

**NEWS ARTICLE**

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**19 DECEMBER 2007 ISSUE****HPV Vaccine – why are we waiting?***Sunita Azariah*

HPV Vaccine – why are we waiting?

A wonderful opportunity for cancer prevention was lost earlier this year when the Government decided not to fund the new cervical cancer vaccine "Gardasil", despite recommendations from the Immunisation Technical Working Group (ITWG) that it be prioritised for the 2008 immunisation schedule.

This was extremely disappointing for those of us working in the field of sexual and reproductive health. Fortunately, the Government seems to be reconsidering its stance.

An article in the Dominion Post on 5 November was headlined: "Labour U-turn over cervical cancer drug". In it, the prime minister was quoted as describing the human papillomavirus (HPV) vaccine as an "international breakthrough", contrasting with her comments in an interview with Mikey Havoc on BFM earlier this year when she said she was unaware there was a cervical cancer vaccine that "worked".

HPV is a very common, widespread sexually transmitted infection that is capable of causing considerable morbidity and mortality due to its well-known sequelae of anogenital warts, cervical intraepithelial neoplasia and cervical carcinoma.

There is also now strong evidence to link HPV infection (in particular HPV 16) to other anogenital cancers, eg, cancers of the vulva, penis and anus. It is estimated that 60 to 70 per cent of young women will acquire HPV infection soon after onset of sexual activity, with a lifetime prevalence in excess of 20 per cent in many western communities.

A prophylactic quadrivalent HPV vaccine targeting, in particular, the most commonly implicated HPV types (16, 18, 6 and 11), such as Gardasil, has the potential to prevent up to 70 per cent of cervical carcinomas and the majority of genital warts.

Phase III, randomised, controlled trials in large numbers of women worldwide have shown quadrivalent HPV vaccines to be both safe and efficacious at preventing genital pre-cancers and genital warts (FUTURE I and FUTURE II).<sup>1,2</sup>

As well as the physical complications, the diagnosis of genital warts or cervical dysplasia (and hence a sexually transmitted infection) often results in considerable psychological distress for the individual and can impact adversely on sexual relationships. HPV vaccination has the potential to reduce many of the emotional, physical and economic sequelae associated with HPV infection.

**Why can't we get it right?**

New Zealand has unfortunately had rather a poor record in the field of cervical cancer prevention. The "unfortunate experiment" at National Women's Hospital badly tarnished the New Zealand medical profession's reputation and shook public confidence.

The National Women's inquiry, however, did have some positive outcomes for consumer rights with the establishment of the health and disability commissioner, the creation of the health information privacy code, and establishment of regional ethics committees.

Unfortunately, just as some sort of equilibrium was starting to be restored, there followed the debacle in Gisborne and yet another major inquiry.

As Professor Ron Jones states in a recent letter to the *New Zealand Medical Journal*: "Thirty years were to elapse between the first recommendation (by an international authority, Dr G Wied) for the introduction of a nationally organised cervical screening programme in New Zealand and its eventual introduction following the Cervical (pre) Cancer Inquiry by Judge Cartwright."<sup>3</sup>

The current delay in the Government decision whether or not to fund the HPV vaccine is yet another unnecessary impediment to reducing the complications of HPV infection including cervical cancer.

Still more perplexing is the major reticence on the part of the National Screening Unit to fully endorse a publicly funded HPV vaccination programme, despite the existence of supportive evidence in the form of extensive well-designed, multi-centre, international, randomised, controlled trials published in peer-reviewed medical journals.

The National Screening Unit's July 2007 newsletter listed a large number of concerns that "needed to be resolved" before a vaccination campaign could be implemented – none of which have any substance.

The newsletter implied that the introduction of HPV vaccination could impact negatively on women's uptake of cervical screening and "lead to widening of inequalities" in cervical cancer incidence and mortality.

**Limitations of cervical screening**

No one would dispute that the development of the cervical "pap" smear as a screening test was a significant

advance in cervical cancer prevention. Since its development, there has been a dramatic effect on cervical cancer rates in countries such as New Zealand where proper screening programmes have been implemented.

However, as a screening test, the cervical smear does suffer from limitations such as a lack of sensitivity (55.4 per cent in one recent study)<sup>4</sup> and poor positive predictive value.

