

The benefits associated with male HPV vaccination in Australia

Marcel Boulat

Fifth Year Medicine (Undergraduate)
Monash University

Marcel has an interest in public health and preventative medicine, which he developed through his past engagement with AMSA Thinktank and his role as Partnerships Officer at AMSA Global Health. He has previously been awarded a summer research scholarship and is a Youth Advisor to Privacy Victoria.

Aishwarya Hatwal

Fifth Year Medicine (Undergraduate)
Monash University

Aish has an interest in public health and advocacy. He is an active member of his local community and an alumnus of Monash University's Ancora Imparo Leadership Program. He has held advocacy roles in his local council as a Youth Councillor and is a Youth Advisor to Privacy Victoria.

Background: Human papillomavirus (HPV) is a family of highly contagious sexually transmitted viruses which are associated with the development of genital warts and certain HPV related cancers in males and females. After conducting a cost-effective analysis, the Australian Government has decided to expand the school based female only HPV vaccination program to include males commencing in 2013. **Methods:** A search of Ovid MEDLINE, The Cochrane Library, Google Scholar, BMJ Journals, and JSTOR was undertaken. **Discussion:** HPV vaccination has proven to have a high safety profile with sustained efficacy rates. Male vaccination will not only offer immunity to its recipients but also provide indirect protection to both sexes and high risk groups through herd immunity. The included high risk HPV strains 16 and 18 are associated with more than 70% of cervical cancers, 80% of anal cancers, 25% of penile cancers and 31% of oropharyngeal cancers worldwide. The quadrivalent vaccine also covers HPV 6 and 11 which are responsible for 90% of genital warts. **Conclusion:** Robust monitoring and surveillance systems are in place which will enable Australia to quantify the impacts of HPV vaccination in the future. Models show that the rates of HPV infection will further reduce by an additional 24% in 2050 compared to female vaccination alone, if vaccination rates for boys reach the same levels attained by girls in 2011. This will result in a significant decrease in the clinical burden of HPV-related diseases, the associated costs of treatment, and the psychological trauma which often accompanies the diagnosis of an HPV-related condition.



account for 90% of all HPV attributable male cancers. [5]

The other two HPV types covered by the quadrivalent vaccine, HPV 6 and 11, are associated with 90% of genital warts and 100% of juvenile onset recurrent respiratory papillomatosis (RRP) cases, resulting in a severe respiratory condition. [14] Recent studies also reveal that more than 4% of all cancers worldwide may be caused by HPV. [15,16]

On the back of such evidence, the Australian Government has announced the introduction of the quadrivalent HPV vaccination for males in the 12-13 age group, with a catch-up program for males aged 14-15 years at school. [11,12] Early data show that 73% of females in the 12-13 age group received the full course of three doses (Figure 1). This level of coverage is significantly higher than the levels in the catch up programs where the lowest level is 30% in the 20-26 year old age group. Therefore, introducing an immunisation program for boys

Introduction

Human papillomavirus (HPV) is a highly contagious family of viruses with over 150 distinct genotypes. [1] The virus infects the squamous epithelium in both males and females, with over 40 genotypes affecting the anogenital region. [2-4] HPV is usually a transient, asymptomatic infection which is transmitted through skin-to-skin contact associated with sexual activity, and the risk of infection increases with a greater number of sexual partners. [2-5] HPV is also the most common sexually transmitted infection (STI), [6] with up to 80% of people being infected with at least one type of genital HPV in their lifetime. [3,7,8]

There is a proven association establishing the relationship between persistent HPV infection and the development of pre-cancerous (CIN) and cancerous lesions in females. [7] Australia was the first of many countries to create a National HPV Vaccination Program for females, and has been providing the school based HPV vaccination to 12-13 year old girls since 2007. [9,10] Males are expected to join their female counterparts commencing in February 2013. [11,12]

Australia provides this vaccination in the form of the quadrivalent Gardasil® vaccine which covers four types of HPV (6, 11, 16 and 18). [8] In women, although there are many 'high risk' types, HPV 16 and 18 alone are associated with 70% of cervical cancers, [2,3,13] and 32% of vaginal cancers worldwide. [14] In men and women, those two types also contribute to over 80% of anal cancers, 24% of oral cancers, and 31% of oropharyngeal cancers. [6,14] Furthermore HPV 16 and 18

