

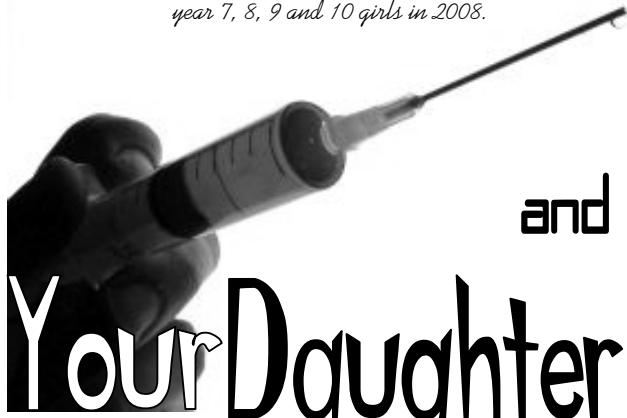
# H.P.V.

*One of the most common and most contagious sexually transmitted infections.*

# Immunisation,

*School based immunisation program targeting girls aged 12 to 18 years of age in 2007 and 2008.*

*The HPV vaccine will be offered in WA schools to year 7, 8, 9 and 10 girls in 2008.*



By Rachel Dalais BA (hons), Dip Ed

[racheld@arach.net.au](mailto:racheld@arach.net.au)

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The administration of the HPV vaccine (commercially known as Gardasil or Cervirax) to teenage girls has been rapidly processed in both Australia and the US. Your school may have notified you of the first of a series of three injections, being introduced under the National Immunisation Programme and funded under the PBS, after the second application for approval by the Therapeutic Goods Administration.

## What is HPV ?

Human Papilloma Virus is one of the most common and most contagious STI's (or Sexually transmitted infections)<sup>1</sup>. Infection with HPV can only occur from genital skin contact during sex.<sup>2</sup> Hence, condoms do not provide adequate protection because they still allow some skin contact. HPV is most common in women 20-26 years of age. There is no treatment for HPV itself - often the body deals with the virus itself within 1-2 years.<sup>3</sup> HPV is the cause of genital warts or can be a silent infection of the cervix.

## How is HPV connected to cervical cancer?

There are approximately 40 different strains of HPV, 15 of those strains are known to cause cancer. HPV strains 16 and 18 cause 70% of all cervical cancers worldwide.<sup>4</sup> Gardasil prevents infection from HPV strains 6, 11, 16 and 18 if vaccination occurs before infection. (Strains 6 and 11 cause 90% of genital warts and are therefore included in Gardasil but not Cervirax which only covers strains 16 and 18)<sup>5</sup>

While HPV is a necessary precursor to cervical cancer, HPV does not automatically lead to cervical cancer. As mentioned above, 98% of HPV infections are resolved by the body with 8- 14 months<sup>6</sup>, and some persistent infections will never cause precancerous abnormalities. It takes much longer for the cell abnormalities caused by HPV to become cervical cancer – upwards of 10 years.<sup>7</sup> The best prevention for cervical cancer is regular screening (pap smears) which test for the cell abnormalities caused by HPV. The National Cervical Screening Program in Australia has cut deaths from cervical cancer by 60% since introduction in 1985 and

halved the number of cases of cervical cancer.<sup>8</sup> Even women who receive the vaccine will still require regular pap smears because the vaccine does not guard against all strains of HPV. This begs the question of whether the vaccine contributes much more to medical care than the screening program has already done. Most cervical cancer cases are found where screening is not done or is inadequate.

## Medical and physical issues

There are several issues with the HPV vaccine which need to be considered, like any vaccine. This drug is new and relatively untested.

- Insufficient testing for the target age group 12-16 year olds. It is untested for the group of females to whom it is being recommended, and for the length of time protection from HPV is required. The effect of the vaccine on pre-pubescent and pubescent physiques is unknown, as the majority of studies were done on women aged 16-26.

