# Is the human papilloma virus vaccine a good investment?

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#### **Abstract**

To the editor:

"There are challenges for countries in terms of cost and so on, but this vaccine is unique and offers tremendous possibilities."

Human papilloma viruses (HPV) are non-enveloped, icosahedral, double-stranded DNA pathogens.<sup>2</sup> They are transmitted with direct contact, including sexual intercourse, infecting skin and mucosal cells.<sup>2,3</sup>

More than 100 different HPV genotypes have been recognised and classified into low and high risk.<sup>3,4</sup> The latter are responsible for a number of anogenital malignancies in both genders.<sup>3</sup> For example, persistent genital infection with HPV 16 or 18, in association with various cofactors (i.e. prolonged Pill use, multiparity, smoking, co-infection with other STIs, etc.), causes cervical cancer 20 to 30 years later.<sup>2,4,5</sup> This long latency period, between exposure and disease development, allows for screening to detect precancerous abnormalities.<sup>4</sup> In contrast, the low risk genotypes are mainly associated with benign conditions. For example, HPV 6 and 11 cause genital warts (Condylomata acuminata).<sup>2,4</sup>

Recently, two preventative vaccines against certain HPV genotypes have been introduced. These are non-infectious and are prepared from virus-like particles using recombinant technology.<sup>3,4</sup> In the UK, they have has been licensed for use only in women.<sup>6</sup> Gardasil® is a quadrivalent vaccine against HPV 6, 11, 16 and 18. The second is Cervarix® targeting only type 16 and 18.<sup>3,4</sup>

Both vaccines will reduce the incidence of infections and consequent diseases, caused by the respective HPV genotypes.<sup>3,4</sup> For example, in 2005, cervical cancer caused almost 260,000 deaths, of which approximately 80% occurred in developing countries.<sup>3</sup> HPV 16 and 18 account

for about 70% of all malignancies of the cervix worldwide.<sup>3,4</sup> Thus, both vaccines have the potential to prevent a lethal disease that affects many women, especially in developing nations where resources are limited to set-up successful cervical screening and treatment programmes.<sup>3,4</sup>

Gardasil® also prevents infections from HPV 6 and 11, which cause genital warts in both genders. Although this is a benign condition, it causes significant physical and psychological morbidity placing a heavy financial burden on patients' and national health resources. The vaccine could alleviate this burden by reducing the incidence of genital warts.

The vaccines, however, will not eradicate all HPV-related conditions, because they have no effect if administered to already infected people.<sup>3,4</sup> They also do not protect against all existing HPV genotypes and the potential of replacement infections to fill the "ecological niche" is a possibility.<sup>4</sup> Thus, screening for cervical cancer will still be required after introducing HPV vaccination.<sup>1,3,4</sup>

The vaccines are administered as 3 separate 0.5mL intramuscular injections over a 6-month period.<sup>3</sup> The ideal delivery age is before sexual début (i.e. at 9 years of age).<sup>1,4</sup> The 3-dose vaccination schedule and the administration age will increase delivery costs and therefore negatively influence the vaccines' availability, especially in developing countries. Thus, further studies are needed to evaluate the possibility of a 2-dose schedule and administration at an earlier age with other vaccines.<sup>3,4</sup>

Currently, HPV vaccines are recommended for use in women, but male vaccination is also under consideration. This will increase the vaccines' acceptability and prevent any stigma or discrimination against vaccinated women. However, in countries with limited health resources, girls should be targeted first. This is because vaccinating men will

only reduce cervical cancer marginally in the presence of high female coverage.<sup>4</sup> Nevertheless, Gardasil®, targeting HPV 6 and 11, will also benefit men by preventing genital warts.<sup>3,4</sup>

The combination of HPV vaccines with existing cervical screening programmes will be a comprehensive and cost-effective approach to prevent cervical cancer.<sup>3,4,5</sup> This will be particularly true, if vaccines contribute to an increase in the age of initial screening and intervals between visits.<sup>3</sup> However, many countries do not have prevention or even vaccination programmes. Thus, new systems will be required to successfully deliver HPV vaccines, increasing the administration costs.<sup>3</sup> In these cases, the vaccines' price will also influence their affordability significantly.<sup>3</sup>

Apart from the cost, the overall benefit of HPV vaccines also depends on other factors. For example, the vaccines' safety and effectiveness has not been assessed in developing countries or areas with highly prevalent infectious diseases (i.e. HIV).<sup>3,4</sup> Thus, further studies should be planned to evaluate the vaccines in these settings.

Undoubtedly, HPV vaccines will reduce the incidence of many malignant and benign diseases, which place a heavy financial burden on national health resources. However, there are still many unresolved issues and limited knowledge, regarding the practical considerations of incorporating HPV vaccination into current healthcare systems.<sup>4</sup>

Further research has to be devoted in this field to provide

data, regarding the vaccines' efficacy for both genders. These studies should also suggest cost-effective solutions for different nations and tailor the vaccination programmes to each country's needs and resources. Our view is that giving HPV vaccines to women around the globe is a good investment. However, more evidence should be gathered regarding male vaccination, before reaching any conclusions for this gender.

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