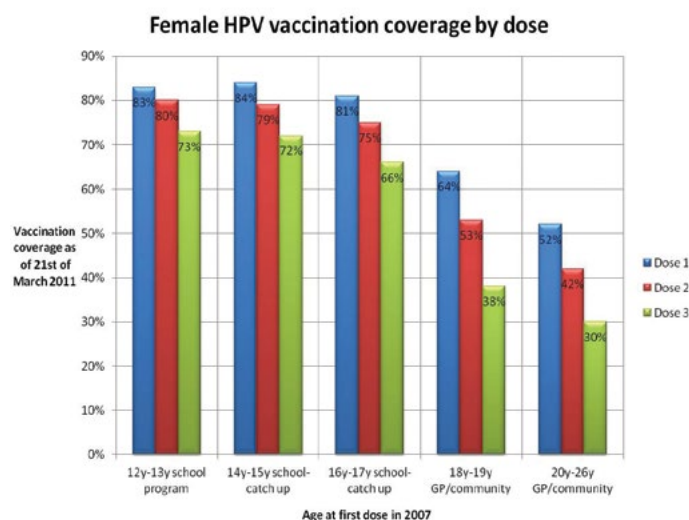


Figure 1. A graphical representation of female vaccination coverage categorised into various target age groups in the 2007 HPV vaccination cohort. Raw data sourced from the Immunise Australia Program. [17]

is a significant move towards preventing the many HPV attributable cancers and genital warts by accelerating coverage and the levels of herd immunity against HPV.

Therefore, the aim of this article is to examine the evidence which exists globally in supporting HPV vaccination and to identify any additional benefits routine male vaccination may provide. The article will also consider high risk population groups, the cost effectiveness of widespread HPV vaccination and the long term monitoring goals for the Australian vaccination program.

Methods

The review of the literature was undertaken through a search of Ovid MEDLINE, The Cochrane Library, Google Scholar, BMJ Journals, and JSTOR. The search aimed to find original research articles, reviews, case studies, and opinion pieces that related to HPV vaccinations and the spread of sexually transmitted infections. The terms used in our search ensured we reviewed a broad range of relevant studies. These terms were: 'human papilloma virus', 'males', 'quadrivalent', 'vaccine', 'sexually transmitted disease', 'cervical cancer', 'penile carcinoma', 'herd immunity', 'genital warts', 'cost effectiveness' and 'pap smear'. We also sought to review the 'grey literature', and therefore searched a broad range of internet sources, including government websites. These were accessed for up-to-date information on the HPV vaccination program, the cervical screening program, and relevant legislation. The studies were limited to those published in the English language after the year 2000.

Using the methodology described above, 63 articles and documents found during the search were selected for consideration. After individually analysing all the identified documents, 39 publications were selected for inclusion in the final review with preference given to more recent publications and those with data which could be applied to the Australian program. Of these remaining publications, 16 were original research articles, 15 were review articles, 6 were Australian Government reports or legislation, 1 was a professional communication, and 1 was a media release. The remaining 24 publications were excluded as they were assessed as not relevant to the Australian program.

Discussion

Evidence for HPV vaccination in men

HPV vaccinations worldwide has revealed no major safety concerns, [5] and recent clinical trial data show that the safety profile for males is the same as for females. [18] The most commonly reported side effects have been mild and include fever, nausea and localised injection site pain. [19] Furthermore, there have been no reported deaths that are directly attributable to the vaccine. [5,20]

Currently, only the quadrivalent vaccine has demonstrated protective effects for males in clinical trials. [18] Boys vaccinated with the quadrivalent vaccine have the same seroconversion rates as girls, which is as high as 99%. [21] In addition, the current implementation of the HPV vaccination program for girls in Australia does not have full coverage. [8] Vaccinating males will provide indirect protection to the targeted females in the school HPV vaccination program who were not fully vaccinated, by increasing herd immunity. [8] This protection is vital because there is good evidence that vaccines which include HPV 16 and 18 prevent persistent HPV infections and precancerous cervical, vulvar, and vaginal lesions in females. [14]

Therefore, the inclusion of males into the HPV vaccination program will provide them, and possibly their unvaccinated sexual partners, with protection from HPV. [14] This will also result in higher levels of herd immunity, which refers to the protective effect offered to the unvaccinated and susceptible population by having high rates of acquired immunity in the vaccinated population. [22] This phenomenon acts to limit the cases of transmission and the reservoirs of disease. One example of herd immunity is the widespread vaccination of males

against rubella even though the virus is of little clinical significance in males. This vaccination program in Australia has led to a significant reduction in the transmission of rubella to susceptible pregnant females and the subsequent development of congenital rubella syndrome. [6,23]

Male vaccination not only provides direct protection to its recipients, it also further reduces rates of transmission [5] and provides indirect population benefits to protect members of both sexes through herd immunity. [24] A retrospective seminal study across Australia compared rates of genital warts before and after female vaccination and post immunisation in the 2004-2009 time period. Results demonstrated a 59% decrease in genital warts in age matched females who were eligible for free vaccination and a corresponding decrease of 28% in heterosexual males in the same age bracket who were ineligible for free vaccination. [25] These trends were supported by another Melbourne study which reported the near disappearance of genital warts in heterosexual females and males under 21 years of age. [26] These studies provide early evidence of the benefits of vaccination providing herd immunity which has reduced the clinical burden of genital warts, the high costs of treatment, [27] and the psychological impact associated with the condition. [28,29]

