



**North Carolina Department of Health and Human Services
Division of Public Health**

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MEMORANDUM

TO: UCVDP Providers

FROM: Beth Rowe-West, RN, BSN, Head *BRW*
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SUBJECT: Immunization Update – HPV Vaccine Safety in the News

HPV vaccine safety has been increasingly in the news. We have received a number of calls regarding news reports on the safety of Gardasil. Below, please find a summary of talking points that may help you quickly answer questions you may be getting – these have been provided by the Centers for Disease Control & Prevention (CDC). For additional vaccine safety information, please refer to the CDC website at: www.cdc.gov/vaccinesafety.

Human Papillomavirus (HPV) Vaccination

- 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, CDC will continue to review the safety of this vaccine and take appropriate action if there are issues with the vaccine.
- The routine recommendation is to administer HPV vaccine at ages 11 and 12 years. People who miss vaccination at those ages can get the vaccine through age 26.
- Syncope, or fainting, is a common event occurring with needle injections and vaccinations, especially in adolescents and has been seen following HPV vaccination. 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 and vaccine information is available at www.cdc.gov/vaccines/vpd-vac/hpv/default.htm.

HPV Vaccine and VAERS

- CDC and FDA are conducting an ongoing study of VAERS reports describing other adverse events after Gardasil. For more information visit: www.cdc.gov/vaccinesafety/vaers/gardasil.htm.



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- 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.
- As of April 30, 2008, VAERS received 7,802 reports after Gardasil vaccination in the U.S.
- The number of serious adverse events reported to 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%–15%; thus, the percentage of serious reports for Gardasil is less than the overall average.
- A report to VAERS does not mean there is a connection between the vaccine and the report. It means the event took place following vaccination, regardless of the interval between vaccination and the event.
- VAERS data are updated continuously and the number of reports and the type of adverse events will vary depending on the date of analysis.
- Information on Gardasil vaccine reports to VAERS can be found on the Immunization Safety Office's web page at www.cdc.gov/vaccinesafety/vaers/gardasil.htm.
- Parents and providers are encouraged to report any adverse events to the Vaccine Adverse Event Reporting System at <http://vaers.hhs.gov> (phone 1-800-822-7967).

VAERS Report– A Case Currently in the News

- In late March 2008, a 14 year old girl's physician submitted a report to the Vaccine Adverse Event Reporting System (VAERS) describing progressive muscular weakness which occurred approximately four months after the patient received her third dose of Gardasil. In addition, the patient's physician directly contacted the CDC to follow-up on the case.
- Upon receipt of the inquiry, CDC's Clinical Immunization Safety Assessment (CISA) Network began a review of the case. Through the CISA Network, CDC and the FDA have received permission from the family to collect medical history from the treating physician, the family, and the medical records. CDC and FDA, in collaboration with internal and external clinical experts, continue to follow the child's clinical course.
- Because the patient was diagnosed with 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.

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