

Family Life International NZ



Gardasil

A guide for parents and caregivers

Introduction

In recent months the New Zealand public has been subjected to an intense marketing campaign promoting the new Gardasil vaccine manufactured by the international pharmaceutical company Merck & CO. This marketing campaign has involved everything from posters in GP clinics, to radio advertisements, and even a New Zealand website. On top of this intensive marketing campaign, the introduction of Gardasil has also been accompanied by a lot of news coverage in the mainstream media.

While the marketing campaign and the media coverage of Gardasil has been widespread and at times very emotive, it hasn't actually fully informed Kiwi parents about all of the important facts about the vaccine. The end result of this has been that many parents have been left unable to make fully informed decisions about this vaccine, and in some cases parents are even dramatically overestimating the actual effectiveness and safety of the Gardasil vaccine because of the lack of information that has been provided to them.

Unlike much of the current and narrowly focused coverage of the Gardasil vaccine, our hope is that this simple guide will provide parents with a broader perspective, and this will empower them with the basic information they need to make truly informed decisions about the Gardasil vaccine.

What is Gardasil and how does it work?

Gardasil is a vaccine that is manufactured by the drug company Merck. It is designed to protect against four different strands of the sexually transmitted infection: human papillomavirus (HPV) - two of these four strands of HPV that the Gardasil vaccine targets cause 70% of all cervical cancer, and the other two strands cause 90% of all cases of genital warts.

Is Gardasil safe?

A definitive answer to this question cannot be given at this stage, and while early on in the marketing campaign parents were advised that Gardasil was no riskier than any other vaccine, new data suggests that there are actually some big questions about the safety of Gardasil which still require urgent attention.

In February 2009, the United States federal Vaccine Adverse Events Reporting System (VAERS), which is a cooperative program for vaccine safety of the US Centres for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA), issued a report which compared the Gardasil vaccine with the Menactra vaccine (a vaccine for the meningococcal virus), and it found that the Gardasil vaccine is associated with a far higher rate of serious adverse effects than the Menactra vaccine is.

Among other things, the report found that:

- Gardasil was associated with at least twice as many Emergency Room visit reports; 4 times more Death reports; 5 times more “Did Not Recover” reports; and 7 times more “Disabled” reports than what Menactra was.
- Compared to Menactra, receipt of Gardasil is associated with at least 4 times as many Cardiac Arrest reports. All 9 reports of Cardiac Arrest following Gardasil **occurred when Gardasil was given alone** without any other vaccines.
- Compared to Menactra, receipt of Gardasil is associated with at least 15 times as many Stroke reports. 16 reports of Stroke following Gardasil **occurred when Gardasil was given alone**.

The February 2009 VAERS report makes the following important point in its summary:

“It is unusual for there to be such a big discrepancy between two vaccines used in similar populations involving serious and relatively rare life threatening adverse events and autoimmune disorders such as death, blood clots, cardiac arrest, lupus, thrombosis, stroke, and vasculitis.”

Among other things the VAERS report recommends that an independent and comprehensive investigation into the safety of Gardasil should be undertaken, and that the CDC should “consider the need to withdraw the recommendation that all girls between the ages of 9 and 26 should receive Gardasil vaccine”.

A full copy of the VAERS report is available online at:

<http://www.cbsnews.com/htdocs/NVICGardasilvsMenactraVAERSReportFeb2009.pdf>

Does Gardasil cure cervical cancer?

No, Gardasil does NOT cure cervical cancer – instead it is designed to provide immunity against two of the many high risk strains of the sexually transmitted human papillomavirus (high risk strains of human papillomavirus (HPV) are acknowledged to be the most important risk factor in the development of cervical cancer).

Some recent media coverage of Gardasil has given parents the impression that Gardasil provides a cure for cervical cancer, but this is simply not true, instead Gardasil actually targets several strains of HPV, not the cervical cancer which is caused by those several strains of HPV.

It is vitally important to remember that a person could still contract cervical cancer even if they have been given the full Gardasil treatment, because Gardasil does not target all of the strains of HPV which cause cervical cancer.

How long does immunity last?

At this stage it is unknown how long immunity will last after Gardasil is given to a person as there is simply no long term data about immunity available yet.

Some people mistakenly believe that Gardasil provides lifelong immunity, and some promoters of the Gardasil vaccine have even irresponsibly touted Gardasil as being likely to provide lifelong immunity, but there is simply no data currently available to support such claims, and some experts are even warning that immunity may be limited, or that a booster shot may be required for continued immunity.

