

The Risk and Facts about Cervical Cancer and HPV Vaccine

- Merck & Co did not trial this vaccine against cervical cancer. It was trialled for 3-4 years in women 16 – 26 years of age against *pre-cancerous lesions*. This was used as a surrogate for cervical cancer even though most pre-cancerous lesions in young women *do not lead to cancer* ¹
- In 2006 Gardasil® was named the pharmaceutical “Brand of the Year” by the magazine *Pharmaceutical Executive* for building a ‘market out of thin air’ ⁹.
- In 2004, before the vaccine was introduced, the death rate from cervical cancer in Australia was 1.9/100,000 women. This represents a very low risk to Australian women ¹
- There are more than 15 high-risk strains of HPV associated with cancer that are not covered by the vaccine and pap smears will still be required ^{1,2,3}
- HPV 16/18 is a common infection in women in all countries but 90% of infections do not progress to warts or cervical cancer ^{3,4}
- Infection with **Human Papillomavirus (HPV) 16/18** rarely progresses to **cervical cancer** ^{3,4}
- The cumulative lifetime risk of developing cervical cancer in developed nations is 0.8% and of dying of cc is 0.25% ²
- Four out of five women who get **cervical cancer** live in developing countries not *developed countries* – such as *Australia, Europe and the USA* ^{2,3}
- The prevalence of **HPV 16/18** is similar in all countries. This indicates that lifestyle and environmental factors play a role in progressing HPV infection to cervical cancer ^{2,5}
- Scientists admit a co-factor is required to trigger cancer development - promiscuity, herpes simplex virus -2, male sexual practices, oral contraceptives etc ^{2,3}
- Sexual behaviour conducive to the acquisition of sexually transmitted infectious diseases increases a women’s risk of developing cervical cancer ^{1,3,4}

Trials of the Vaccine:

- Trials of this drug did not observe that it would prevent any cervical cancer ¹
- Researchers were observing the incidence of pre-cancerous lesions in 16-26 year old women - an age group that rarely gets cervical cancer ¹
- In young women pre-cancerous lesions have a high clearance rate and do not always lead to cancer ¹
- CSL (pharmaceutical company) funded this research at the University of Queensland ¹

- Trials of the vaccine were funded by Merck (manufacturer of the vaccine) 1
- 10 of the authors of the trials were employed by Merck and the company has financial arrangements with several of the other authors 6

Duration of the Vaccine

- The duration of this vaccine is unknown as it has only been tested in adults for 3-4 years 1
- Cervical Cancer takes 8 -25 years to develop 1

Other Concerns

- Since it was introduced in 2007 until August 2011 there have been 94 deaths and 21,635 adverse reactions globally to Gardasil®. This is recorded from a *passive* surveillance system which is believed to represent only one- tenth of the possible reactions 8.
- It is a genetically modified vaccine 1
- It contains 225 micrograms of aluminium adjuvant. Many times more than most vaccines and known to cause allergies/anaphylaxis and autoimmune reactions in humans 6
- The trials did not use a true placebo to test the safety of the vaccine. The manufacturer funded clinical trials used the adjuvant, aluminium hydroxyphosphate sulphate as the placebo in the unvaccinated group: a chemical known to be linked to adverse events including autoimmune diseases 7
- In the safety trials it was found that there was 3 times the number of serious medical problems in the vaccine group than the placebo group. Including juvenile arthritis, rheumatoid arthritis and arthritis 6 These are autoimmune diseases which have significantly increased in the population since vaccination use increased 1

Judy Wilyman

www.vaccinationdecisions.net

References:

1. Australian Government, Department of Health and Ageing, Office of Health Protection, 2009.
2. Parkin DM, Bray F, Ferlay J, Pisani P, 2005, Global Cancer Statistics 2002, *CA: A Cancer Journal for Clinicians*, 2005; 55; 74-108
3. International Agency for Research on Cancer (WHO), 1995, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, volume 64, Human Papillomaviruses.
4. Pfister H (Ed.), 1990, Papillomaviruses and Human Cancer, CRC Press Inc, USA
5. Clifford et al, 2005, Worldwide distribution of human papillomavirus types in cytologically normal women in the International Agency for Research on Cancer HPV prevalence surveys: a pooled analysis, *The Lancet*, Vol 366, Is. 9490,2005,Pages 991-998

6. Merck and Co. 2006: Gardasil® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18), Prescribing Information as cited in *Investigate before you Vaccinate: Immunisation Awareness Society*, New Zealand.
7. Shoenfeld Y and Agmon-Levin N, 2011, ASIA – Autoimmunity/inflammatory syndrome induced by adjuvants, *Journal of Autoimmunity*, 36 p. 4-8.
8. S.A.N.E Vax Inc. Safe, Affordable, Necessary and Effective Vaccines, www.sanevax.org visited 28 April 2011
9. Herskovits B. 2007, Brand of the Year, *Pharmaceutical Executive*, 27 (2): 58-65