Cervical screening coverage in New Zealand is unfortunately still abysmally low in Maori and Pacific women (46 and 45 per cent, respectively) as reported in the New Zealand Cervical Cancer Audit in 2002.

Furthermore, while regular cervical screening is an effective means of detecting cervical pre-cancers, it does not provide any protection against the causative agent of cervical cancer.

Professor Jones states in his *NZMJ* letter: "cervical cytology screening and HPV vaccination are complementary", thereby implying both are needed for an effective cervical cancer prevention programme.<sup>3</sup>

The question of whether a fully funded HPV vaccination programme would be cost-effective has been addressed in an economic analysis conducted by Auckland University associate professor in clinical economics Richard Milne.

The analysis examined the impact of annual vaccination of girls 11 or 13 years of age with a quadrivalent HPV vaccination, without any changes to the current cervical screening programme.

Professor Milne concluded: "When a programme of vaccination with HPV vaccination is added to current clinical screening and management of dysplasia and cervical cancer, over the lifetime of a birth cohort of girls 11 or 13 years of age the incidence of cervical cancer would decline two-fold, the cost of detection and management of cervical dysplasia and cervical cancer would decline appreciably and the cost of providing each additional quality-adjusted life-year would be very modest by international standards."

This is not taking into account any possible reduction in genital warts, anal cancers and cancers of the head and neck that are also caused by the HPV virus types implicated in cervical cancers.

One of the major obstacles I fear will be overcoming public misconceptions about the likely impact of vaccinating pre-pubertal girls against a sexually transmitted infection.

As we debate these issues in the medical arena, I am sure there will be various religious groups and concerned citizens girding their loins (no pun intended) to mount an attack on the vaccine's imminent introduction.

I anticipate there will be widely dispersed misinformation on adverse effects of vaccination and fear-mongering that vaccination will promote early sexual "promiscuity" and erode "family values", etc, etc.

Enough of all that, in the words of the well-known song – "Why are we waiting, why-y-y are we waiting?" I trust the New Zealand public to judge the issues for themselves and I think most will welcome the introduction of the vaccine.

Let both the Government and the medical profession embrace an opportunity to bury the legacy of the past and move into a better, more enlightened future.

#### References

1. *NEJM* 2007; 356(19):1915–27.
  2. *NEJM* 2007; 356(19):1928–43.
  3. *NZMJ* 2007; 120(1260)
  4. *NEJM* 2007; 357(16):1579–88.
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#### Feedback

**From Lynne Eldridge (MD, author, *Avoiding Cancer One Day At A Time: Practical Advice for Preventing Cancer*, [www.avoidcancer.com](http://www.avoidcancer.com) )**

I appreciate so much your comments regarding the HPV vaccine, yet I believe those in New Zealand are doing better with regards to HPV than those of us in the US where the vaccine is widely used. Your diet is healthier.

Yes, I think the HPV vaccine could save many lives. Cervical cancer is the second leading cancer worldwide in women. I tend to like to see vaccines tested on higher risk individuals for a year before using it on the masses - but we are there now.

Where I see New Zealand ahead of the US despite lacking widespread HPV vaccination, is in diet. Many studies have been done, and published in credible medical journals, on the role of diet in clearing the HPV virus. As you know the HPV virus does not cause cancer per se but chronic infection causes inflammation which can lead to cancer.

Dietary elements can greatly increase clearance of the HPV virus and consequently lower risk (for one of the several articles see *Cancer Epidemiology Biomarkers and Prevention* 14:1149-1156, or *Journal of Infectious*

Diseases 188: 1508-1516).

Despite this knowledge, our US diet is horrendous and I do not know of a single physician that recommends dietary changes for women that have abnormal Pap smears or have been diagnosed with HPV.

In the US, we are strongly encouraging adolescents to get the vaccine, but many at risk lie outside the age recommendation of 12 to 26, and in fact the peak age of cervical cancer is age 48.

My point – there are things, in addition to the HPV vaccine, that can make a difference in the risk of cervical cancer, and in the area of diet, New Zealand outshines some of us that are liberally using the vaccine. With the vaccine, you will be far ahead!

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