New! ACIP recommends routine vaccination of males 11 through 21 years old against human papillomavirus infection

On December 23, 2011, CDC issued updated recommendations of the Advisory Committee on Immunization Practices for vaccinating males with quadrivalent human papillomavirus vaccine (HPV4; Gardasil; Merck). HPV4 is directed against human papillomavirus (HPV) types 6, 11, 16, and 18. One of ACIP’s primary goals in recommending that males be vaccinated is to protect them against some anal, penile, and oropharyngeal cancers caused primarily by HPV type 16. Previously, ACIP had recommended permissive use of HPV4 in males age 9–26 years for the prevention of genital warts.

Following are the recommendations published in MMWR (www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.htm) for administering HPV4 to males:

• Routinely vaccinate males age 11–12 years with a 3-dose series of HPV4. The series can be started in males as young as age 9.
• Vaccinate males age 13 through 21 if they have not been vaccinated previously or have not completed the 3-dose series.
• Males age 22 through 26 years may be vaccinated.

This means that any male in this age range who wishes to be protected against human papillomavirus may receive the 3-dose series of HPV4 vaccine.

• Routinely vaccinate males through age 26 years if they are immunocompromised as a result of infection (including HIV), disease, or medications and have not been vaccinated previously or have not completed the 3-dose series.
• Routinely vaccinate men who have sex with men (MSM) through age 26 if they have not been vaccinated previously or have not completed the 3-dose series. MSM are at higher risk for infection with HPV types 6, 11, 16, and 18 and associated conditions, including genital warts and anal cancer.

And be sure to continue vaccinating young women with HPV vaccine. HPV vaccine is routinely recommended for young women age 11 through 26 years. According to CDC National Immunization Survey data, only 49% of females 13–17 years have started their HPV series and only 32% have completed the 3-dose series. There is lots of work to do!

how these new recommendations differ from the previous ones.
ACIP recommends routine vaccination of males age 11–12 years with HPV4 (Gardasil, Merck) administered as a 3-dose series. The vaccination series can be started beginning at age 9 years. Vaccination with HPV4 is recommended for males age 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males age 22 through 26 years may be vaccinated with HPV4.

ACIP recommends that immunocompromised males who have not been vaccinated previously or who have not completed the 3-dose series receive routine vaccination with HPV4 through age 26 years.

Men who have sex with men (MSM) are at higher risk for infection with HPV types 6, 11, 16, and 18 and associated conditions, including genital warts and anal cancer. ACIP recommends that MSM who have not been vaccinated previously or who have not completed the 3-dose series receive routine vaccination with HPV4 through age 26 years.

Previously, ACIP had issued permissive recommendations for HPV4 use in males age 9–26 years for the prevention of genital warts.

To obtain a copy of the new recommendations, which were published in MMWR in December 2011, see www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a3.htm.

Is it recommended that patients age 26 years start the HPV vaccination series even though they will be older than 26 when they complete it?
Yes. HPV vaccine is recommended for all women through age 26 years and also may be given to men through that age. So, the 3-dose series can be started at age 26 even if it will not be completed at the same time as the series for females.

(continued on page 10)
age 26. The series should be completed regardless of the age of the patient (i.e., even if the patient is older than 26). In certain situations, some clinicians choose to start the 3-dose HPV series in patients who are older than 26 years. This, however, is an off-label use.

**Will patients who have already had genital warts benefit from receiving Gardasil?**

A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, people with this history might not have been infected with both HPV 6 and 11 or with HPV 16 or 18. Vaccination will provide protection against infection with HPV vaccine types the patient has not already acquired. Gardasil (HPV4) protects against HPV vaccine types 6, 11, 16, and 18; Cervarix (HPV2; GlaxoSmithKline) protects against HPV 16 and 18. Providers should advise their patients/clients that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or genital warts.

**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. You should not withhold HPV vaccine from 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.

