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# **Cervical Cancer Health Center**

## **Gardasil Linked to Nerve Disorder**

## Cervical Cancer Vaccine May Raise Risk of Guillain-Barre Syndrome

By Charlene Laino WebMD Health News Reviewed by Louise Chang, MD

April 30, 2009 (Seattle) -- Girls and women who receive the Gardasil vaccine to prevent cervical cancer may be at increased risk of a rare but serious disorder of the nervous system in the first few weeks after getting their shots, researchers report.

Overall, the vaccine does not raise the odds of developing Guillain-Barre syndrome (GBS), a disorder of the peripheral nervous system, says Nizar Souayah, MD, of the University of Medicine and Dentistry of New Jersey in Newark.

"But there is clear evidence from our database of an increased incidence of Guillain-Barre syndrome in the first six weeks, especially the first two weeks, after vaccination," he tells WebMD.

Still, the risk is extremely low: 26 in 10 million in the first two weeks and 30 in 10 million in the first six weeks after vaccination. That compares to 5 in 10 million odds in the general population. Souayah says.

In response to the study, a spokesperson for Merck, which makes Gardasil, notes that the CDC says that "the data do not currently suggest an association between Gardasil and GBS."

The findings were presented at the annual meeting of the American Academy of Neurology.

#### **Guillain-Barre Syndrome and Vaccination**

Guillain-Barre syndrome is a rare nervous system disorder in which the body's immune system attacks part of the nervous system. This immune system malfunction is usually triggered by an infection, such as with flu virus, or other illness. Occasionally, surgery or vaccinations will trigger the syndrome.

The link between Guillain-Barre syndrome and vaccinations isn't clear. But researchers say concerns emerged after an association was noticed during the 1976-1977 "swine flu" season. Since then, "there is always a concern when any vaccine program is introduced," says Ken Gorson, MD, a neurologist at Tufts University/St. Elizabeth's Medical Center in Boston.

In January 2007, the CDC added Gardasil to its routine childhood immunization schedule. The CDC recommended Gardasil for all girls aged 11-12 and even for girls as young as 9, with catch-up doses for girls and women 13-26 who hadn't been vaccinated earlier.

HPV is a sexually transmitted virus, with dozens of strains.

As of December 2008, more than 23 million doses of the vaccine were distributed, according to Souayah.

#### Guillain-Barre Syndrome and Vaccination: Study Details

For the study, researchers examined data from the Vaccine Adverse Event Reporting System (VAERS), which is managed by the CDC and the FDA.

There were 53 cases of Guillain-Barre reported after HPV vaccination in the United States from 2006 to 2008. In nearly three-fourths of cases, the disorder developed within six weeks after vaccination. More than one-

third of cases occurred in the first two weeks.

The fact that so many cases occurred in the first few weeks after vaccination strongly suggests that "some cases are caused by the vaccine," Souayah says.

## Guillain-Barre Syndrome and Vaccination: Study Details continued...

Merck spokeswoman Pamela Eisele points to the FDA and CDC statement on the safety of Gardasil: "The FDA and CDC have reviewed the reports of GBS that have been submitted to VAERS. To date, there is no evidence that Gardasil has increased the rate of GBS above that expected in the population."

Gorson says much more study is needed before any conclusions regarding Gardasil and GBS can be made. Plus, the chance of developing Guillain-Barre syndrome, regardless of whether you're vaccinated, is extremely low, he says.

"I would discourage women to look for the problem in the first six weeks after vaccination as it will just cause undue anxiety. Guillain-Barre syndrome is not subtle, with weakness, paralysis, balance problems, and numbness and tingling of the limbs developing in a rapidly progressing fashion. It won't be missed," Gorson tells WebMD.

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