



STIs in Gay Men Action Group

Supplement

HPV vaccination to prevent cancers in gay men

In Australia, a decline of more than 70% in genital warts cases has been seen in young female residents since the introduction of the quadrivalent HPV (qHPV) vaccine (Gardasil; Merck Sharpe Dohme Australia Pty Ltd), as well as in young heterosexual males (possibly through a herd immunity effect)¹. No such decline was seen in female non-residents or men who have sex with men (MSM). Additionally, the qHPV vaccine has been shown to be effective in preventing HPV infection and HPV-related pre-cancerous lesions, including cervical, vulval, and vaginal lesions in women². But what does this mean for our MSM patients? HPV infection causes the majority of anal cancer and a substantial proportion of penile and oropharyngeal cancers, MSM patients are not benefiting from a herd immunity effect as only females receive the qHPV vaccine.

A study by Palefsky *et al*⁴ on the efficacy of Gardasil in 602 MSM, demonstrated 77.5% efficacy at preventing HPV 6, 11, 16, and 18-related anal intraepithelial neoplasia (AIN grades 1-3) and anal cancer in HPV naïve individuals. Analysis of all randomised MSM individuals in the study group (irrespective of HPV status at enrolment) demonstrated vaccine efficacy for prevention of HPV 6, 11, 16 and 18-related intraepithelial neoplasia of 50.3%. In response to this and other ongoing research in males, **the TGA has extended the indication for Gardasil to include the prevention of anal disease.**

*GARDASIL is indicated in males 9 through 26 years of age for the prevention of anal cancer, precancerous or dysplastic lesions, external genital lesions and infection caused by HPV types 6, 11, 16, and 18 (which are included in the vaccine)*⁵.

Despite this new indication, Gardasil is not currently part of the National Immunisation Programme in males. Since February 2012, the American Academy of Pediatrics recommends that the qHPV vaccine be given to *all* 11-12 year old children as part of the adolescent immunisation platform in the United States⁶. In Australia, submissions have been put to the Commonwealth Government to include both male and female qHPV vaccination in the National Immunisation Programme.

Is a HPV vaccine the whole answer? About 85% of anal carcinoma is HPV positive (possibly more in MSM) and rates of anal cancer are approximately 30-fold higher in MSM than non-MSM⁷. Many HPV subtypes have been identified in anal specimens in MSM including other 'high-risk' HPV subtypes which are not included in the qHPV vaccine^{8,9}.

What about vaccination in MSM patients over 26? The selection criteria in the Gardasil study² was healthy men aged 16-26 who had five or fewer lifetime sexual partners and had engaged in anal or

oral sex with another male within the past year. This may have an implication in older patients who have had few sexual partners and GPs may be faced with the dilemma as to whether to vaccinate these men. There is no robust study data to support this 'off-licence' use of Gardasil, however research is ongoing.

In summary, HPV vaccination in male patients for the prevention of HPV-related anal disease is a new indication for Gardasil and may provide a promising intervention to address the increased risk of anal cancers in MSM. Identification of MSM at a young age and before much sexual activity will be required to get maximal benefit from the vaccine. Studies will continue to assess the efficacy of vaccination in this group and potentially the efficacy of reducing other HPV-related cancers.

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References

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