TO: California Vaccines for Children (VFC) Program Providers

FROM: Howard Backer, MD, MPH, Chief Immunization Branch

SUBJECT: ADOLESCENT VACCINE UPDATES: HPV, Tdap, and MCV4

This letter updates information regarding preteen and adolescent immunizations, including the quadrivalent human papillomavirus (HPV) vaccine (see also December 2006 letter); tetanus, diphtheria, and pertussis vaccine (Tdap); and meningococcal conjugate vaccine (MCV4).

1. PROMOTION OF ADOLESCENT VACCINES
Two materials are available in English and Spanish online at www.GetImmunizedCa.org or from your local health department to promote newly recommended vaccines for your preteen and adolescent patients. These materials are designed to assist you in your efforts to ensure that preteens and adolescents in your practice receive all recommended vaccines.

- “Immunizations are Your Best Shot” (IMM-851, preteen doctor visit brochure)
- “Vaccinate Before You Graduate” (IMM-765, for high school students; IMM-765M for middle school students). Available in English and Spanish.

2. HPV VACCINE
Final Advisory Committee on Immunization Practices (ACIP) recommendations for the quadrivalent HPV vaccine was published in March 2007 (see link below). As with all vaccines, post-licensure surveillance is important. Please make sure to report all clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by telephone (800-822-7967).

Through January 2007, the second most common report to VAERS after administration of the HPV vaccine was syncope. In general, syncope after vaccination is more common among adolescents and young adults. As included in the 2006 ACIP General Recommendations on Immunization (see link below), health care providers should consider observing patients for signs of syncope for 15 minutes after they receive any vaccine. If syncope occurs, observation should continue until symptoms resolve.

- HPV Fact Sheets: A new fact sheet “The HPV Vaccine: What Health Care Providers Need to Know,” developed in collaboration with the California HPV Vaccine Work Group, can be downloaded at www.HpvVaccineCa.org or ordered from your local health department. Other fact sheets from the CDC on HPV disease and the HPV vaccine can
be found online at www.cdc.gov/nip/vaccine/hpv/hpv-faqs.htm and http://www.cdc.gov/std/hpv/default.htm.

- Updated Vaccine Information Statement (VIS): The HPV Vaccine VIS (2/2/07) for quadrivalent HPV vaccine can be found at http://www.cdc.gov/nip/publications/VIS/#hpv.
- AAP recommendations and other information about HPV are available at www.cispimmunize.org/.

3. Tdap VACCINE

Five new materials to promote use of Tdap vaccine have now been conveniently assembled into the enclosed Tdap Suite of Materials flyer. You can order these materials from your local health department.

4. MCV4 VACCINE

Do not forget to order MCV4 for your young adolescents! As the prior supply shortage of MCV4 has resolved, there is currently an adequate supply to vaccinate 11-12 year olds at their preteen visit. There have been a few cases of meningococcal disease in middle school and high school students this year, so we want to take this opportunity to remind providers to administer MCV4 at the preteen and adolescent visits. You should also recall 13 year olds to the office if they missed their MCV4 immunization last year due to the shortage.

Enclosures: Preteen Doctor Visit brochure; Vaccinate Before You Graduate Flyer, High School and Middle School version; HPV Vaccine Fact Sheet, Updated HPV VIS; Tdap Suite flyer

cc: DHS Immunization Branch Field Representatives
Local Health Officers
Local Health Department Immunization Coordinators
Local Health Department CHDP Program Directors
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Marian Dalsey, M.D., Chief, Children Medical Services Branch, CDHS
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Villita Lewis, Deputy Director, Benefits and Quality Monitoring, MRMIB
Marcia Ehinger, M.D., Medi-Cal Benefits Branch, CDHS
Kathy Chance, M.D., Children Medical Services Branch, CDHS
Check it out!

Whether you’re into playing soccer, getting good grades, listening to music, or just hanging out with your friends—if you’re 11 or 12 years old, it’s time for your preteen doctor visit.

