

The South African human papillomavirus vaccination programme for grade 4 girls: facts and fallacies

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Since 1995 the South African Expanded Programme on Immunisation (EPI-SA) has given healthcare professionals several occasions to celebrate by adding new vaccines to the national universal infant immunisation program, against diseases of significant public health importance. This year EPI-SA has again given cause for celebration, as 2014 sees the introduction of the vaccine against the human papillomavirus (HPV), the causative organism of cervical cancer. This is a joint program of EPI-SA and the Integrated School Health Program, providing free HPV vaccination using a two dose schedule, to grade 4 girls attending public schools, who are 9 years or older.

Cervical cancer is the second most common cancer in South African women, affecting mostly black women, and causing the death of eight women every day.¹ Thus the introduction of this vaccine in the public sector is long overdue, and it is hoped that this year EPI-SA will meet their target of vaccinating 80% of eligible girls with both doses of the vaccine, and sustain or increase this high coverage for many years to come. A review of several studies on the acceptance of HPV vaccination² found that healthcare professionals play a very important role in increasing HPV vaccination uptake among their patients.

However, it also found that many healthcare professionals do not have the necessary information to reassure concerned caregivers who have been exposed to anti-vaccination claims.² This article gives details on anti-HPV vaccination fallacies that have arisen in South Africa, mostly spread from the USA via the internet, and gives healthcare professionals the necessary facts to counter these claims. The HPV vaccine selected for use in the EPI-SA program is the bivalent

HPV vaccine called Cervarix® although other HPV vaccines are equally efficacious..

Fallacy: There is no evidence that the HPV vaccine prevents cervical cancer.

Fact: Almost 100% of cervical cancers are caused by persistent infection with high risk types of HPV (types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68, 73, and 82). HPV types 16 and 18 cause over 70% of all cervical cancers globally. Persistent infection with these two types of HPV is prevented by HPV vaccination, when the vaccination course is completed before women are infected by HPV 16/18.^{3,4,5} The vaccine is highly immunogenic, the efficacy (i.e. how the vaccine performs at preventing infection or disease under trial conditions) in girls and women without HPV 16/18 infection at baseline has been shown to be:

- 74%-98% for preventing new HPV 16/18 infections;^{3,4,5}
- 100% for preventing 12 month persistent infection with HPV 16/18;^{3,4,5}
- 100% for preventing HPV 16/18-associated cervical intraepithelial neoplasia (CIN) 1+ lesions^{3,4}
- 100% for preventing HPV 16/18-associated CIN2+ lesions^{4,5} and
- 100% for preventing HPV 16/18-associated CIN3+ lesions and adenocarcinoma in situ⁶

In addition, these studies have shown significant cross-protection against other high risk HPV types, the most important being types 31 and 45, which together accounts for an additional 10% of cervical cancer cases worldwide. As it takes up to 20 years following HPV infection for cervical cancer to develop, not enough time has elapsed

since the introduction of HPV vaccination to directly measure the population impact on cervical cancer incidence. However, the CIN3+ and adenocarcinoma findings mentioned above are based on a large sample size of women who were negative for HPV 16/18 at baseline (vaccine n=5824; control n=5820),⁶ and clearly indicate the efficacy of this HPV vaccine at preventing HPV 16/18 associated cervical cancer.

Fallacy: The HPV vaccine has never been tested in 9 year-old girls.

Fact: A multi-national (Canada, Denmark, Hungary and Sweden) clinical trial on 9-15 year-old girls found that not only was the vaccine safe and highly immunogenic in 9 year-olds, but also that much higher antibody levels against HPV are obtained in 9 year-olds than in 10-15 year-olds.⁷ In addition, the HPV vaccine has been used from the age of 9 years in Austria since 2006⁸ and in Canada since 2008.⁹

Fallacy: Statement by anti-vaccination lobby that Dr Diane Harper, the lead developer of Gardasil, has admitted that the HPV vaccine is “useless and deadly”.

