received a series of 2vHPV or 4vHPV?**

ACIP has not recommended routine revaccination with 9vHPV for persons who have completed a series of another HPV vaccine. There are data that indicate revaccination with 9vHPV after a series of 4vHPV is safe. Clinicians should decide if the benefit of immunity against 5 additional oncogenic strains of HPV is justified for their patients.

**Is 9vHPV included in the Vaccines For Children (VFC) program?**

Yes.

**Do women and men whose sexual orientation is same-sex need HPV vaccine?**

Yes. HPV vaccine is recommended for females and males regardless of their sexual orientation.

**If a dose of HPV vaccine is significantly delayed, do I need to start the series over?**

No, do not restart the series. You should continue where the patient left off and complete the series.

**To accelerate completion of the HPV vaccine series, can doses be given at 0, 1, and 4 months?**

No, there is no accelerated schedule for completing the HPV vaccine series. You should follow the recommended schedule of 0, 1–2, and 6 months.

**What are the minimum intervals between doses of HPV vaccine?**

Minimum intervals are used when patients have fallen behind on their immunization schedule or when they need their dosing schedule expedited (for example, if there is imminent travel). The minimum interval between the first and second doses of HPV vaccine is 4 weeks. The minimum interval between the second and third dose is 12 weeks. ACIP recommends an interval of 24 weeks between the first and third dose. However, the third dose can be considered to be valid if it was separated from the first dose by at least 16 weeks and from the second dose by at least 12 weeks.

**If HPV vaccine is given subcutaneously instead of intramuscularly, does the dose need to be repeated?**

Yes. No data exist on the efficacy or safety of HPV vaccine given by the subcutaneous route. All data on efficacy and duration of protection are based on a 3-dose series given on the approved schedule

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



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and administered by the intramuscular route. In the absence of data on subcutaneous administration, the Centers for Disease Control and Prevention (CDC) and the manufacturers recommend that a dose of HPV vaccine given by any route other than intramuscular should be repeated. There is no minimum interval between the invalid (subcutaneous) dose and the repeat dose.

**If a patient has been sexually active for a number of years, is it still recommended to give HPV vaccine or to complete the HPV vaccine series?**

Yes. HPV vaccine should be administered to people who are already sexually active. Ideally, patients should be vaccinated before onset of sexual activity; however, patients who have already been infected with one or more HPV types still get protection from other HPV types in the vaccine that have not been acquired.

**I read that HPV vaccination rates are still low. What can we do as providers to improve these rates?**

Coverage levels for HPV vaccine are improving but are still inadequate. Results from the CDC's 2013 National Immunization Survey-Teen (NIS-Teen) indicate that HPV vaccination rates in girls age 13 through 17 years increased between 2012 and 2013. Just over 57% of girls age 13 through 17 years had started the series that they should have completed by age 13 years and 38% had completed the series. In 2013, 35% of boys age 13 through 17 years had received one dose but only 14% had received all three recommended doses. A summary of the 2013 NIS-Teen survey is available at [www.cdc.gov/mmwr/pdf/wk/mm6329.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6329.pdf), page 625–633.

Providers can improve uptake of this life-saving

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### Needle Tips correction policy

If you find an error, please notify us immediately by sending an email message to [admin@immunize.org](mailto:admin@immunize.org). We publish notification of significant errors in our email announcement service, *IAC Express*. Be sure you're signed up for this service. To subscribe, visit [www.immunize.org/subscribe](http://www.immunize.org/subscribe).

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vaccine in two main ways. First, studies have shown that missed opportunities are a big problem. Up to 88% (depending on year of birth) of girls unvaccinated for HPV had a healthcare visit where they received another vaccine such as Tdap, but not HPV. If HPV vaccine had been administered at the same visit, vaccination coverage for one or more doses could be 91% instead of 57%. Second, the 2013 NIS-Teen data show that not receiving a healthcare provider's recommendation for HPV vaccine was one of the five main reasons parents reported for not vaccinating their daughters and the number one reason for not vaccinating their sons.

CDC urges healthcare providers to increase the consistency and strength of how they recommend HPV vaccine, especially when patients are age 11 or 12 years. The following resources can help providers with these conversations.

- CDC's "Tips and Time-savers for Talking with Parents about HPV Vaccine," available at [www.cdc.gov/vaccines/who/teens/for-hcp-tipsheet-hpv.pdf](http://www.cdc.gov/vaccines/who/teens/for-hcp-tipsheet-hpv.pdf)

- IAC's "Human Papillomavirus HPV: A Parent's Guide to Preteen and Teen HPV Vaccination," available at [www.immunize.org/catg.d/p4250.pdf](http://www.immunize.org/catg.d/p4250.pdf)

For more detailed information about HPV vaccination strategies for providers, visit [www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html](http://www.cdc.gov/vaccines/who/teens/for-hcp/hpv-resources.html).

### ***If a 30-year-old female patient insists that she wants to receive HPV vaccine, can I give it to her?***

HPV vaccine is not FDA-licensed for use in women older than age 26 years. Studies have shown that the vaccine is safe in women age 27 years and older. ACIP does not recommend the use of this vaccine outside the FDA licensing guidelines unless the series was started but not completed by age 26 years. Clinicians may choose to administer HPV vaccine off-label to men and women age 27 years or older.