I wanna stay healthy so I can do my best at everything! That’s why I went to my preteen doctor visit.

Want to know more?

Your preteen doctor visit is a great time to ask questions about shots and the diseases they prevent. You can also talk to your parents, school nurse, or local health department’s clinic staff.

For more information, check out:

www.bam.gov

For parents:

www.GetImmunizedCA.org
www.cdc.gov/nip
www.immunize.org
(800) CDC-INFO/(800) 232-4636

Get your shots at your preteen doctor visit!
What is a preteen doctor visit?

Preteen years are full of changes. It’s a good idea to check in with your doctor about ways to stay healthy.

At your preteen visit, you will talk about things like:
- being active
- eating right
- being safe
- standing up to peer pressure
- getting shots (immunizations)

The shots that your doctor recommends will protect you from some very dangerous diseases.

Talking with the doctor was pretty cool. She knew tons of stuff.

Ouch! Don’t shots hurt?

Getting shots (immunizations) may sting a little, but getting sick from diseases is much worse.

Shots are worth it!

Here are some tips to help you relax during shots:
- Have a parent keep you company
- Take slow, deep breaths
- Focus on something in the room, like a poster
- Bring along your favorite music
- Close your eyes and think of your favorite place or activity

Talk to your parents about your preteen doctor visit!

Why should I get shots?

Immunizations are your best shot at preventing some very serious diseases so you can keep doing the things you love to do—instead of being sick.

If you are protected from a disease, you won’t pass it on to your friends or family. And, you’ll help others by keeping your school and neighborhood disease-free!

Did you know? Some shots even prevent cancer! The new HPV shots can protect girls from getting cervical cancer when they are older. Hepatitis B shots can prevent liver cancer.
Recommended Vaccines

Meningococcal Conjugate

This vaccine protects you against a serious bacterial infection that could cause you to lose an arm or leg or even become paralyzed. Because college students in dorms live in close quarters, they are more likely to get the disease than other university students as a whole. Meningococcal disease is easily spread by coughing, sneezing or sharing drinks and kissing.

Human Papillomavirus (HPV)

The HPV 3-shot series can protect teen girls against cervical cancer later on in life.

Tetanus, Diphtheria, & Pertussis (Whooping Cough) (Tdap)

Tdap is a new tetanus booster that also protects you against whooping cough, a disease that can make you cough so hard that you break your ribs.

Varicella (Chickenpox)

Chickenpox is usually worse for teens than for kids. If you’ve only had one chickenpox shot, you need a second shot, unless you’ve had chickenpox disease.

Are you up-to-date on your hepatitis B and MMR (measles, mumps and rubella) shots? The hepatitis B series is required for all UC and Cal State students up to age 18. MMR is also required for Cal State students. Many other colleges may require certain vaccines as well.

Most of these shots are now covered by your family’s health plan. Get them at your next physical so you won’t have to pay for them out of your own pocket later.

Want to know more? Visit www.GotMyShot.org or www.cdc.gov/nip/.

DON’T WAIT – VACCINATE BEFORE YOU GRADUATE!

A message from your school nurse and the California School Nurses Organization

Vaccinate Before You Graduate, a CSNO campaign in partnership with the California Department of Health Services and Your Local Health Department

IMM-765 (3/07)
Some diseases can be serious enough to put you in the hospital, or worse. Before you enter High School, protect yourself with vaccines.

### Recommended Vaccines

<table>
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You have probably received your Hepatitis B and MMR (measles, mumps, and rubella) shots. But if you haven’t, make sure you also get them at your adolescent doctor visit.

Being a teenager is more than social events, sports or hanging out with friends; it’s also about taking charge of your health.

Talk to your parents about getting these vaccines at your next physical!


**DON’T WAIT – VACCINATE BEFORE YOU GRADUATE!**
Cervical Cancer in the United States: What is the Risk?

Early diagnosis via Pap screening and follow-up treatment has significantly reduced the morbidity and mortality of cervical cancer in the United States. Despite this, in 2007, an estimated 11,150 women will be diagnosed with cervical cancer, and 3,670 women will die from it. More than half of women with cervical cancer have not had a recent Pap test.

