



## Illinois Chapter

### ICAAP Member Alert—HPV Vaccine Safety

**Chicago, IL, August 29, 2008**—Consumers, parents, health care professionals and others have raised questions regarding the safety of the human papillomavirus (HPV) vaccine, Gardasil®, due to recent media coverage of isolated cases of sudden illness or death in girls who had been vaccinated.

#### Overview

Based on ongoing assessments of vaccine safety information, FDA and CDC have found no link indicating that the illness and deaths were related in any way to the vaccine. Therefore, CDC and FDA regard the vaccine as safe and effective and continue to recommend HPV vaccination because of its effectiveness in preventing the four types of HPV (6,11, 16 and 18) that cause 70% of all cervical cancers.

As with all vaccines, FDA and CDC continue to monitor its safety, with the public's health and safety their top priority.

#### Vaccine Recommendations

CDC recommends the HPV vaccine for all 11 and 12 year old girls. The recommendation allows for vaccination to begin at age nine. Vaccination also is recommended for females aged 13 through 26 years who have not been previously vaccinated or who have not completed the full series of shots.

#### CDC and FDA Monitoring Methods

FDA and CDC closely monitor the safety of all vaccines through the Vaccine Adverse Event Reporting System (VAERS). VAERS receives unconfirmed reports of possible side effects following the use of Gardasil and all vaccines licensed in the U.S. VAERS reports are regularly reviewed for safety concerns or trends of adverse events (possible side effects).

Vaccines are manufactured in batches called lots according to strict manufacturing standards. All vaccine lots are routinely tested and must pass all tests before they can be used. FDA also analyzes adverse events (possible side effects) associated with individual lots to look for any unusual patterns. No such patterns have been observed in FDA's review of HPV vaccine lots since the vaccine was licensed.

In addition to VAERS, CDC has two other systems in place to monitor the safety of all licensed vaccines:

- The Vaccine Safety Datalink (VSD) Project is a collaborative effort between CDC and eight managed care organizations that monitors vaccine safety and addresses the gaps in scientific knowledge about rare and serious side effects following immunization.
- The Clinical Immunization Safety Assessment (CISA) Network is collaboration with six academic centers in the United States to conduct clinical research on vaccine-associated adverse events.

#### Recent Gardasil® Monitoring Activities and Findings



## Illinois Chapter

- In late March 2008, a single report to the Vaccine Adverse Event Reporting System (VAERS)\*\* described progressive muscular weakness that occurred after a patient received her third dose of Gardasil®.
  - **FINDING:** Because the patient has symptoms of peripheral motor neuropathy, CDC and FDA scientists reviewed the VAERS database and found no other reports describing lower motor neuron lesion, amyotrophic lateral sclerosis, or peripheral motor neuropathy occurring after Gardasil® vaccination.
  
- As of June 30, 2008, there have been 9,749 VAERS reports of adverse events following Gardasil® vaccination. Since licensure, more than 12 million doses of Gardasil® vaccine have been distributed in the U.S.
  - **FINDING:** Of the VAERS reports of adverse events, 94% were classified as reports of non-serious events, and 6% as serious events.
  
- As of June 30, 2008, 20 deaths had been reported to VAERS.
  - **FINDING:** There was not a common pattern to the deaths that would suggest they were caused by the vaccine. In cases where autopsy, death certificate and medical records were available, the cause of death was explained by factors other than the vaccine.

### Additional Resources and Information

CDC Vaccine Safety web section:

[http://www.cdc.gov/vaccinesafety/vaers/FDA\\_and\\_CDC\\_Statement.htm](http://www.cdc.gov/vaccinesafety/vaers/FDA_and_CDC_Statement.htm)

FDA website: <http://www.fda.gov/cber/safety/gardasil071408.htm>

CDC Features web section: <http://www.cdc.gov/Features/HPVvaccineSafety>

Links to HPV resources from CDC and NCIRD follow.

CDC fact sheet "HPV Vaccine: Questions and Answers for the Public":

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

NCIRD HPV Vaccine web section (including links to information for the public, healthcare professionals, and the media): <http://www.cdc.gov/vaccines/vpd-vac/hpv>

### ICAAP Contact

Members seeking additional information should contact Michelle Esquivel, [mesquivel@illinoiscaap.com](mailto:mesquivel@illinoiscaap.com) or 847/608-5308. August 29, 2008