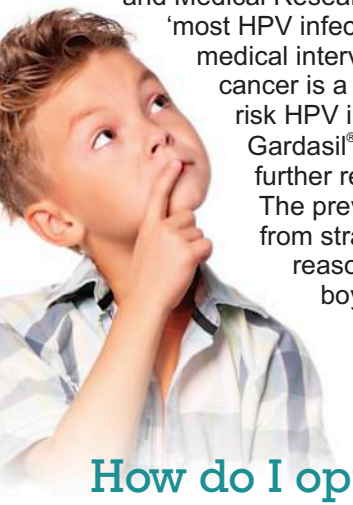
Who can receive Gardasil®?

Gardasil® is marketed for use by females aged 9-26yrs and boys aged 9-15yrs.

Why are boys being offered Gardasil®?



The Australian Government's National Health and Medical Research Council maintains that 'most HPV infections resolve without medical intervention' and that 'cervical cancer is a rare outcome even of high risk HPV infection'. Despite this, Gardasil® was authorised for boys to further reduce sexual transmission. The prevention of anogenital warts from strains 6 and 11 was cited as a reason to expand this vaccine to boys.

The other reason cited was to reduce the prevalence of wart virus in homosexuals[12].

How do I opt out?

Gardasil® vaccination programs in Australian schools require written parental consent. If the letter which the school sends home to obtain your consent for Gardasil® is not signed by you, the school has no authority to administer this vaccine to your child.

The facts that you deserve

Particular safety for the human ovary still needs to be determined. The absence of research assessing ovarian safety following this vaccination raises concerns for its use in young female populations. Suspension of this vaccination program pending further mammalian research and teenage cohort studies is ethically required.

You have a right to be fully informed with the facts before providing your full consent to receive this vaccination. If you require more information on this matter, please visit our website or contact Family Life International.

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11. Myths and realities: responding to arguments against immunisation. A guide for providers; 5th ed. 2013
12. Dept of Health Fact Sheet: *National Immunization Program HPV Vaccination for Boys*. Canberra Dept of Health 2012.

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What you should know about

the Gardasil® vaccine

What is Gardasil®?

Gardasil® is a vaccine against some of the sexually transmitted infection caused by Human Papillomavirus (HPV). It protects against the two virus strains responsible for 90% of genital warts (strain 6 and 11) and two other strains which cause up to 70% of cancer of the cervix (strain16 and 18).

Gardasil® is a vaccine administered intramuscularly, ideally before infection is acquired. It cannot prevent cancer if the infection is already present. It consists of three injections in the upper arm, usually given over six months. These injections stimulate an immune response against the four viral strains, HPV 6, 11, 16 and 18.

The **Human Papillomavirus** (HPV) is a virus spread through sexual contact. It is a small, DNA virus causing abnormal skin tissue. While most HPV infection clears spontaneously in one to two years, infection persists in 3-10% of cases. In some women whose systems do not clear HPV infection, skin cell changes may arise within this ongoing infection and, over a period of years, can progress on to cancer of the cervix. This is why we have Pap smears every two years, giving us many opportunities to pick up and treat cell changes which could be pre-cancerous[6].

Is there a need for Gardasil®?

Gardasil®will not cover other strains which cause 30% of cancer in the cervix. There is no statistically significant evidence that the HPV vaccine has prevented cancer of the cervix. Accordingly, Pap smears and Pap programs continue with increasing success in reducing cancer of the cervix.

By 1998 it was already known that 70% of squamous (skin cell) cervical cancers in Australia were being prevented by Pap smears.

Most HPV infections resolve naturally in 1-2 years and spontaneously, unless some other disease process is affecting the immune system at the time.

Mutual chastity prevents anogenital wart virus infections and the cancers arising from them.

What is in Gardasil®?

225 micrograms of aluminium adjuvant, 0.78 milligrams of L-histidine, 50 micrograms polysorbate 80*, 35 micrograms sodium borate, water, and salt, as well HPV 6 L1 protein, HPV 11 L1 protein, HPV 16 L1 protein, and HPV 18 L1 protein.

*- *Polysorbate 80 causes infertility in rats and was toxic to very young rat ovaries at all doses tested over a ten-fold range[10]. It was included in the 'normal saline' placebo given to adolescents in placebo controlled Gardasil® safety trials. There is no dose-response curve to establish a safe injected dose or toxicological endpoint known.*

The absence of research reviewing the integrity of the female ovary after vaccination is a serious deficiency in this vaccine's promotion. This missing vaccine research into ovarian safety and research cited above is at odds with unreferenced assurances issued from the Dept of Health and Ageing which claims that there is 'no biologically plausible way in which the HPV vaccine could cause infertility'[11]. This misinforms consent and is at odds with published auto-immune research, 'HPV and Primary Ovarian Failure: another facet of the Autoimmune/Inflammatory Syndrome".

Can Gardasil® have ill effects?

The manufacturer of Gardasil®, Merck Sharp and Dohme (MSD), advises of very few ill effects apart from fainting, allergic reactions, fever and injection site problems from studies largely designed and funded by MSD.

However,

- In June 2013, Japan announced withdrawal of its support for Gardasil® on the grounds of multiple adverse events and inadequate research.
- MSD provided a study of the microscopic cellular appearance (histology) of the testes of vaccine-tested rats, but no such study is available of vaccine-tested rat ovaries[1].
- No clinical trials had the capacity to evaluate ovarian harm following Gardasil® vaccination, since most participants were aged 16 to 25 and were using hormonal contraception (which masks the evidence of toxicity effects on the ovary throughout the study period[2]). New medical conditions arising in the safety trials after the 7th month from the first vaccination were deemed not to be adverse events related to the vaccine.
- Premature menopause occurring after Gardasil® vaccination has been reported since 2009 in girls as young as 13 years of age[3]. In Australia several girls are reported to have ceased menstruating after having Gardasil[4] injections. An additional case in a 16 yr old girl was investigated by the physician and the *British Medical Journal* published the history and report[5]. Other medical researchers have recently published a case series of this phenomenon.[6]
- Gardasil was a fast-tracked vaccine, receiving only a six month approval process. One in three fast-tracked drugs are withdrawn from the market for safety reasons[7].

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- By Sept 2012, 60% of all vaccine adverse events reported to the Vaccine Adverse Event Reporting System followed HPV vaccination[8]. Reports include those of thromboembolism, vaginal hemorrhage, auto-immune conditions, paralysis and other neurological diagnoses such as Guillaine Barre. These reports do not establish a cause but provide a database to direct further research.
- The largest safety study of this vaccine, performed after introduction to school children, concludes 'it was not designed to investigate long term safety outcomes or risk of HPV associated recurrence/progression of disease' and had 'insufficient power' to detect very rare conditions'[9]. It assessed emergency department visits after vaccination and hospitalizations within specified times.
- Long term risks are unknown and un-assessed.