What is HPV?

There are more than 100 different types of HPV; over a third of these infect genital epithelial cells (skin and mucous membranes) and cause genital warts in men and women. The vast majority of HPV infections are asymptomatic and resolve without ever causing disease.

How is HPV Transmitted?

HPV is transmitted sexually through genital contact and cannot be entirely prevented by condom use.

How Common is HPV Infection?

HPV is among the most common sexually transmitted infections in the United States. Well over half of sexually active people will be infected with genital HPV at some point in their lives. More than 20 million men and women are currently infected, and there are about 6.2 million new infections each year.

How Many HPV Vaccines are There?

Gardasil®, produced by Merck, is a quadrivalent vaccine against HPV types 6, 11, 16, and 18 that is currently licensed for use in females ages 9 to 26. A second vaccine, Cervarix®, developed by GlaxoSmithKline, is a bivalent vaccine against HPV types 16 and 18. Cervarix® has not yet been licensed but is expected to be submitted for review by the Food and Drug Administration (FDA) during 2007.

Additional resources can be found at:

- California Department of Health Services
  www.hpvvaccineca.org
- Advisory Committee on Immunization Practices (ACIP)
  www.cdc.gov/nip/ACIP/default.htm
- American Cancer Society
  www.cancer.org
- American Medical Association (AMA), Sexually Transmitted Infections Vaccine Program
  www.bigshouldersdubs.com/clients/AMA/vaccines04.htm
- American Social Health Association, HPV Resources
  www.asha2001.org/learn/learn_hpv.cfm
- California Medical Association Foundation: Cervical Cancer and HPV Project
  www.calmedfoundation.org/projects/HPV/index.aspx
- Centers for Disease Control and Prevention, HPV Vaccine Fact Sheet
  www.cdc.gov/std/hpv
- Food and Drug Administration
  www.fda.gov
- National Cancer Institute
  www.cancer.gov/cancer-topics/types/cervical
- National STD/HIV Prevention Training Center
  www.stdhivtraining.org
- Vaccine Information Statements in Multiple Languages (Immunization Action Coalition)
  www.immunize.org
- Vaccines for Children (VFC) Program, HPV Vaccine (Resolution No. 6/06-02)
  www.cdc.gov/vfc/acip_resolutions/0606hpv.pdf
- Vaccines for Children (VFC) Program in California
  www.vfcca.org

What are the Main Messages About Human Papillomavirus Vaccine (HPV) for Your Patients?

- Preventing cervical cancer is the most important benefit of HPV vaccine.
- The HPV vaccine includes protection from four HPV types, including two types that cause 70 percent of cervical cancer.
- Three doses of HPV vaccine over six months are needed.
- It is important to receive routine Pap screening for cervical cancer regardless of vaccination against HPV.

Medical Literature


Arnold Schwarzenegger, Governor—State of California
Kimberly Belshé, Secretary—Health and Human Services Agency
Sandra Shewey, Director—Department of Health Services

visit: www.hpvvaccineca.org

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

(AHA-869) (2/07)
The HPV Vaccine: What Health Care Providers Need to Know

How is HPV Vaccine Administered?
The licensed quadrivalent HPV vaccine is given intramuscularly as a 0.5 mL dose in a three-dose series. The second dose is given two months after the first dose. The third dose is given six months after the first dose.

What if a Patient Cannot Complete the Series on Schedule?
If the vaccine series is interrupted, administer the next dose when possible. It is not necessary to restart the series, even if a significant amount of time has passed.

How Safe is HPV Vaccine?
HPV vaccines appear safe. No increase in serious adverse effects have been observed in large clinical trials. The licensed quadrivalent HPV vaccine has been associated with an increase in local injection-site reactions, especially pain.