If a patient’s vaccination history indicates she received the third dose of HPV vaccine earlier than the recommended minimum interval of 24 weeks, should she be given a fourth dose? Maybe. If the 3-dose series was given with minimum intervals of at least 4 weeks between dose #1 and dose #2 AND at least 12 weeks between dose #2 and dose #3, do not repeat any doses. If the third dose was given at less than 12 weeks from dose #2, repeat dose #3 at least 12 weeks after the invalid dose.

**Will VFC cover HPV vaccination for males?**

Yes. VFC funding will cover HPV4 (Gardasil) vaccination for VFC-eligible males age 9 through 18 years.

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

No, the dose does not need to be repeated. Vaccines should always be administered by the route recommended by the manufacturer; however, if a vaccine is inadvertently administered SC instead of IM, or IM instead of SC, ACIP recommends that the dose be counted as valid with two exceptions: Hepatitis B or rabies vaccine administered by a route other than IM should be repeated.

**Hepatitis B vaccine**

Would you please provide details about the new ACIP recommendations for the use of hepatitis B vaccine in adult diabetic patients? In December 2011, CDC published new ACIP recommendations that hepatitis B vaccine be given to adults with diabetes. The vaccine series is recommended for unvaccinated adults with diabetes age 59 years and younger. At the discretion of the treating clinician, the vaccine may also be administered to unvaccinated adults with diabetes age 60 years and older.

The recommendations were prompted by a number of outbreaks of hepatitis B virus infection in settings that provide assisted blood glucose monitoring for people with diabetes.

Administration of the hepatitis B vaccine series should be completed as soon as feasible after diabetes is diagnosed. No serologic testing or additional hepatitis B vaccination is recommended for adults who received a complete series of hepatitis B vaccinations at any time in the past.

Hepatitis B vaccine may be administered during healthcare visits scheduled for other purposes, as long as minimum intervals between doses are observed. No maximum interval between doses exists that would make the hepatitis B vaccination series ineffective or that would require restarting the series.

You can read the details of this recommendation and the rationale behind it in MMWR at www.cdc.gov/mmwr/preview/mmwrhtml/mm6050a4.htm.

**Tdap vaccine**

Is it true that ACIP no longer specifies a time interval between administering doses of Td and Tdap to teens and adults? In January 2011, CDC issued updated ACIP recommendations (www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm) on the use of Tdap vaccine. They clearly state that pertussis vaccination, when indicated, should not be delayed and that Tdap should be administered regardless of the interval since the last tetanus- or diphtheria-toxoid-containing vaccine was given. This means that if Td was administered inadvertently when Tdap was indicated, the dose of Tdap can be given on the same day the dose of Td was given.

If a teen or adult patient received a dose of Td vaccine 2 years ago, should I wait approximately 8 more years before administering a dose of Tdap to the patient? No. ACIP recommends that people age 11 through 64 who have not yet received Tdap receive their one-time Tdap dose now. ACIP specifies no waiting interval between administering Td and Tdap to anyone in this age group. Adults age 65 years and older do not need to delay Tdap vaccination following Td either.

If a teen or adult mistakenly received a dose of Td when they should have received Tdap, what is the optimal time to give the missing Tdap dose? As soon as possible, even if it is the same day.

*As stated on page 11*
Is there any reason not to administer Tdap vaccine to adults age 65 and older who want the vaccine but are not in contact with an infant? It seems like it would be a good idea to vaccinate them to protect them, their family, and their community from pertussis.

No medical reason exists for withholding Tdap from adults age 65 and older unless they have a medical contraindication.

We intend to start vaccinating family contacts of pregnant women with Tdap to protect the newborn. Can you tell me how long it takes for the Tdap vaccine to provide protection?

To best protect infants, CDC recommends that teens and adults who haven’t been vaccinated receive Tdap 2 weeks or more before having contact with an infant.