"According to Merck's clinical study documents on Gardasil, 20,541 women ages 16 to 26 participated in four studies..... Merck conducted two clinical trials that involved 1,121 girls ages 9 to 15, according to Merck's labeling documents for Gardasil. "The clinical trials tested younger girls, but they only looked at immune response to the vaccine, not whether it prevented cervical cancer," Dr. Young (a gynaecologist from Texas) said. "It has not been studied long enough to know that it prevents cervical cancer.""<sup>9</sup>

- No long term testing. The long term effects and benefits of the vaccine are unknown, because the vaccine is only new. The manufacturers, CSL/Merck, are only prepared to ensure protection from HPV for 4.5 years from the time of vaccination for women and the results for men are not complete. Trials have only been conducted in the last 2-3 years. The quote above shows that there is no evidence of its effectiveness against cervical cancer in the long term. Typically it

<sup>1</sup> Estimates are 4 out of 5 sexually active people will have contact with HPV at some time. "The link between HPV and cervical cancer." National Cervical Screening Program (A joint Australian, State and Territory Government Initiative. pg. 3 ) Publication found online at [http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cv-hpv/\\$file/hpv.pdf](http://www.cancerscreening.gov.au/internet/screening/publishing.nsf/Content/cv-hpv/$file/hpv.pdf)

<sup>2</sup> *ibid.* pg. 4

<sup>3</sup> *ibid.* pg. 5

<sup>4</sup> "HPV Vaccines for Australians: Fact Sheet for GPs and Immunisation Providers" National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases.(NCIRS) University of Sydney

<sup>5</sup> *ibid.*

<sup>6</sup> Australian Immunisation Handbook (draft 9<sup>th</sup> edition 2007 ), National Health and Medical Research Council pg. 138 ( see : "www.immunise.health.gov.au" )

<sup>7</sup> *op.cit.* National Screening Programme. pg 6

<sup>8</sup> *op.cit.* NCIRS fact sheet Also, Australia currently has the second-lowest incidence of cervical cancer and the lowest mortality rate from cervical cancer in the world. This amounts to 250 deaths, 1800 hospitalisations and 750 cases annually. (Australian Immunisation Handbook 2007 9<sup>th</sup> edition draft pg. 139)

<sup>9</sup> "Cancer Virus Vaccine targets wrong age group" The Washington Times . Feb. 21, 2007

takes 10-20 years for cervical cancer to develop, from contraction of HPV (which statistically occurs in a woman's 20's). By the time a 12 year old has become sexually active in her later teens/twenties and then contracted HPV and then waited for the possible development of cancerous cells, she is over 30. The long term protection of the vaccine for cervical cancer is not established and can not be until long term trials or observation is done. This suggests that a booster may be necessary, which leaves times where women are possibly unprotected by the vaccine, between treatments.

- Side effects. Side effects have been reported in the US where mandatory vaccination is underway in many states. The side effects prompted the National Vaccine Information Centre in the US to issue warnings to doctors and parents about possible complications. "NVIC is calling on the FDA and CDC to warn parents and doctors that GARDASIL should not be combined with other vaccines and that young girls should be monitored for at least 24 hours for syncopal (collapse/fainting) episodes that can be accompanied by seizure activity, as well as symptoms of tingling, numbness and loss of sensation in the fingers and limbs..."<sup>10</sup> In Australia, the side effects have included fever, swelling and soreness of injection sites, headaches and nausea.<sup>11</sup>

"...nearly 25 percent of those children (reporting severe adverse reactions to VAERS in the US) having received simultaneously one or more of the 18 vaccines that Merck did not study in combination with GARDASIL"<sup>12</sup> The vaccine was only studied in combination with Hep. B vaccine but not with others such as rubella, DPT, tetanus, etc.

- Long term side effects. The long term side effects of the vaccine are obviously unknown. Concerns have been raised about the effect on fertility, and also on the possibility of the rise of the other cancerous strains of HPV if strains 16 and 18 are reduced by the vaccine.