In August 2008 the New York Times featured an article about Gardasil which stated the following...

“Merck’s vaccine was studied in clinical trials for five years..., so it is not clear how long the protection will last. Some data from the clinical trials indicate immune molecules may wane after three to five years. If a 12-year-old is vaccinated, will she still be protected in college, when her risk of infection is higher? Or will a booster vaccine be necessary?”

Read the full New York Times article here:

http://www.nytimes.com/2008/08/20/health/policy/20vaccine.html?_r=3&ref=health&pagewanted=all&oref=slogin

The New York Times also ran another article about Gardasil in August 2008 which stated...

“Despite great expectations and promising results of clinical trials, we still lack sufficient evidence of an effective vaccine against cervical cancer,” Dr. Charlotte J. Haug, editor of The Journal of the Norwegian Medical Association, wrote in an editorial in Thursday’s issue of The New England Journal. “With so many essential questions still unanswered, there is good reason to be cautious.”

In her article, Dr. Haug points out the vaccines [Gardasil and a second anti-HPV vaccine made by another company] have been studied for a relatively short period — both were licensed in 2006 and have been studied in clinical trials for at most six and a half years. Researchers have not yet demonstrated how long the immunity will last, or whether eliminating some strains of cancer-causing virus will decrease the body's natural immunity to other strains."

Read the full New York Times article here:

http://www.nytimes.com/2008/08/21/health/21vaccine.html?_r=1&ref=health&oref=slogin

Can a female still get cervical cancer even if she has had the Gardasil vaccine?

Yes, a female can still contract cervical cancer even if she has had the full treatment of Gardasil.

Gardasil does not protect against all of the strains of HPV which cause cervical cancer, it only protects against the two strains which cause 70% of all cases – this means that even after vaccination a person could still develop cervical cancer by contracting one of the other high risk strains of HPV that the vaccine does not protect against.

This is quite an important point, because some media coverage and marketing of the Gardasil vaccine has implied that women will be guaranteed total immunity from cervical cancer if they are vaccinated with Gardasil.

If someone DOESN'T get the Gardasil vaccine are they more likely to contract cervical cancer?

The marketing campaign, and much of the media coverage, surrounding the Gardasil vaccine has strongly implied that any female who does not get vaccinated with Gardasil is at greater risk of contracting cervical cancer than a female who has received the vaccine treatment.

But this is actually a total oversimplification of what is a very complex issue, due to the fact that there are many different variables involved.

Firstly, as has already been explained above, there are still big questions about how long immunity from Gardasil will actually last. In real terms; if a young girl was to receive the Gardasil treatment, and then the immunity from the vaccine was to wear off over time, once the immunity had lapsed that girl would almost certainly be in no better position than someone who hadn't received the vaccine at all.

Secondly, the Gardasil vaccine does not protect against cervical cancer, instead it targets the two strains of HPV which currently cause 70% of all cervical cancer cases. This means that a successfully vaccinated female could still develop cervical cancer if she was to contract one of the other high risk strains of HPV that cause the remaining 30% of cervical cancer cases.

Thirdly, sexual decision making actually has a huge impact upon whether or not a female is likely to contract HPV and then go on to develop cervical cancer. The more sexual relationships a female

engages in during her lifetime, the greater the risk becomes that she will contract HPV, which is one of the most common sexually transmitted infections.

The simple fact is that a female who does not engage in sexual activity before marriage, and then goes on to marry someone who has also not engaged in sexual activity prior to marriage, will almost certainly never contract a high risk strain of HPV which causes cervical cancer.

It is also important to note that condoms do not provide any real advantage to sexually active females as they provide very limited protection against HPV.

These important realities may not be very popular in our current social climate, where many people have been supplied with inadequate information about sexual diseases (like HPV), and condom failure rates (and as a result they have been led to believe the erroneous idea that all risk is completely removed as long as condoms are used during every sexual act), but none the less they are still very important facts.

Remember, it is irrelevant whether you disagree with the morality of choosing to abstain from sexual activity until marriage, we are talking here about medical facts, and those facts are very clear – females who choose to refrain from sexual activity until marriage, and who marry someone who has done the same, have provided themselves with an almost foolproof level of protection against the sexually transmitted strains of HPV which cause cervical cancer.

On the other hand, females who are vaccinated with Gardasil, but then choose to be sexually active with more than one person, still remain at risk of contracting a strain of HPV which causes cervical cancer (and this risk will still remain present even if future research shows that Gardasil provides lifelong immunity).