However, the impact of genital warts in the Australian community can be further reduced. One model of HPV transmission suggests that if vaccination rates for boys reached the same 73% level attained by girls in 2011, then by 2050 the vaccination of boys would have prevented an additional 24% of new HPV infections. [5] Other mathematical models suggest that while vaccination of 12 year old girls alone would reduce the incidence of genital warts by 83% and cervical cancer by 78%, including boys in the vaccination program would reduce the incidence of genital warts by 97% and cervical cancer by 91%. [30]

The vaccination of males would not only help the female population, but would also reduce the disease burden for males. This was demonstrated in study of 4065 healthy boys which demonstrated a clear reduction in the development of external genital lesions. [18] One month after the boys received their third and final vaccination, seroconversion for all four types of HPV had occurred in 97.4% of boys, with an additional 1.5% of the cohort seroconverting for only three types of the four. [18] Vaccination was shown to reduce the incidence of external genital lesions, due to infection with HPV types 6, 11, 16 and 18, by 90.4% in the per-protocol population. [18]

Nonetheless, the lack of long term data means there is currently no clinical evidence demonstrating a reduction in HPV related male cancers after vaccination. However, two of the quadrivalent vaccine types, HPV16 and HPV18, are responsible for 90% of all HPV attributable cancers in men. [5] Therefore, since the quadrivalent vaccine has demonstrated a reduction in high grade cervical lesions in women, [8] there is an expectation that vaccination will have the same effect for cancers in men. [8,31] Worldwide, HPV types 16 and 18 are associated with over 80% of anal cancers, 25% of penile cancers [6,14,15] and 31% of oropharyngeal cancers, [14] so the potential for benefit is significant.

In addition, with the reduced rates of smoking, HPV is becoming an increasingly significant cause of oropharyngeal cancer. [32] Most of the oropharyngeal cancers in non-smokers are caused by HPV infections, and the majority of patients are men. [32] Vaccinating women alone is less effective in reducing the rates of infection and both males and females need to be vaccinated for maximal benefit. [22] Male HPV vaccination is expected to lead to a reduction in the oncogenic HPV prevalence in the community and together with female HPV vaccination, it may reduce the incidence of HPV related oropharyngeal cancers in non-smokers. [32]

However, the lack of long term data means that it is uncertain how long immunity will last before a booster is necessary. Current follow-up studies suggest that the vaccine remains effective in a population

vaccinated 8.5 years ago. [8] Further follow-up is necessary to ensure that the vaccine continues to be effective over longer periods of time.

Populations at risk

There is poor uptake of the National Cervical Screening program among women of Aboriginal and Torres Strait Islander (ATSI) background. [7] Among other factors, this poor uptake is one of the reasons why they have twice the risk of developing cervical cancer and their mortality rate is 5 times higher than the general population. [7]

Including boys in the vaccination program has been modelled to further decrease the rates of genital warts and cervical cancer beyond that which would be attained by female vaccination alone. [30] However, the argument has been made that if there is sufficient uptake of vaccination among girls most males would eventually be protected through female vaccination alone. [22] This argument has merit if the vaccination rates among girls are extremely high, but it assumes transmission only through heterosexual relationships. One of the populations at highest risk of HPV infection is men who have sex with men (MSM). [5] This population acquires little benefit from the current HPV vaccination program, [5] and logic suggests that the HPV infections would persist in this population even with immunisation of all females. MSM are at 30 times the risk of anal cancer when compared with other men. [5] As 90% of anal cancers are associated with HPV, [6] the vaccine has the potential to provide significant benefits for this high risk population. However, it would be difficult on many levels to target the MSM population for immunisation. Targeted immunisation would need to reach MSM at an early stage of sexual activity, but at that time many may be reluctant to disclose their sexual orientation due to a fear of stigma. [5] Therefore, a program of routine male vaccination solves the need to target this group specifically by immunising all young boys prior to sexual debut.

Another population which is at higher risk of HPV infection is men and women with impaired immunity such as organ transplant recipients. [6] Although heterosexual males with impaired immunity may have some protection from the HPV vaccination program for girls, [5,30] heterosexual females and MSM with impaired immunity would not receive the same degree of protection. Immunosuppressed populations are more likely to develop persistent infections which progress to dysplasia and cancer. [6] Wide vaccine coverage would ensure high levels of immunity in the community that should lower the risk of HPV transmission to all high risk groups.

