

HPV: Gardasil and GBS

CDC/Office of the Chief Science Officer/
Immunization Safety Office

Fast facts that address statements made in a press release by the National Vaccine Information Center on 08/15/07 regarding Gardasil and Guillain-Barre Syndrome (GBS).

Fast facts:

The Vaccine Adverse Event Reporting System (VAERS) is a national program that monitors the safety of vaccines after they are licensed. VAERS is managed by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS is designed to collect reports of potential adverse events following immunization. VAERS reports can be submitted by anyone. When evaluating data from VAERS, it is important to note that for any reported event, no cause and effect relationship has been established. VAERS is interested in all potential associations between vaccines and adverse events. Therefore, VAERS collects data on any adverse event following vaccination, be it coincidental or truly caused by a vaccine. The report of an adverse event to VAERS is not documentation that a vaccine caused the event, nor is VAERS designed to calculate absolute or relative risks. **Please Note:** VAERS defines "serious adverse events" by Code of Federal Regulations as involving hospitalization, death, disability, life threatening illness, or certain other medically important conditions. Also, VAERS data is continuously updated and the number of reports will vary from the date of an analysis.

VAERS reports related to Gardasil:

Since the licensure of Gardasil, more than 7 million doses of vaccine have been distributed. As of June 30, 2007, VAERS had received a total of 2531 reports. Nearly 95% of the reports received to date have been classified as non-serious. The number of serious adverse events reported is less than 6% 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 are less than half of the overall average.

At this time the U.S. does not have a national registry for immunization and vaccination and therefore can not report the total number of persons who have received Gardasil.

CDC's review of VAERS reports concerning Gardasil and GBS:

As of June 30 2007, VAERS had received 13 reports concerning GBS after Gardasil. These 13 GBS reports are currently undergoing expert review. Our efforts to date are below:

- Only 2 meet the case definition of GBS, occurred within six weeks after vaccination, and had received Gardasil alone.
- Six of the 13 reports also involved simultaneous receipt of Menactra vaccine. Current studies are underway to evaluate the small increased risk of GBS, which might be associated with receipt of Menactra vaccine.
- Six of the 13 reports occurred after Gardasil was given alone (without any other vaccine).
- Thirteen reports of GBS are within the numbers of reports that could be expected to occur by chance alone after a vaccination.
- As of June 30 2007, there have been seven deaths reported after Gardasil vaccine. These reports are currently being investigated.

After a careful review of the GBS reports received by VAERS, many appear to have insufficient clinical data. Because GBS occurs at a rate of 1-2/100,000 person years during the second decade of life, it is likely that, some cases will occur after vaccination but will not be due to vaccination. A temporal association does not confirm a causal association. In summary, the number of serious adverse events has been relatively very rare, in the context of more than 7 million doses distributed across the U.S.

Approximately 90% of the reports received by the VAERS regarding Gardasil do not involve co-administration of another vaccine. The recommendation of co-administration is consistent with the General recommendations of the Advisory Committee on Immunization Practices (ACIP).

Scientists recognize the potential for syncope (fainting) after any medical procedure involving a needle and therefore recommend a 15 minute waiting/observation period after all vaccines. Syncope after vaccination is most common in adolescent and young adults and has been reported after other vaccines. About 50% of young adults experience at least one syncope episode at some point in their lives.

In conclusion, there are no changes to any of the existing HPV recommendations.

Additional resources and links:

Quadrivalent Human Papillomavirus Vaccine (HPV4): United States Post-licensure Safety Update.

Presented by John Iskander, MD, MPH

Immunization Safety Office, Office of the Chief Science Officer, CDC

<http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-jun07/35-hpv3-iskander.pdf> The PDF can also be found at: <http://www.cdc.gov/vaccines/recs/acip/>


The Advisory Committee on Immunization Practices (ACIP), Vaccine for Children Program, Vaccine to Prevent Human Papillomavirus (HPV) Infection. The link below is a PDF of the ACIP Resolution No. 6/06-2

<http://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/0606hpv.pdf> The PDF can also be found at: <http://www.cdc.gov/vaccines/programs/vfc/>

CDC Questions and Answers (Qs & As) Concerning the Safety and Efficacy of **Gardasil®**, dated: June 4, 2007. The link list is a PDF with the top 7 Qs & As. [HPV Vaccine- Q&A Concerning Safety and Efficacy of Gardasil](#) Additional information and the PDF can also be found at: <http://www.cdc.gov/vaccines/vpd-vac/hpv/>

Vaccine Testing and the Approval Process: this link will describe vaccine development and testing such as basic research, clinical studies, side effects and adverse reaction. For additional information please visit:

<http://www.cdc.gov/vaccines/resdev/test-approve.htm>

HPV and HPV Vaccine: Information for Healthcare Providers. This PDF is a fact sheet that provides an overview of HPV including information on Safety and Efficacy. [Hi-resolution print version](#)  (6.4MB).

Additional information and the PDF can also be found at: <http://www.cdc.gov/std/HPV/>

Quadrivalent HPV Vaccine: Efficacy and Provisional Recommendations. Presented by Lauri Markowitz, MD, National Centers for HIV, Viral Hepatitis, STD and TB Prevention, CDC

<http://www.cdc.gov/vaccines/ed/ciinc/archived/hpv/downloads/3-HPV.ppt> Additional information and the PDF can also be found at: <http://www.cdc.gov/vaccines/ed/ciinc/>

Infectious Diseases in Children: *What's Hot in Pediatric ID*. Article: Severe adverse events associated with HPV vaccine are rare – August 2007, Volume 20.Number 8: 23 -24.