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<sup>10</sup> Vaccine Safety Group Releases GARDASIL Reaction Report. February 21, 2007. NVIC Press Release -FDA and CDC Should Warn Doctors

<sup>11</sup> op.cit. Australian Immunisation Handbook pg. 142-143

<sup>12</sup> ibid.

### Lifestyle issues and moral decisions

Until now, the aim of our vaccination schedule for smallpox, polio and the host of other diseases was/is to eliminate the possibility of acquiring those diseases which proved a public health concern, were life threatening and often "randomly" acquired. In the case of HPV, the only way to acquire the virus and the inherent possible consequences (cervical cancer, genital warts etc.) is to engage in sexual activity. This is one of the first vaccines against a lifestyle choice and an avoidable disease.

There is no warning label or counselling given to the patient about the possible alternatives to the vaccine. A brilliant opportunity is being missed to educate young folk about the real consequences of choosing sexual activity outside marriage. Nor are there any "disclaimers" – this vaccine will not protect you from the other HPV strains, and more than 50 other STI's, pregnancy and the social and emotional consequences to sexual activity.

Instead we risk a possible "over confidence" response where patients feel invincible – much like the pill brought about a consequent rise in teenage pregnancies because suddenly, people felt safe. There is no safe sex – the only safe sex is with one faithful person for a lifetime.

### Family values and purity issues

There is some concern that this vaccine challenges the role and primacy of the family in the setting of moral standards and deciding life style, especially if the decision becomes mandated, rather than voluntary. It also presents a dilemma for schools if they become the "administrative arm" of the vaccine program – are they then encouraging a double standard that interferes with the family values of their school?

The proponents of this vaccine are anxious to administer it to minors before they become sexually active, because it is not effective once patients have been exposed to HPV through sexual activity. Hence, the administration

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<sup>13</sup> "The FDA staff also questioned whether the "HPV types not contained in the vaccine might offset the overall clinical effectiveness of the vaccine."...It is unknown whether non-vaccine HPV types will become more dominant in the future. However, there are indications this could occur because some of the seven strains of pneumococcal contained in Wyeth's PREVNAR vaccine, which was recommended by the CDC for universal use in all babies in 2000, have been replaced by some of the more than 80 other pneumococcal strains not contained in the vaccine." Op.cit. NVIC press release, Feb 21, 2007

of the vaccine is being thrust upon children before they have the maturity or opportunity to make any decisions about what type of lifestyle they wish to pursue or think through the other implications of those decisions.

For Christians, if we wish to encourage our children to pursue God's holiness in all things, including our relationships, this presents a challenge to the desire for and encouragement of sexual purity. The message to our teens risks becoming double minded (James 1.8) – sexual purity in words but here's a vaccine just in case. It also poses a dilemma if explaining these issues would mean a loss of innocence for children whose age has precluded the necessity for that type of information.

There are always difficult cases, even where sexual purity has been maintained. The marriage to a previously active partner is a good example. However, the engagement time would allow for vaccination in the event of marriage where one partner who had been sexually active while the other had not. There is the issue of protecting oneself and one's children from "unexpected sex" through a myriad of circumstances. Unexpected sexual contact (rape, incest, spontaneous or sex under the influence are but a few examples) is hard to address and there is a temptation to take out an "insurance policy" against the fear of such an event. However, the HPV vaccine does not provide a very effective cover from the ramifications of such an event.

The decision about vaccination needs to be made in a fully informed fashion, weighing consequences as well as the possibility of it being interpreted by the child as a lack of faith or trust in them or God.

It is our hope that this brochure helps parents to make an informed decision about the HPV vaccine without compromising their own family and spiritual values, knowing each of our children well. Perhaps this whole issue is yet another opportunity to expand upon what it means to "live in the world but not of it", and to fulfill God's best picture of holiness for each of us. It is certainly an opportunity to discuss with our children the reality of the choices we make and the outcomes we inherit as a consequence.

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