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Gardasil: we must not ignore the risks

By Renate Klein and Melinda Tankard Reist Posted Friday, 1 June 2007

The much trumpeted inject-every-girl-free with Gardasil campaign has run into a bit of a snag. Four Melbourne schoolgirls were rushed to hospital recently after receiving the vaccine promoted as preventing cervical cancer.

Sixteen other girls were reported sick. One student was left paralysed for six hours. "I couldn't move at all," she said. "There were girls dropping like flies."

Similar reports are emerging from other schools.

Of course, the vaccine couldn't be at fault. CSL, the company that makes Gardasil, said the reactions were due to "stress" and "anxiety". The girls were all worked up. They'd got themselves into a state and panicked. The vaccine's inventor, Ian Frazer, said it was a case of auto-suggestion.

We shouldn't dismiss the bad experience of these girls just because we really want the vaccine to work. Women's health is more important.

"We're not aware of a problem with this particular vaccine" a Victorian Department of Health spokesperson said.

The spokesperson seemed blissfully unaware of at least three deaths in the US related to the vaccine. US Food and Drug Administration (FDA) records cite a physician's assistant report that a female patient "died of a blood clot three hours after getting the Gardasil vaccine". Two other girls, aged 12 and 19, died as a result of heart problems and/or blood clotting after receiving the vaccine.

A visit to the website of the United States National Vaccine Information Center also reveals real problems with the vaccine. The centre collects voluntary information about adverse reactions to vaccinations.

According to NVIC President Barbara Loe Fisher: "There are twice as many children collapsing and four times as many children experiencing tingling, numbness and loss of sensation after getting a Gardasil vaccination compared to those getting a tetanus-diphtheria-acellular pertussis vaccination."

The FDA has detailed 1,637 reports of adverse reactions to the vaccine. But as Fisher points out, very few adverse events are ever reported in the US. "If only 1 to 4 per cent of all adverse events associated with Gardasil vaccination are being

reported, there could have been up to 38,000 health problems after Gardasil vaccination in 2006 which were never reported," she says.

Other case studies published online describe cold sweats, difficulty in walking, disorientation, dizziness, dyskinesia, headache, hyperventilation, bronchospasms, pallor, paraesthesia, tinnitus and tremors.

Parents are right to question whether the vaccine is in the best interests of their daughters. A lack of trial data - especially on girls this age - suggests that Australia¹s rush to be the first country to provide a fully funded immunisation campaign was premature.

A recent editorial in the *Journal of the American Medical Association* stated: "it is important to emphasise that the vaccine is supported by limited efficacy and safety data."

Do the girls and their parents know that Gardasil was tested on fewer than 1,200 girls under 16 and that most trials to-date were sponsored by Merck, which sells Gardasil in the USA? In fact only 5 per cent of the 25,000 women in Merck's research - that is 1,148 - were girls younger than 16. Given that girls as young as 12 are targeted by the Australian mass immunisation campaign by all standards Gardasil is an untested product in this age group. Parents should be worried about these experiments in which their daughters are the guinea pigs.

Also, are they told that Gardasil is a genetically engineered vaccine?

Australian girls are taking part in what is really a major experiment. Antibodies produced in response to a vaccine can at times mistakenly attack normal body cells. This can lead to autoimmune diseases such as arthritis and multiple sclerosis. Does Gardasil carry this risk? We just don't know.

Then there is the central question of whether Gardasil will actually prevent cervical cancer. There are more than 100 strains of the human papilloma virus (HPV). At least 13 of these can cause cancer. Gardasil vaccinates against only two.

Some research estimates that almost 80 per cent of the sexually active population is infected with dozens of HPV types, including the high risk strains 16 and 18. But in most cases a well functioning immune system and good nutrition clears the infection before cervical cancer develops.

With the rush to inject Australian girls with a drug of uncertain efficacy and safety, it's important to keep the risk of cervical cancer in perspective. A recent US study concluded that less than one quarter of 1 per cent of all American women are at risk of infection with one of the HPV types associated with cervical cancer that Gardasil vaccinates against.

And there are other risk factors for cervical cancer such as smoking, malnutrition, a weak immune system, the pill, multiple sex partners and sex without a condom (although condoms do not entirely eliminate transmission of HPV). The recently reported increase in a rare throat cancer linked to oral sex is also associated with HPV.

Health authorities seem to prefer to offer needles than talk about changing behaviour.

Even Gardasil's promoters note that pap smears are still necessary. And to totally eradicate HPV, all adolescents - including all boys - would have to be vaccinated. But as often happens, the burden falls on women.

The Therapeutic Goods Administration should have demanded long-term trials involving younger girls be conducted before Gardasil was approved.

Rushing this product on the market in Australia for mass immunisation might be good for CSL shareholders, with global sales from Gardasil estimated to amount to US$3 billion by 2010. But we just don't know enough to say whether Gardasil really is "good news about cancer".

At this stage, Gardasil administration is barely justified for anyone, let alone vulnerable pre-teen girls entering puberty.

This is an expanded version of an article first published in *The Age*, May 25, 2007.

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