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July 28, 2008

Dear Vaccines for Children (VFC) Program Participants:

Vaccine Safety Monitoring and Human Papillomavirus (HPV) Vaccination

Human Papillomavirus (HPV) vaccine safety has recently been mentioned in both the national and state news. The Florida Department of Health, Bureau of Immunization, provides the following summary of points that may help you quickly answer current questions from the general public, healthcare providers, and the media.

Human Papillomavirus (HPV) Vaccination

- The Centers for Disease Control and Prevention (CDC) continues to recommend HPV vaccination because of its importance for the health of women. CDC maintains this is a safe and effective vaccine. However, as with all vaccines, we will continue to review the safety of this vaccine and take appropriate action if there are issues with the vaccine. The risk of any vaccine causing serious harm, or death, is extremely small.
- Parents and providers are encouraged to report any adverse events to the Vaccine Adverse Event Reporting System (VAERS) accessing the VAERS website at <http://vaers.hhs.gov/> or calling telephone number (800) 822-7967.
- Parents are encouraged to discuss HPV vaccination with their pre-teen's doctor. The routine recommendation is to administer HPV vaccine at ages 11 to 12 years.
- The recommendation allows for vaccination to begin at age 9 years.
- Vaccination also is recommended for females ages 13 to 26 years who have not been previously vaccinated or who have not completed the full series of shots.
- Syncope, or fainting, is a common event occurring with needle injections and vaccinations, especially in adolescents. CDC recommends that patients who receive HPV vaccine remain in the clinic for 15 minutes after vaccination to avoid potential injury from a fall.

HPV Disease

- HPV is a common virus. It is the major cause of cervical cancer in women.
- HPV infection usually occurs in people in their teens and early 20s.
- There are about 20 million people currently infected with HPV.
- Each year in the U.S., about 11,000 women will be diagnosed with cervical cancer and 3,600 will die.

- Women have an 80% chance of developing HPV by age 50.
- Because the vaccine is a preventative, and not a cure, it is important that the vaccine be given prior to beginning sexual activity.

Please refer to the CDC website for more information about the vaccine and the disease:

<http://www.cdc.gov/vaccines/vpd-vac/hpv/default.htm>

<http://www.cdc.gov/vaccines/vpd-vac/hpv/#disease>

http://www.cdc.gov/cancer/cervical/basic_info/

<http://www.cdc.gov/std/hpv/default.htm>

HPV Vaccine in the United States

- On June 8, 2006, the Food and Drug Administration (FDA) licensed the first vaccine (Gardasil®), developed to prevent cervical cancer and other diseases in females caused by certain types of genital human papillomavirus (HPV). The quadrivalent vaccine, Gardasil®, protects against four HPV types (6, 11, 16, and 18), which are responsible for 70% of cervical cancers and 90% of genital warts. You may find the FDA HPV fact sheet at the link provided below:

<http://www.fda.gov/womens/getthefacts/pdfs/hpv.pdf>

- On June 29, 2006, the Advisory Committee on Immunization Practices (ACIP) voted to recommend routine vaccination of females ages 11 and 12 years. Gardasil® was tested in over 11,000 females (ages 9 to 26 years) in many countries around the world, including the U.S. These studies found that the HPV vaccine was safe and caused no serious side effects. Adverse events were mainly injection site pain. This reaction was common but mild.
- Since licensure, more than 12 million doses of Gardasil® vaccine have been distributed in the U.S. In 2006, a total of 2,151,000 doses were distributed and in 2007, another 11,317,902. At this time, the U.S. does not have a national registry for immunization and vaccination and therefore cannot report the total number of people who have received Gardasil®.
- The number of serious adverse events reported in the Vaccine Adverse Event Reporting System (VAERS) following HPV vaccine is less than 7% of the total number of reports received. In comparison, the overall average in VAERS for any serious adverse event ranges from 10% to 15%; thus, the percentage of serious reports for Gardasil® is less than the overall average.

Vaccine Safety Monitoring: Vaccine Adverse Event Reporting System (VAERS)

The Vaccine Adverse Event Reporting System (VAERS) is part of a larger system that helps to make sure vaccines are safe and work as intended. VAERS is managed by the CDC and the FDA. To ensure vaccines are safe, vaccines are developed in accordance with the highest standards of safety. FDA requires extensive safety testing before a vaccine is licensed and distributed to the public. After licensing, VAERS is used to continually monitor vaccines for safety and efficacy.

VAERS receives reports of many events that occur after immunization. Some of these events may occur coincidentally following vaccination, while others may truly be caused by vaccination. It is important to remember that many adverse events reported to VAERS may not be caused by vaccines. More in depth studies are usually required to investigate the association between a vaccine and an adverse event. Since 1990, most of the reported adverse events describe mild side effects such as fever and rash. Through continued monitoring, VAERS helps to ensure that the benefits of vaccines are far greater than the risks. You may find more information about VAERS at the link provided below:

<http://www.cdc.gov/vaccinesafety/vaers/>

Enclosed are a CDC fact sheet, a Vaccine Information Statement (VIS) sheet, and a FDA fact sheet from the Office of Women's Health, to provide additional information about HPV.

Please widely distribute this information to colleagues, members, coalitions, and partners with an interest in the supply, distribution, management, and administration of child and adolescent vaccines.

If you have any questions or comments regarding the CDC recommendations, or VAERS, please contact Phyllis Yambor, R.N., Bureau of Immunization, at (850) 245-4342. For information regarding the VFC Program vaccine supply, please contact Robert Griffin, VFC Program Coordinator, or your VFC Program Representative, at (800) 483-2543.

Sincerely,

Signature on file

Charles H. Alexander, Chief
Bureau of Immunization
Division of Disease Control
Florida Department of Health

CHA/sdh

cc: Phyllis Yambor, R.N., Executive Community Health Nursing Director,
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