Continuing studies are monitoring the safety of HPV vaccines. Adverse events occurring after vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS), which is maintained by the FDA and the Centers for Disease Control and Prevention (CDC). To receive a copy of the vaccine reporting form, call VAERS at (800) 822-7967 or report online at www.vaers.hhs.gov.

How Effective is HPV Vaccine?
In clinical studies, the HPV vaccines have been demonstrated to be over 90 percent effective in preventing infection and precancerous lesions in women caused by high-risk HPV types 16 and 18. The vaccine will not prevent disease in women who already have been infected by the specific HPV types included in the vaccine. The vaccine has no value in eliminating pre-existing HPV infection or in treating HPV disease. There are no data yet on effectiveness in males.

How Long Does Immunity Last?
The duration of immunity is not known; current studies have demonstrated protection up to five years. It is not yet known if booster doses will be needed in the future.

For Which Patients is HPV Vaccine Licensed?
Gardasil® is licensed by the FDA for use in females 9 to 26 years of age. The vaccine has not been licensed for use in males.

Who Should Get HPV Vaccine?
The federal Advisory Committee on Immunization Practices (ACIP) recommends three doses of the licensed quadrivalent HPV vaccine for:
- females ages 11 to 12 years on a routine basis, though physicians may vaccinate girls starting at age 9.
- females ages 13 to 26 years, if not yet vaccinated.

Based on current data, females who have not been infected with HPV types included in the HPV vaccine are likely to benefit most from vaccination. Although HPV vaccine can not treat prior HPV infection, sexually active women are unlikely to have been exposed to all HPV types covered by the quadrivalent vaccine. Therefore, sexually active women can still benefit from the vaccine for the virus type(s) in the vaccine they have not yet acquired.

Currently, there are no data on the efficacy of the vaccine in men or women over 26 years of age. Studies in these populations will provide data in the future.

Who Should not be Immunized with HPV Vaccine?
Females who have a history of immediate hypersensitivity (e.g., anaphylaxis) to yeast or to any component of the quadrivalent HPV vaccine should not receive HPV vaccine. Immunization should also be deferred during pregnancy or moderate to severe illness until the illness improves.

Should Pregnant Women Receive HPV Vaccine?
The HPV vaccine is not recommended for use during pregnancy. The vaccine has not been associated casually with adverse outcomes of pregnancy or adverse events to the developing fetus; however, data on vaccination during pregnancy are limited. If a woman begins the vaccine series and then becomes pregnant, the series should be suspended until after the pregnancy. No treatment is recommended for women who receive one or more doses of the HPV vaccine while pregnant. Exposures to Gardasil® during pregnancy should be reported to the manufacturer’s pregnancy registry at (800) 986-8999 so that the vaccine can be better assessed for safety.

Is HPV Vaccine Required for Entry into Grade School or College?
No. Regardless, providers are encouraged to provide a routine medical visit for children 11 to 12 years old and to urge parents to vaccinate their children according to the ACIP recommendations.

Does the HPV Vaccine Replace Pap Screening?
No. It is important that women continue to receive routine Pap screening. Because the HPV types targeted by the vaccine account for 70 percent of cervical cancer, the cancer risk is significantly decreased, but not eliminated.

Is HPV Testing Needed with HPV Vaccine?
No. There is no role for serologic or DNA testing for the HPV virus before or after administering the HPV vaccine. Currently, a positive result from HPV DNA testing cannot specify which among the high-risk HPV types is present. Even after infection with one type of HPV, immunization can still protect against other types covered by the vaccine.

Is this Vaccine Covered by Health Plans or Other Programs?
The Vaccines for Children (VFC) program provides the HPV vaccine for eligible girls 9 to 18 years of age. Children and adolescents up to and including 18 years of age who are either uninsured, Medi-Cal eligible, Native American, or Alaska Native are eligible for the VFC program. Eligible children and adolescents can also get VFC vaccines through federally qualified health centers or rural health centers if their private health insurance does not cover the vaccine.