### ***What adverse events can be expected following HPV vaccine?***

In clinical trials involving more than 35,000 subjects, the most common adverse event was injection site pain, which was reported in 58% to 90% of recipients (depending on vaccine and dose number). Other local reactions, such as redness and/or swelling, were reported in 30% to 40% of recipients. Local reactions were reported more frequently among 9vHPV recipients than among 4vHPV recipients, probably because of the larger amount of aluminum adjuvant present in 9vHPV. Systemic reaction, such as fever, headache, and fatigue, were reported by 2% to 50% of recipients (depending on vaccine and dose number). These symptoms generally occurred at about the same rate in vaccine and placebo recipients.

### ***Do HPV vaccines cause fainting?***

Nearly all vaccines have been reported to be associated with fainting (syncope). Post-vaccination syncope has been most frequently reported after receipt of any of the three vaccines commonly given to adolescents (HPV, MCV4, and Tdap). However, it is not known whether the vaccines are responsible for post-vaccination syncope or if the association with these vaccines simply reflects the fact that adolescents are generally more likely to experience syncope.

Syncope can cause serious injury. Falls that occur due to syncope after vaccination can be prevented by having the vaccinated person seated or lying down. The person should be observed for 15 minutes following vaccination.

## MMR vaccine

***In regard to the current measles outbreak, some people are saying that children who have not had the vaccine should pose no threat to vaccinated people. It is my understanding that during an outbreak, vaccinated people can still contract it. Am I correct?***

You are correct that vaccinated people can still be infected with infections against which they are vaccinated. No vaccine is 100% effective. Vaccine effectiveness varies from greater than 95% (for diseases such as measles, rubella, hepatitis B) to much lower (influenza this year 23%, and 60% in years with a good match of wild and vaccine viruses, and the acellular pertussis vaccines after 5 years or so offer only about 70% protection). Therefore, we encourage as many people as possible to be vaccinated to avoid outbreaks, while working towards the development of better vaccines (such as for influenza and pertussis). More information is available for each vaccine and disease at [www.cdc.gov/vaccines/vpd-vac/default.htm](http://www.cdc.gov/vaccines/vpd-vac/default.htm) and [www.immunize.org/vaccines](http://www.immunize.org/vaccines).

***We received a call from a healthcare provider who inadvertently administered MMR vaccine to a woman who was 2 months pregnant. Please advise as to appropriate action steps.***

No specific action needs to be taken other than to reassure the woman that no adverse outcomes are expected as a result of this vaccination. MMR vaccination during pregnancy alone is not a reason to terminate a pregnancy. You should consult with the provider to determine if there is a way to avoid such vaccination errors in the future. Detailed information

about MMR vaccination in pregnancy is included in the most recent MMR ACIP statement, available at [www.cdc.gov/mmwr/pdf/rr/rr6204.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf).

## Hepatitis B vaccine

***If an infant got a dose of the adult formulation of hepatitis B vaccine in error, should the dose be counted? When should the next dose be scheduled for this infant? Do we need to be concerned about a possible adverse event?***

If an infant received an adult dose of hepatitis B vaccine (contains twice the antigen in a dose of the infant/child formulation), the dose can be counted as valid and does not need to be repeated. Hepatitis B vaccine is a very safe vaccine and no unusual adverse events would be expected because of this administration error. The next (age appropriate) dose should be given on the usual schedule.

## Meningococcal vaccine

***We have a 65-year-old male seeking vaccination due to international travel. Meningococcal polysaccharide vaccine (MPSV4, Menomune, Sanofi Pasteur) is unavailable, and we aren't sure when we can get it. How should we proceed? Is this a circumstance in which a conjugate vaccine is appropriate at his age?***

ACIP recommends off-label use of quadrivalent meningococcal conjugate vaccine (MCV4: Menactra, Sanofi Pasteur; Menveo, GlaxoSmithKline) in adults age 56 years and older who (1) were vaccinated previously with MCV4 and now need revaccination or (2) are recommended to receive multiple doses (e.g., adults with asplenia, microbiologists working with *Neisseria meningitidis*). Although MPSV4 is recommended in the situation you describe, it is acceptable to use MCV4 if MPSV4 is not available.

## Asplenia and vaccines

***Do any of the bacterial vaccines that are recommended for people with functional or anatomic asplenia need to be given before splenectomy? Do the doses count if they are given during the 2 weeks prior to surgery?***

Pneumococcal conjugate vaccine (PCV13, Prevnar 13, Pfizer), *Haemophilus influenzae* type b vaccine (Hib), meningococcal conjugate vaccine (MCV4), and meningococcal B vaccine should be given 14 days before splenectomy, if possible. Doses given during the 2 weeks (14 days) before surgery can be counted as valid. If the doses cannot be given prior to the splenectomy, they should be given as soon as the patient's condition has stabilized after surgery. Pneumococcal polysaccharide vaccine (PPSV23, Pneumovax, Merck) should be administered 8 weeks after the dose of PCV13 for people 2 years of age and older.

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