Shingles vaccine

When people are in their 80s, is it still recommended for them to get the shingles vaccine? I’ve heard it doesn’t work as well in the elderly. ACIP recommends the vaccine for everyone age 60 and older, even though the vaccine’s efficacy decreases with the recipient’s age. The clinical trials found approximately an 18% efficacy rate in people age 80 and older as compared with 64% efficacy in people age 60 through 69 years (see pages 13–14 at www.cdc.gov/mmwr/PDF/rr/rr5705.pdf). In general, with increasing age at vaccination, the vaccine was more effective in reducing the severity of zoster and post-herpetic neuralgia than in reducing the occurrence of zoster itself.

Hib vaccine

Occasionally we have asplenic adult patients who want to get the Hib vaccine. We know it’s given only to infants and young children, but what about using it in this situation?

Although the vaccine is not routinely recommended for adults, CDC states in the General Recommendations on Immunization: “No efficacy data are available on which to base a recommendation for use of Hib vaccine for older children and adults with the chronic conditions that are associated with an increased risk for Hib disease. Administering 1 dose of Hib vaccine to these patients who have not previously received Hib vaccine is not contraindicated.” For additional information, consult page 22 of the General Recommendations, published January 2011, at www.cdc.gov/mmwr/pdf/rr/rr6002.pdf.

General vaccine questions

ACIP and CDC’s Vaccine Storage and Handling Guide say that refrigerated vaccines should be stored between 35°–46°F, but some vaccine package inserts list 36°–46°F as the proper range. Should I use 35°F or 36°F as the low boundary of the range?

On the Celsius scale, the appropriate storage range for refrigerated vaccines is 2°C–8°C. Because 2°C converts to 35.6°F, some manufacturers have rounded the Fahrenheit reading to 36°F. However, 35°F is still considered acceptable for storage of any refrigerated vaccine. Providers should make an effort to store vaccines toward the midpoint of the range (approximately 40°F or 5°C) rather than at either end of the scale.

What should I do if my thermometer indicates my refrigerated vaccine has been stored between 32°–34°F? Since the vaccine wasn’t “frozen,” will it be OK to use? And what about people who received the vaccine before we discovered the temperature excursion—will we need to revaccinate them?

This is a complex question that requires case-by-case review. First, while you’re assessing the situation, return the vaccine to proper storage temperatures and mark it “Do Not Use.” Then, contact your state or local immunization program or the appropriate vaccine manufacturer(s) to discuss the potential usability of the vaccine. They will need to consider several variables related to vaccine storage conditions. For example, their guidance will be affected by the accuracy of the thermometer, whether the thermometer probe was in a liquid or was reading the temperature of the air, the type of vaccine involved, the length of time of the excursion, etc.

In general, if it can be reliably determined that the vaccine in question was not stored below 32°F and the manufacturer’s stability data concurs, most immunization programs and vaccine manufacturers would not recommend wasting the vaccine or revaccinating recipients.

Does the federal law that requires providing patients with VISs apply when administering influenza vaccine to employees and volunteers in hospitals or other workplaces?

Yes. Employees and volunteers are considered patients, and you need to provide them with a VIS.

If a vaccine is covered under the National Childhood Vaccine Injury Act—and almost all vaccines routinely administered to adults are (with the exception of PPSV and zoster)—it is mandatory under federal law to give the VIS for that vaccine to the vaccinee. Therefore, when you give influenza vaccine to employees and staff, you are required by law to provide them with a VIS.

You can find more details about the requirements for using VISs at www.cdc.gov/vaccines/pubs/vis/downloads/vis-Instructions.pdf.

For VISs in multiple languages, go to www.immunize.org/vis.

If you place a needle on a pre-filled syringe and then don’t administer the vaccine, how long can you store the pre-filled syringe with the needle attached?

In general, a vaccine should not be prepared until the provider is ready to administer it to a patient. This is because once the syringe cap is removed or a needle is attached, the sterile seal is broken. However, if a sterile seal has been broken, staff should be sure to maintain the syringe at the appropriate temperature and either use it or discard it at the end of the clinic day.

CDC’s Pink Book has a new chapter about vaccine storage and handling at www.cdc.gov/vaccines/pubs/pinkbook/downloads/vac-storage.pdf.