



Response from the Immunisation Advisory Centre to Fitness Life Magazine article about Gardasil® vaccine

“Health researcher” Lynda Wharton has written an article “delving” into the safety of the vaccine Gardasil®. Despite having spent over 100 hours on research she has not managed to report any facts and instead has used a range of fallacies in arguing that the vaccine is dangerous. Her article is scaremongering and dishonest to science. Following is a summary of the fallacies and confusions along with corrections in fact.

Fallacy:

The vaccine contains ‘dead’ forms of the virus.

Fact:

The vaccine contains virus-like particles (small amounts of purified protein) not dead virus.

Confusion:

Vaccine recipients produce antibodies however claims that Gardasil® can prevent cancer are premature because it takes many years to develop.

Fact:

The claims that Gardasil® can prevent cancer do not come from the fact that the vaccine initiates antibodies. The claims that the vaccine prevents against cancer come from the fact that the vaccine recipients did not develop cancer and pre-cancerous lesions whereas the recipients of the placebo did.

Fallacy:

Cervical cancer is a largely preventable disease due to PAP smears.

Fact:

While it is true that the rates of cervical cancer have dropped due to early detection and invasive treatment there are still around 160 new cases each year in New Zealand and around 60 deaths.

Not all women get regular smears and not all cancer is found by PAP smears alone. Some cases are aggressive and rapidly fatal. Cervical screening, while vital to preventing many cases of cancer, is not perfect and many women miss out. The other important point here is that treatment for cervical abnormalities is unpleasant at best and can result in higher rates of infertility and miscarriages. Prevention is generally a better strategy than treatment.

Fallacy:

There is an increasing catalogue of adverse reactions and deaths associated with Gardasil®.

Fact.

Gardasil® frequently causes local reactions such as sore arms. Reporting events that are filed with the American Vaccine Adverse Event Reporting System (VAERS) as having been actually caused by the vaccine is dishonest. VAERS collects any adverse events that occur following administration of a vaccine. This system is effective in looking for any rare, serious events that may be caused by the vaccine not detected during clinical trials. **Just because something is reported, it doesn't mean that it was vaccine induced.** Assessment of causality for every case is carried out by medical experts using rigorous criteria. The latest evaluations of the reports of events following Gardasil® are available to view on the VAERS and CDC websites. Other published articles are also available, including articles from Australia. There are no new concerns about the safety of Gardasil® and it has not been found to increase the risk of any of the serious conditions (other than anaphylaxis) noted in Whartons' article, Because this information is widely available and clearly stated on the website it suggests that either Wharton is careless in her research or dishonest in her reporting of it.

Confusion:

Gardasil may cause infertility because according to Wharton one of the vaccine ingredients causes infertility in rats.

Facts:

The fact that polysorbate 80 may cause sterility in neonatal rats when administered in extremely high doses tells us nothing about the human safety of small doses of polysorbate 80 used in foods such as icecream, vaccines and many other pharmaceutical products. Most substances are toxic in some way in large amounts, for example sodium chloride (i.e. salt and essential to life) is fatal in doses from around 0.75g/kg. The quantity of any substance is important and will dictate whether it is essential to life, harmless, dangerous or even fatal. Formaldehyde is toxic and even fatal at high doses however is essential in small amounts in our bodies for DNA synthesis. It should also be stated that toxicology information sheets describe dangers of high levels of exposure which can occur particularly in warehousing, storage and industrial use.

Another important point is that vaccines undergo strict non-clinical safety evaluation. There are 5 distinct categories of potential toxicological effects that need to be addressed:

1. Intrinsic toxicity of the test article
 - a. All vaccine components are assessed in acute toxicity studies
2. Toxicity linked to the pharmacodynamic activity or its components
 - a. Such as cross reactivity with autoantigens, requires careful selection of animal models.
3. Biological toxicity
 - a. i.e. exacerbation of existing autoimmune conditions
4. Toxicity of contaminants and impurities
 - a. Absence of impurities essential criteria
5. Evaluation of potential adverse reactions due to the interaction of vaccine components

Vaccines used in women of childbearing age are evaluated for embryo-fetal and postnatal toxicology. Gardasil® was assessed in rats prior to mating, during gestation and lactation at 300 times human dose. There were no treatment related effects. In addition, there were antibodies against all 4 types transferred to offspring.

Merck also monitored the pregnancy outcomes of those women who became pregnant during the trials. There was no difference in the number of live births, fetal loss, congenital abnormalities etc between the groups.

Fallacy:

The vaccine may only last 2 ½ years before boosters are required.

Fact:

Protection from the vaccine has been measured for over 5 years so far and there is no sign of a need for boosters. Antibody levels remain high with no sign of waning. Good immune memory has been demonstrated beyond 5 years and is suggestive of long term immunity.

A note on Diane Harper: After involvement with Merck and Gardasil® clinical trials, Diane Harper disappeared and was found working for GSK on the Cervarix® clinical trials. Her position on Gardasil® may not be neutral.

For further information and references refer to: www.immune.org.nz HPV facts and fallacies