Fact: In 2009 Dr Diane Harper (who did not develop Gardasil - quadrivalent HPV vaccine, but was one of the lead investigators in clinical trials that tested the efficacy of both Gardasil and Cervarix) was invited to a meeting held by the National Vaccine Information Centre (NVIC), one of the most influential anti-vaccination groups in the USA. Unfortunately she accepted, and apparently did not realize that the meeting participants had no intention whatsoever of trying to understand the science behind HPV vaccination, and that the organisers

are very adept at misinterpretations, misrepresentations and out-of-context quotations that make it seem as if someone who supports vaccination, actually rejects it. She has subsequently denied making these negative statements, and has continued to work in the field of HPV vaccination, having published an article on HPV vaccine acceptance as recently as February 2014.¹⁰

Fallacy: There is evidence that the HPV vaccine is not safe.

“There are thousands of reports of sudden collapse with unconsciousness within 24 hours, seizures, muscle pain and weakness, disabling fatigue, Guillain Barré Syndrome, facial and limb paralysis, brain inflammation, rheumatoid arthritis, lupus, blood clots, optic neuritis, strokes, heart and other serious health problems, including death, following the receipt of this vaccine”.

Fact: All of the above-mentioned clinical trials have shown that this vaccine is very safe. In addition, post-marketing surveillance has also found the vaccine to be very safe.¹¹ Finally, the World Health Organization (WHO) recently reviewed safety data after >175 million doses of HPV vaccine had been administered worldwide, and found that none of the serious adverse events following immunisation (AEFIs) that have been reported were related to the HPV vaccine.¹² Anti-vaccination claims that the vaccine is not safe have mostly originated from the Vaccine Adverse Events Reporting System (VAERS), a USA database that was designed to detect rare AEFIs that may be missed during clinical trials because of the relatively small sample sizes. This system has a very high sensitivity (i.e. it can detect all AEFIs that are caused by a vaccine) but almost a zero specificity (i.e. it cannot discriminate AEFIs that are caused by a vaccine from those that are not caused by a vaccine). Unfortunately VAERS is open to abuse, since anyone can report an AEFI without any verification, and the vast majority of reports for all vaccines, including the HPV vaccine, concern events that coincidentally



Fallacy: Giving the HPV vaccine to young girls will make them more likely to start having sex and less likely to practice safe sex.

occurred following immunisation and are in no way linked to the vaccine. The abuse that can occur with this system is well illustrated by an anecdotal report from James Laidler, a doctor from Portland Oregon, who submitted a report to VAERS that the influenza vaccine had turned him into the Incredible Hulk. The report was duly accepted and entered into the database. He was later contacted by officials from VAERS, and it was only with his permission that this report could be removed from the VAERS database – otherwise it would still be there today. See the story at http://en.wikipedia.org/wiki/Jim_Laidler

Fallacy: The HPV vaccine contains toxic metals that result in brain damage and cause cancer.

Fact: Each dose of Cervarix® contains 0.5 mg aluminium hydroxide, a salt of aluminium that has been safely used as an adjuvant (a substance that enhances the immune response) in infant vaccines for over 70 years in hundreds of millions of people.¹³ Aside from vaccines, aluminium and its compounds make up 8% of the earth’s surface, thus it is present in the air

we breathe, the soil our children play upon, the fruit and vegetables we eat, and our drinking water. Also, aluminium compounds are widely used in processed foods as fillers, colourants, anti-caking agents, emulsifiers, baking powders, and soy-based baby formula. Aluminium hydroxide specifically is used in personal care products and a number of over-the-counter medicines such as antacids and anti-diarrhoeal medication, and in anti-acne, anti-fungal, and anti-nappy rash creams. Finally, the amount of aluminium that is used in the HPV vaccine is miniscule compared to what a girl is exposed to in everyday life (e.g. one stick of chewing gum can contain as much as 4 mg of aluminium).¹⁴

Fallacy: Giving the HPV vaccine to young girls will make them more likely to start having sex and less likely to practice safe sex.

Fact: Studies have found that there are no differences between vaccinated and unvaccinated girls with regards to:

- age at sexual debut¹⁵
- number of sexual partners^{15,16}
- high risk sexual practices^{15,16,17} and
- increased sexual activity outcomes, which include pregnancy, sexually transmitted infection testing or diagnosis, and contraceptive counselling.¹⁷

HPV vaccination has only recently come to the attention of South African anti-vaccination lobbyists, and no doubt more claims will arise in the near future. If there are any other claims that have not been covered by this article, they will be of great interest to the South African Vaccination and Immunisation Centre at the University of Limpopo, Medunsa Campus. Please send these claims to Rose.Burnett@ul.ac.za for further investigation.

References available on request.