Cost effectiveness

The immediate costs of implementing and monitoring the female-only HPV program was reported in 2007 to be AU\$103.5 million over five years. [33] The addition of males to the program added AU\$21.1 million over four years in 2012. [12] Although the Australian Government has approved the addition of males to the HPV vaccination program, the cost effectiveness of such a move is still debated in Australia and worldwide. [5,14,34,35]

Some studies have reported that the vaccination of males is not cost effective when compared to female vaccination alone. [5,14,34,35] These reports were made with the commonly used consideration that an incremental cost-effectiveness ratio (ICER) of greater than US\$50,000 per quality-adjusted life-year (QALY) is not considered cost-effective. [5] However, other studies have shown that the equation becomes much more favourable when protection against all HPV related diseases affecting men and women are included, as that drops the ICER to US\$25,664 per QALY. [36]

Although the Australian Government has not released their analysis on the cost effectiveness of including males in the HPV vaccination program, past experience suggests that anything below an ICER of less than AU\$60,000 per QALY is generally accepted. [5]

The cost models can only provide an estimation of the impact of HPV

vaccination and the true benefits of the HPV vaccination program will not be apparent for some time. This is due to the time interval between HPV infection and the development of cancer. [3,36] However, the rates of genital warts, which are more prevalent and develop more quickly, are already decreasing. [25,26]

The cost per person of vaccination may seem high initially but when the cumulative effects of herd immunity are taken in to account the equation becomes more favourable. [24] In addition, the benefits of HPV vaccination are many, and cost effectiveness studies should take into account the psychosocial benefit, the reduction in the clinical burden of disease, as well as the reduced costs of treating the various presentations of HPV related cancers and genital warts. For example, the treatment of genital warts alone is estimated to cost AU\$14 million annually in Australia. [27]

Future research and monitoring

Monitoring the efficacy, safety and the impact of HPV vaccination is an important step in measuring the effectiveness of the vaccination program and in guiding future policy. There are some challenges in vaccine program monitoring due to the long time interval between HPV infection and the development of HPV related cancers, as well as the asymptomatic and transient nature of infection. [3,37] However, the setup of the National HPV Vaccine Program Register (NHVPR) is a key step towards collecting vaccine coverage and dose status data of the target population, as well as collecting basic demographic data of recipients across Australia. [33] This information is only collected with prior consent and enables administrators to match accurate data collected from different registers to individuals. This allows them to run follow up programs to send reminders for missed doses or for boosters if they are required in the future. These data, combined with the information collected by state based cervical cytology registers and the Australasian Association of Cancer Registries provides a powerful tool to quantify the impact of the vaccination program on the incidence of cervical and other HPV related cancers in the long term.

Information regarding the safety of the vaccine and any associated adverse effects is collected by the Medicines Safety Monitoring office of the Therapeutic Goods Administration. [20] However, currently there are no nationally funded programs which monitor HPV genotypes in the general population and the vaccinated group. This could be a method to monitor HPV prevalence in the future or a way to screen for HPV related cancers. [7] The impact of vaccination on targeted groups such as MSM and ATSI Australians should also be monitored to evaluate the impact of the prophylactic vaccine on these high risk groups.

Summary

The aim of the Australian immunisation program is to introduce immunity against the included HPV types before the commencement of sexual activity through a prophylactic HPV vaccine. Through this program, males and females in the pre-adolescent age group are immunised before their sexual debut (which usually creates a peak in incidence of HPV). [38]

Although the use of barrier contraception such as condoms, and male circumcision may offer some protection, any skin-to-skin contact during sexual activity can result in the transmission of HPV. [3] Currently, HPV vaccination is the only reliable and realistic method of primary prevention of HPV infection. It has proven to be safe with a high efficacy and minimal side effects. [20,21] The vaccination has the potential to significantly reduce the clinical burden of HPV-related disease, the associated high costs of treatment, and the adverse psychological impact which can be caused by the diagnosis of a HPV related disease. [28,29]

Male vaccination not only provides benefits to its recipients but also provides indirect benefits to females and the wider population. This will result in accelerated herd immunity and increase the protection offered to susceptible and high risk groups such as unvaccinated

females, MSM, immunocompromised individuals, and members of the ATSI community.

Furthermore, the introduction of HPV vaccination for all young males and females will further Australia's contribution to the prevention of HPV associated diseases worldwide and provide invaluable data describing the long term effects of HPV vaccination. For a population based primary prevention program to be successful there needs to be strict and persistent surveillance and monitoring of its implementation. Currently, Australia has no national program for the surveillance of HPV or genital warts, although it has setup the NHVPR, which monitors the population vaccination coverage. In collaboration with the PAP test and cancer registries, the information collected through this register should provide invaluable data on the impact of HPV vaccination in females. This monitoring will be extended in 2014 to include males,

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providing a robust data set enabling the measurement of the impact of HPV vaccination on the incidence of HPV related cancers in the coming years.

Conflict of interest

None declared.

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Correspondence

M Boulat: mbou13@student.monash.edu

A Hatwal: ahat5@student.monash.edu

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