

Good as gardasil?

» Women's health | By Lynda Wharton

Following our Issue 29 feature on the introduction of anti-cervical cancer vaccine Gardasil, Lynda Wharton provides an update on the latest developments you may not find widely publicised

It's here at last. The long-touted first vaccine that claims to protect us from cancer. It's Gardasil, Merck's potential blockbuster cervical cancer vaccine.

New Zealand mothers are being urged to vaccinate their daughters between the ages of nine to 26, to prevent them from developing cervical cancer further down the track. Sounds good, doesn't it? A quick injection and then the peace of mind that comes from knowing you will never have to worry about the sexually transmitted HPV virus known to cause the vast majority of cervical cancers.

However, is there another side to this latest pharmaceutical superstar, and should we be digging deeper before we line our nine-year-olds up to receive their injection? What are we doing vaccinating children against an STD in the first place? How many nine-year-olds do you know who are sleeping with their boyfriends? Is this a safe vaccine to give to girls of this age... or any age?

The truth is that there are only three years' of safety and efficacy data in women aged 16 – 26 backing up the recommendation. There is absolutely no efficacy data for girls aged 9–12, and when it comes to safety findings for these young pre-teens, just 1184 subjects were studied for a duration of only 18 months.

The question of whether there are any slow-developing long-term health complications with this vaccine is at present completely unanswered. Only after it has been in use for 10 or more years, and the data carefully analysed, will there be any evidence attesting to the long-term safety of Gardasil.

And there's more to worry about when you look closely at the methodology of the safety trials in general. Drug trials always involve giving a group of subjects the actual drug – in this case the Gardasil vaccine – and another group of subjects a placebo or inert substance. Neither the researchers nor the subjects know if they are receiving the real drug or the other.

Oddly, the FDA allowed Merck to use a placebo containing aluminium, instead of an inert saline solution. Thus a potentially reactive control was used, possibly skewing the results. Gardasil contains 225mcg of aluminium hydroxide in each injection – Merck and the FDA have not disclosed how much aluminium was in the placebos.

A number of side-effects were noted at the time of testing, but were discounted in view of the potential advantages offered by the vaccine. However, now that it

is actually being administered in medical centres around the world, data shows that there are twice as many girls collapsing, and four times as many experiencing neurological symptoms such as tingling, numbness and loss of sensation, with Gardasil, compared to those receiving tetanus vaccines.

And the Gardasil trials looked at the safety of the treatment when administered alone. In general practice, however, it is frequently administered along with other vaccines, such as hepatitis B, despite the fact that there is absolutely no safety data on the concurrent use of other immunisations. To date, there have been more than 40 cases of the dangerous immune disorder Guillian Barre Syndrome in young girls given the Gardasil and hepatitis injections concurrently.

And if you are a pregnant woman or are planning to become pregnant, stay well away. Safety trials showed an increased incidence of birth defects in women receiving Gardasil within 30 days of conception. Infants of breast-feeding mothers who received the vaccine are also at increased risk of respiratory disorders.

And if a woman already has HPV at the time of vaccination, it will be a waste of time. In fact, there is evidence that infected women who receive the vaccine may experience an increase in the risk of developing cervical cancer precursors.

Isn't this all worth the risk if Gardasil prevents cervical cancer, though? In reality, however, we don't yet know that Gardasil will do any such thing. Yes, during the trial period, there was not a single case of cervical cancer – in either the test or placebo group – but the disease is very slow growing, which is why it's so preventable and treatable.

And, while Merck is celebrating its next potential billions on the bottom line and hoping that Gardasil will offer some redemption from the devastating financial impact of the Vioxx debacle, savvy analysts are aghast at the potential cost of widespread Gardasil use. It promises to be our most expensive vaccine ever, with the requisite three shots costing around \$450 – that's \$600 when you add in the cost of the GP visits.

In New Zealand, 14 women in every 100,000 will develop cervical cancer. One in three of these will die from it. Taking into consideration this low incidence of cervical cancer mortality, the cost of vaccination, and the fact that virtually all cases of cervical cancer can be prevented through regular pap smears (and safe sex), it is easy to see their point!