

HPV Vaccine: Answers Needed from Government Health Ministers



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In Australia, as in some other countries, the HPV vaccine - Gardasil® - is being promoted to adolescents, woman and now boys, as a vaccine to prevent cervical cancer. Government health departments are not addressing the concerns parents have about this vaccine.

There are many scientific and ethical concerns regarding the HPV vaccine and the community would like the following issues addressed:

- This vaccine was not proven to be safe or effective against cervical cancer (CC) prior to its marketing in 2006. Phase 3 trials were not completed until 2007 and the vaccine is only *assumed* to be effective against CC because the relationship between pre-cancerous cells in young adults and cervical cancer 20 to 40 years later is unknown ¹
- Gardasil® has 3 times the number of adverse reactions reported as all other vaccines *combined*.²
- Each of the 3 injections contains 225 ug of aluminium hydroxyphosphate sulfate, an adjuvant known to be linked with autoimmune diseases, the chronic illnesses that are increasing in our population ^{3, 4}
- Each of the 3 injections contains sodium borate (a pesticide), which has been linked to infertility, seizures and paralysis. In 2005 the National Library of Medicine (NLM) of the National Institutes of Health declared this to be a dangerous poison and stated 'it is no longer commonly found in medical preparations' ^{5, 6}. HPV vaccine was approved in 2006.
- Each of the 3 injections also contains polysorbate 80, an emulsifier linked with anaphylaxis, convulsions, collapse, seizure (twitching) and infertility in animals ^{5, 6}.
- Since it was introduced, 94 deaths and 21,635 adverse reactions to Gardasil have been documented. Many have included the events listed above ⁷.
- There is no systematic, long-term surveillance of adverse events to the HPV vaccine. The reporting system is a passive surveillance system. The CDC states "This (VAERS) data cannot be used to infer causal associations between vaccines and adverse events"². If no one

carefully monitors adverse reactions, there is no proof that it is safe. Yet parents are told combining vaccines is safe. This also means it will not be possible to determine whether women vaccinated against HPV will have a higher rate of infertility and autoimmune diseases in 10 – 15 years time.

- The placebo in the clinical trials contained *more aluminium adjuvant* (a chemical linked with autoimmune diseases) than the vaccine itself². This is not a properly designed scientific study.

Why has this vaccine been marketed so aggressively to Australian women when cervical cancer is a very low risk in Australia (indeed in all developed countries) and the vaccine contains chemicals linked with infertility? The other HPV vaccine (Cerverix) does not contain sodium borate or polysorbate 80, so why is it necessary to use infertility chemicals in Gardasil® which is being marketed to adolescent girls and women of all ages?

Please could you provide information and answers to the issues raised above.

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The Pathogenesis of Human Papillomavirus (HPV) in the Development of Cervical Cancer: Are HPV vaccines a safe and effective management strategy for this disease?

Whilst it can be claimed that HPV infection is a necessary pre-cursor to most cervical cancer, it must also be emphasized that most high risk HPV infections do not progress to cervical cancer^{1,2}. Scientists recognize that HPV infection with one of 15 or more high-risk strains is not sufficient on its own to induce cervical cancer^{1,2,3}. Several environmental and lifestyle factors have been identified as necessary for the progression of normal epithelial cells to carcinoma^{1,2,3}. In 2006, when scientists declared Human Papillomavirus (HPV) Type 16 and 18 to be the determining cause of cervical cancer⁴, it was known that HPV infection on its own was not sufficient to cause cervical cancer. Over the past century several co-factors have been identified as necessary for the progression of normal epithelial cells to carcinoma. Whilst there is still doubt about the identity of some co-factors, those that are confirmed are: multiple partners for the male and female, presence of HPV plus other viruses (for example HPV + Herpes Simplex Virus Type 2), prostitution, sex without a condom/microbicides, low socioeconomic status (poor hygiene/sanitation/nutrition conducive to sexually transmitted diseases), immunosuppression, smoking, and oral contraceptives^{1,2,3}.

The biological plausibility of an etiological theory requires that the incidence of the causal agent varies with the incidence and mortality of the disease⁵. Yet it is noted that the incidence and mortality of cervical cancer does not vary with the incidence of infection with HPV strains 16 and 18 worldwide^{6,7}. HPV 16 and 18 are less prevalent in the countries with the highest rates of cervical cancer: the developing countries⁷. Clifford et al (2003) state a vaccine targeting HPV strains 16 and 18 may prevent more invasive cervical cancer in developed nations where cervical cancer rates are low, than in the developing countries which carry the highest burden of this disease⁷ (Figure 1). HPV infection is prevalent in all countries yet cervical cancer rates vary significantly from country¹. This is evidence that a co-factor is a determinant, in conjunction with HPV in the progression to cervical cancer.

The trials for the Human Papillomavirus (HPV) vaccine did not observe that the vaccine would prevent any cases of cervical cancer⁸. The clinical trials for this vaccine observed pre-cancerous lesions in women 16 – 26 years of age⁹. This was an inadequate surrogate for cervical cancer because studies show that eighty percent of lesions in this demographic clear quickly without requiring treatment². In addition, it is a demographic which rarely gets cervical cancer and the participants in the trials were not selected for the risk factors known to progress HPV infection to cervical cancer in later years⁹.

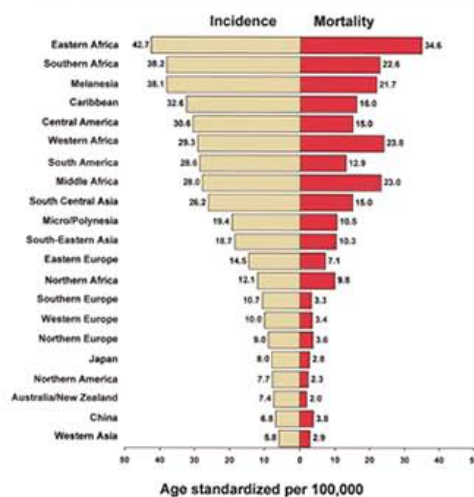
This research concludes that the decision to use a vaccine to prevent cervical cancer was based upon the assumption that it would prevent cervical cancer: circumstantial evidence and not empirical evidence. HPV vaccines have been promoted to women on misleading information and the long-term risks of the vaccine have not been determined. A reduction in the burden of cervical cancer globally would be assisted by targeting the risk factors for this disease. This has already been demonstrated in China and other developed nations where the incidence of cervical cancer has been very low since the seventies⁶. This was achieved by altering the environmental/lifestyle factors listed above and introducing screening programs.

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Figure 1: Global Incidence and Mortality Rates for Cervix Uteri Cancer



Ref: Figure 11: Age-Standardised Incidence and Mortality Rates for Cervix Uteri Cancer, Parkin D, Bray F, Ferlay J and Pisani P, Global Cancer Statistics 2002, CA Cancer J Clin 2005; 55: 74 - 108

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