

WHAT YOU SHOULD KNOW about Gardasil

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Gardasil is a new vaccine targeting four strains of Human Papilloma Virus (HPV) generally believed to be the cause of cervical cancer. Two of these strains, HPV-16 and HPV-18 apparently account for about 70% of all cervical cancers. However, it is worth noting that the National Cancer Institute in the USA says that “direct causation has not been demonstrated”.

The Human Papilloma Virus (HPV) is a sexually transmitted disease, often associated with promiscuity. It has been found that progesterone-based contraceptives, such as Depo

Provera, significantly thin the vaginal linings, making bruising, abrasions and subsequent infection more likely.

Gardasil has been fast-tracked in Australia by the Therapeutic Goods Administration (TGA) and is being highly recommended for ‘adolescent’ males 9 to 15 years and females 9 to 26 years of age. Large bill boards around Sydney advertise the vaccine free from GPs for young women between the ages of 18 and 26, and the pressure is really on in schools for parents to agree to have their young daughters vaccinated with Gardasil.

However, the vaccine is far from safe. In fact, the only thing known for certain about Gardasil is that there are many uncertainties.

A worst-case scenario comes from the USA where a Washington based public interest group, Judicial Watch, has reported that the vaccine has been tied to the deaths of three young women, the youngest only 12 years of age. The deaths were caused by myocarditis, coronary artery thrombosis and pulmonary embolism. Judicial Watch also reported that, of 42 women who got

the vaccine while pregnant, 18 experienced side effects ranging from spontaneous abortion to foetal abnormalities.

Also in the USA, The

Vaccine Adverse Event Reporting System (VAERS) has received 385 individual Gardasil adverse event reports, most requiring additional medical care and about one-third of these were for children 16 years and under. VAERS is a programme co-sponsored by the Food & Drug Administration (FDA) and the Centers for Disease Control (CDC). VAERS report covered the last six months of 2006. It is estimated that fewer than 10 percent, and sometimes as low as 1–4 percent, of adverse reactions occurring after prescription drug or vaccine are ever reported. This could mean that there may have been up to 38,000 health problems associated with Gardasil in that period.



Adverse reactions reported to VAERS include:

- *loss of consciousness and syncope*
- *seizures*
- *dizziness, shakiness, "feeling faint"*
- *loss of vision, decrease in quality of vision, dryness of eyes*
- *abnormal speech*
- *nausea, vomiting*
- *headache*
- *pallor, purple coloration of the lips*
- *fever, chills*
- *dyskinesia (difficulty or distortion in performing voluntary movements)*
- *difficulty swallowing*
- *joint pain*
- *Guillain-Barre Syndrome (an immune disorder which effects the peripheral nervous system and in extreme cases can cause paralysis)*
- *Hives, itching, rashes, blisters, vesicles, and skin ulcers*
- *Swelling of the arms, swelling of the lower extremities, swelling of the lymph nodes*
- *Severe pain at the site of injection.*

The National Vaccine Information Center (NVIC), which analysed the VAERS report, has warned that "Although adverse event reports to VAERS do not prove causation, they can provide an early warning sign that a new vaccine may be causing health problems that could be important". NVIC's conclusion is "With cervical cancer causing about one percent of all cancer deaths in American women due to routine pap screening, it was inappropriate for the FDA to fast track Gardasil. It is way too early to direct all young girls to get three doses of

a vaccine that has not been proved safe or effective in their age group."

It is usually a worry when the manufacturers of drugs are the very people who do the research into their safety. This is the case with Gardasil, since the manufacturers, Merck & Co., also did the research. The Alliance for Human Research Protection (AHRP), a national network of lay people and professionals dedicated to advancing responsible and ethical medical research practices, says that FDA's hasty approval of Merck's HPV vaccine has not been proven safe and effective in clinical trials.

Other concerns have been expressed by researchers about the ingredients of the vaccine, which include aluminium and yeast. Also, the vaccine is delivered in three doses over a seven month period and nothing is yet known about how long the immunity will last beyond four years. Meanwhile, back in Australia, Gardasil is on the fast track and is being subsidized by the Australian Government under the National Immunisation Program, commencing with school-based programmes in 2007 for 12–18 year old girls and for women up to and including 26 years through community-based programmes generally delivered through general practice.

The expected cost of the vaccine is \$436 million over four years. It is an expensive vaccine and was first rejected by our Pharmaceutical Benefits Advisory Committee (PBAC) but that decision was overturned following negotiations with the Commonwealth Serum Laboratory in which a reduced price and other favourable conditions of supply were offered.☐