FACT SHEET
Update: HPV Vaccine Safety

This fact sheet is designed to provide a basic summary of existing data on the safety of HPV vaccines. As demonstrated in extensive clinical trials and through post-marketing surveillance, HPV vaccines continue to show very good safety profiles, with no causal links to any deaths and with very low rates of serious side effects.

HPV Vaccines and Cervical Cancer: Basic Facts

Every year nearly 500,000 women are diagnosed with cervical cancer and over 250,000 die from this disease. More than 80% of deaths occur in developing countries. Virtually all cases of cervical cancer are caused by human papillomavirus (HPV). Two HPV vaccines, Gardasil™ and Cervarix™, protect against the types of HPV that most commonly cause cervical cancer. These vaccines are made up of non-infectious particles and contain no live virus or viral DNA. Neither vaccine contains thiomersal, a mercury compound that has been used as a preservative in some vaccines.

When a new vaccine becomes available, licensing agencies review the risks and adverse events from large clinical trials and then monitor the vaccine after it enters the market and is used by many more individuals. Pre-licensure safety data for the HPV vaccines were based on clinical trials that included well over 10,000 girls and young women for each of the two vaccines.¹⁻³ In the US, 24 million doses of Gardasil were distributed as of May 2009⁴ and over 40 million doses have been distributed worldwide. Seven million doses of Cervarix were distributed worldwide as of May 2009.⁵

Monitoring agencies including the Vaccine Adverse Event Reporting System (VAERS) within the US Food and Drug Administration, the European Medicines Agency (EMEA), the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom, the Therapeutic Goods Administration (TGA) in Australia and the Global Advisory Committee on Vaccine Safety (GACVS) at the World Health Organization (WHO) evaluate the safety of vaccines on an ongoing basis. GACVS has summarized available data on the safety of HPV vaccines and determined that the vaccines are safe and that the benefits far outweigh the risks.⁶⁻⁷ Many other agencies also have concluded that HPV vaccines are safe and effective.
**What are the side effects of HPV vaccines?**

Common side effects are minor and include pain, swelling, or redness at the injection site. Fever and nausea also are common but these side effects are not more common in girls who receive an HPV vaccine compared to girls who receive a placebo vaccine. Such side effects are only temporary.

Serious adverse events involving hospitalization, death, disability, life threatening illness, or other medically important conditions account for approximately 3 per 100,000 VAERS reports for Gardasil in the US. Less serious events—including temporary vomiting, fainting, fever, nausea, and headache—make up 7% of VAERS reports, with about 54 events per 100,000 individuals vaccinated, similar to other adolescent vaccines and below the average of 10%-15% across all vaccines. The rate of serious adverse events for Cervarix is similar to Gardasil.

The small number of deaths reported following HPV vaccination do not appear to be causally related to the vaccine. In the US where autopsy and medical records were available for 20 of the 32 deaths reported, 80% of fatalities were found to have occurred for reasons other than vaccination while 20% (4 cases) had unknown causes. There was no common pattern that would suggest that any of the deaths were caused by the vaccine. The one reported death for Cervarix also was found not to be caused by the vaccine.

Fainting after an injection is more common among teens than among young children or adults and is most often a response to the vaccination process rather than a side effect of the vaccine itself. A US study showed that fainting was not more common after HPV vaccination compared to other vaccines given to teenagers and young women. In order to prevent injuries due to fainting, a fifteen minute waiting period for people of all ages is recommended after any vaccination.

Guillain Barre Syndrome (GBS) is an autoimmune disease of unknown cause that affects the nervous system and may lead to paralysis (though this usually is temporary). Severe cases are life-threatening but most patients recover. Occasionally, surgery or vaccinations trigger GBS. A recent study of girls and young women who received more than 375,000 doses of HPV vaccine showed no increased risk of GBS. The reporting rate to VAERS is 2 per 1,000,000 individuals vaccinated with Gardasil in the US.

The relative risk of venous thromboembolic events (VTEs) such as deep vein blood clots is 2 per 1,000,000 individuals vaccinated with Gardasil in the US. Ninety percent of cases (28 of 31 VAERS reports, all in women ages 15-39) had a known risk factor for VTEs including use of oral contraceptives and family history.

Serious allergic reactions are a rare side-effect of most vaccines. The rate of anaphylaxis, the most serious kind of allergic reaction, is not higher after HPV vaccination compared to other vaccines.

**How is safety monitored?**

Agencies in individual countries and at WHO rigorously monitor reports of adverse events that occur after vaccination. Such reports usually come from health professionals, people who have been vaccinated, parents, vaccine manufacturers, or third parties. In the United States anyone
can use the internet to make a report, so it is important to remember that an initial report of a problem does not mean that the vaccine caused the problem or increased the risk of that event, only that the event occurred after vaccination. If scientists monitoring the reports begin to see a potential pattern of problems following vaccination, they initiate an intensive investigation to determine if the event was merely coincidental with immunization, or if the vaccine could have caused the problem.

News stories linking HPV vaccination to deaths or serious issues often fail to explain how the reporting system works, and they confuse reports of events following immunization (there can be many such reports) with confirmed causal links between the vaccine and the health problem (very few). Misleading headlines cause a lot of confusion and unnecessary anxiety.

Limitations of such monitoring systems (called “passive surveillance”) include underreporting, reporting bias, and the absence of denominator data or base rate of each event within the general population. In spite of these limitations, monitoring systems can and do provide early alerts about rare safety issues that only become evident when millions of people are using a vaccine or drug.

**Which women should not be vaccinated against?**

HPV vaccines are not recommended for pregnant women. If a woman finds out she is pregnant after she has started the three dose series, she should wait until after her pregnancy to complete the series. That said, no increase in spontaneous abortion rates or congenital abnormalities has been observed for either HPV vaccine, though data are limited.

People who have had a serious allergic reaction following a specific vaccine or are seriously allergic to anything in a vaccine should not receive that vaccine again.

Vaccination is ineffective in women who have already been exposed to HPV, so is less likely to be protective in older women, although there are no known safety issues specific to this group.

**Cervical Cancer Action**

Cervical Cancer Action: A Global Coalition to Stop Cervical Cancer (CCA) was founded in 2007 to expedite the global availability, affordability, and accessibility of new and improved cervical cancer prevention technologies to women in developing countries.

For more information:
Cervical Cancer Action
[www.cervicalcanceraction.org](http://www.cervicalcanceraction.org)
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References