By law, California’s managed care plans must cover all recommended vaccines for children. Co-payments may apply for those visits. It is anticipated that most health plans will cover the vaccine but some may not cover the vaccine for adults. Please check with the specific health plan for more information.

How Can I Participate in the VFC Program?
VFC has more than 4,000 enrolled provider sites participating in California. VFC provides free routine vaccines for eligible children through age 18. Any medical practice providing vaccinations to low-income children meeting VFC eligibility may choose to become a VFC provider. To learn more about California’s VFC program, including how to become a VFC provider, visit www.vfcca.org or call the VFC program office toll-free at (877) 243-8832.

Are There Patient Information Materials Available?
Fact sheets on the HPV vaccine produced by CDC can be accessed at www.hpvaccine.ca.gov. An interim Vaccine Information Statement, required to be given to patients, parents, or guardians, is available at www.cdc.gov/nip/publications/vis/vic HPV.pdf.
Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States.

There are about 40 types of HPV. About 20 million people in the U.S. are infected, and about 6.2 million more get infected each year. HPV is spread through sexual contact.

Most HPV infections don’t cause any symptoms, and go away on their own. But HPV is important mainly because it can cause cervical cancer in women. Every year in the U.S. about 10,000 women get cervical cancer and 3,700 die from it. It is the 2nd leading cause of cancer deaths among women around the world.

HPV is also associated with several less common types of cancer in both men and women. It can also cause genital warts and warts in the upper respiratory tract.

More than 50% of sexually active men and women are infected with HPV at sometime in their lives.

There is no treatment for HPV infection, but the conditions it causes can be treated.

HPV vaccine is an inactivated (not live) vaccine which protects against 4 major types of HPV.

These include 2 types that cause about 70% of cervical cancer and 2 types that cause about 90% of genital warts. HPV vaccine can prevent most genital warts and most cases of cervical cancer.

Protection from HPV vaccine is expected to be long-lasting. But vaccinated women still need cervical cancer screening because the vaccine does not protect against all HPV types that cause cervical cancer.

**Routine Vaccination**

- HPV vaccine is routinely recommended for girls 11-12 years of age. Doctors may give it to girls as young as 9 years.

**Why is HPV vaccine given to girls at this age?**

It is important for girls to get HPV vaccine before their first sexual contact – because they have not been exposed to HPV. For these girls, the vaccine can prevent almost 100% of disease caused by the 4 types of HPV targeted by the vaccine.

However, if a girl or woman is already infected with a type of HPV, the vaccine will not prevent disease from that type.

**Catch-Up Vaccination**

- The vaccine is also recommended for girls and women 13-26 years of age who did not receive it when they were younger.

HPV vaccine is given as a 3-dose series:

1st Dose: Now
2nd Dose: 2 months after Dose 1
3rd Dose: 6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

**Some girls or women should not get HPV vaccine or should wait**

- Anyone who has ever had a life-threatening allergic reaction to yeast, to any other component of HPV vaccine, or to a previous dose of HPV vaccine should not get the vaccine. Tell your doctor if the person getting the vaccine has any severe allergies.
What are the risks from HPV vaccine?

HPV vaccine does not appear to cause any serious side effects.

However, a vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of any vaccine causing serious harm, or death, is extremely small.

Several mild problems may occur with HPV vaccine:

- Pain at the injection site (about 8 people in 10)
- Redness or swelling at the injection site (about 1 person in 4)
- Mild fever (100°F) (about 1 person in 10)
- Itching at the injection site (about 1 person in 30)
- Moderate fever (102°F) (about 1 person in 65)

These symptoms do not last long and go away on their own.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Like all vaccines, HPV vaccine will continue to be monitored for unusual or severe problems.

What if there is a severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

How can I learn more?

- Ask your doctor or nurse. They can show you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO)
We are pleased to announce that a suite of materials is now available to promote the use of Tdap, the new tetanus booster that also protects against whooping cough!

Taken together, the items target health care workers, adults, and grandparents.

Check out the items on this page and think of how they may be used in your community.