It is also important to remember that cervical cancer experts are very clear that regular cervical smear tests still remain the most effective means of addressing and protecting against death from cervical cancer. This message has not changed since the introduction of Gardasil, and in fact many medical professionals have strongly reiterated this important point in recent media interviews about this issue.

Finally, parents must also consider the possibility that their daughters could be harmed by adverse effects caused by the vaccine itself.

Is Merck a reliable company?

Merck is a company that has been no stranger to controversy. In 1999 they released a pain relief drug called Vioxx, but by 2004 Vioxx had been withdrawn from the market because it had been linked to a serious increased risk of heart attack and stroke in its users. Merck's failure to adequately warn consumers about the risks of Vioxx has resulted in many lawsuits, and so far Merck has had to pay out millions of dollars in damages to those who were harmed by Vioxx.

Then in May 2009, The Australian published an article which revealed the following about Merck and the way it marketed Vioxx...

"The world's largest medical publisher, Elsevier, has expressed embarrassment at its role in a deceptive marketing ploy by the giant drug company Merck after it was revealed in a Melbourne court.

Elsevier said it had failed to meet its own "high standards for disclosure" when it produced a magazine that pretended to be an independent scientific journal but was actually a marketing front for Merck's anti-inflammatory drug Vioxx.

The Amsterdam-based publisher is part of the Reed Elsevier group, which produces the Lancet, the authoritative medical journal that has accused Merck of selling Vioxx after it became aware of the drug's heart risks.

More than 1000 Australians, led by Graeme Peterson, who claims Vioxx caused him to have a heart attack in 2003, have mounted a class action against Merck. They claim the US company and its Australian subsidiary knew about the increased cardiovascular risks of Vioxx, but played them down in the lead-up to the drug being voluntarily recalled in 2004.

Between 2003 and 2005, Elsevier produced several issues of a magazine called The Australasian Journal of Bone and Joint Medicine, which carried articles about Merck's medicines Fosamax and Vioxx without any disclosure it was funded by Merck."

The full article can be read online here:

<http://www.theaustralian.news.com.au/story/0,25197,25441167-601,00.html>

In no way are we trying to defame the reputation of Merck, we merely think that it is important for parents to tread cautiously before allowing their children to be vaccinated with a product released by a company that has recently been embroiled in a scandal involving another drug that was obviously rushed on to the market without sufficient prior testing, and which was also accompanied by deceptive marketing strategies.

A final word

All of the issues raised in this simple guide are very important, because during the recent push for Gardasil many parents have been subjected to strongly worded, overly emotive advertisements, and from some quarters they have even been presented with the completely false notion that if they don't get their daughters vaccinated with Gardasil they are being irresponsible and would be consigning them to certain death.

While we in no way consider this guide to be a comprehensive examination of this issue, we do believe that it raises some important questions and issues that parents must be encouraged to pursue further when confronted by the Gardasil issue.

We must never lose sight of the fact that parents have the right to decide what is best for their daughters, and it is completely unfair and unethical for marketing campaigns to target parents with unsubstantiated emotional blackmail, instead of comprehensive and factually correct information.

Further reading:

The following are articles and commentary about the Gardasil vaccine that are available online.

Please note: while we believe that the following articles provide parents with important information about the Gardasil Vaccine, this should not be considered an official FLI endorsement of every sentiment or idea expressed in these articles, or an official FLI endorsement of the people or organisations that have authored these articles.

Gardasil – Cartwright's Daughter?

(Transcript of an address given at the Cartwright Anniversary Seminar, New Zealand, August 2008)

<http://www.womens-health.org.nz/uploads/pdf/Paper%20from%20the%20August%205th%20Seminar%20-%20Gardasil%20Cartwrights%20Daughter.pdf>

Blaming the Media for Gardasil Hype (from the New York Times):

<http://well.blogs.nytimes.com/2008/08/29/blaming-the-media-for-gardasil-hype/>

When a shot in the arm's no silver bullet (opinion column from the NZ Herald, March 2009):

http://www.nzherald.co.nz/health/news/article.cfm?c_id=204&objectid=10559401&pnum=2

Following A Girl's Death, the CDC is Finally Looking at Gardasil Links:

<http://www.newsinferno.com/archives/5267>

Gardasil Vaccination Results in Three Outbreaks of Genital Warts in Fiji School Children:

<http://www.lifesitenews.com/ldn/2008/nov/08111803.html>

Allergic reactions high after HPV jab:

<http://tvnz.co.nz/view/page/1318360/2051761>