

Briefing for the Public Petitions Committee

Petition Number: PE01477

Main Petitioner: Jamie Rae acting for Throat Cancer Foundation

Subject: Gender-neutral Human Papillomavirus vaccination

Calls on the Parliament to urge the Scottish Government to extend the current Human Papillomavirus (HPV) immunisation programme in Scotland to include boys.

Background

The petitioner contends that there is inadequate protection for males in the Human Papillomavirus (HPV) immunisation strategy, which is currently restricted to adolescent girls. The petitioner therefore proposes that the HPV immunisation programme should include adolescent boys as well as girls.

The HPV Virus

Five per cent of all cancers are attributed to HPV infections¹. Infection with HPV represents the most common sexually transmitted virus world-wide. Consequently, the majority of HPV-associated malignancies arise in tissues associated with sexual contact. Despite the high likelihood that individuals will become infected during their lifetime, the vast majority of these infections are cleared by the immune system and have no effect on the individual².

There are 120 identified sub-types of HPV; these are indicated by a number, for example HPV-16. These different sub-types are separated into low- and high-risk categories². Of these, HPV-16 and HPV-18 are considered high-risk subtypes and are found in 70% of cases of cervical cancer and 80% of anal cancers³. In addition to anal cancer, HPV-associated penis, mouth and throat cancers are found in men. In comparison, low-risk subtypes, for example, HPV-6 and HPV-11, are more commonly associated with genital warts in both men and women.

¹ Stanley, M. (2012). Perspective: vaccinate boys too. Nature, 488: S10

² Prabhu, S.R. and Wilson, D.F. (2013). Human papillomavirus and oral disease - emerging evidence: a review. Aust. Dental J 58:2-10

³ Low, G.M.I., Attiga, Y.S., Garg, G., *et al* (2012). Can male vaccination reduce the burden of human papillomavirus-related disease in the United States? Viral Imm., 25(3):174-86

Prevalence of HPV infection in Scotland:

A recent study tested unvaccinated Scottish adolescents for infection with different strains of HPV⁴. The study found a low prevalence of infection in 11-14 year olds (1%). In girls aged 15-18 there was a HPV infection prevalence of 15.2%; in the same age group for boys the prevalence was considerably lower at 2.9%. This lower prevalence could be associated with the poor sensitivity of the test in boys, shorter duration of infection and tendency to have younger female partners with lower rates of infection. The study concluded that further research was required to define the contribution of female vaccination to the protection of males. This is commonly termed 'herd immunity'.

'Herd Immunity' relates to the indirect protection that is conferred to the unvaccinated population by vaccinating a majority, or other critical subpopulation, thereby reducing the circulation of the virus.

A strategy of ensuring high-coverage (>80%) HPV vaccination in adolescent girls is expected to ensure that the risk of viral infection is reduced in the male population⁵. An immunisation programme for girls aged 12-13 years was introduced in Scotland in September 2008. The last period for which vaccination data is available (2011/12) demonstrated high uptake of the HPV vaccination in Scotland with 93.1% and 91.7% of girls in S2 receiving the first and second doses respectively⁶. However, this type of strategy does mean that some key groups are left unprotected, including 'men who have sex with men' (MSM) or men who travel to areas with low vaccine uptake or no vaccination policy.

Global immunisation status

Currently, 18 European countries vaccinate adolescent girls, but none have introduced a gender-neutral vaccination strategy. The considerable cost associated with female vaccination is often cited as the main obstacle in introducing gender-neutral immunisation strategies⁷.

Only Australia and the USA recommend the vaccination of adolescent males. In Australia, the average coverage across states was 70.6% for girls turning 15 in 2011/12⁸. The male vaccination strategy started in February 2013 and so no data is available on uptake. On 12 July 2012, the Australian Minister for Health, announced funding of AUS\$21.1 million (£14.3m) over four years to

Department of Health and Ageing, Immunise Australia Program Statistics 2011/12

⁴ O'Leary, M<u>.</u>C., Sinka, K., Robertson, C., *et al* (2011). HPV type-specific prevalence using a urine assay in unvaccinated male and female 11- to 18-year olds in Scotland. Br J Cancer, 104(7):1221-6.

⁵ Jit, M., Choi, Y.H., and Edmunds, W.J. (2008). Economic evaluation of human papillomavirus vaccination in the United Kingdom. BMJ, 337:a769

⁶ HPV Immunisation Uptake Rates, 25th September 2012, Information Services Division, NHS Scotland Publication <u>Summary</u>

⁷ Sander, B.B., Rebolj, M., Valentiner-Branth, P., *et al* (2012). Introduction of human papillomavirus vaccination in Nordic countries. Vaccine, 30(8):1425-1433

extend the National HPV Vaccination Program to include males⁹. This was in response to a change in the <u>position</u> of the Pharmaceutical Benefits Advisory Committee following analysis of cost-effectiveness. As HPV-associated cancers in men take decades to develop there is no evidence available on the impact of HPV vaccination on adolescent boys. However, recent data from Australia relating to the incidence of genital warts in men attributable to female vaccination has been published¹⁰. In a 5 year period, 9% of people presenting at sexual health clinics for the first time were diagnosed with genital warts. In heterosexual men under 21 years, the proportion with genital warts rose in the pre-vaccination period, from 7.2% in 2004 to 12.1% in 2007, and then decreased in the vaccination period to 2.2% in 2011. In MSM, there was a modest decrease from 8.5% in 2007 to 6.4% in 2011, however, no decreasing trend was found in bisexual men. The paper concluded that the decline in MSM was unlikely to be due to herd immunity.

Impact of male vaccination

The incremental cost-benefit of male HPV immunisation depends on the clinical outcome that is assessed, the available disease incidence data, and vaccination coverage. There is research that suggests that if the public health objective is to reduce rates of cervical cancer the additional benefit to women of male vaccination is likely to be limited⁵. Cost-benefit studies of male vaccination that have been performed in the USA and Australia are unlikely to be comparable to Scotland where vaccination coverage in girls is very high.

Scottish Government Action

Advice on vaccination and immunisation is provided to Scottish Ministers through the Joint Committee for Vaccination and Immunisation (JCVI), a statutory committee that advises the Secretary of State for Health and Welsh Ministers. Whilst the JCVI has no statutory basis for providing advice to the Scottish Government, Ministers may choose to accept the Committee's advice or recommendations. Specific advice given by the JCVI in response to a request from Scottish Ministers is not binding on any Minister.

Extending HPV vaccination provision to male immunisation was <u>discussed</u> by the (JCVI) on 13 June 2012 and presented the following conclusions summarised here

 Emerging evidence suggests that HPV vaccination could provide protection against a wider range of HPV-related diseases. The committee noted that the potential impact of HPV vaccination on non-cervical cancers would make the current HPV immunisation programme even more cost effective. However, it would remain the case that, given the expected

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Department of Health and Ageing, Australian Government Health Minister's <u>Statement July</u> 2012

¹⁰ Hammad, A., Donovan, B., Wand, H., *et al* (2013). Genital warts in young Australians five years into national human papillomavirus vaccination programme: national surveillance data. BMJ, 346:f2032

- effects of immunisation on HPV transmission and the indirect protection of boys that accrues from high levels of coverage of HPV vaccination in girls, vaccination of boys in addition to girls was unlikely to be cost effective.
- MSM are likely to get less direct protection from the current strategy and vaccination strategies to protect MSM should be evaluated. Data was limited on the prevalence of HPV infection in MSM, but research was underway

On 14 August 2012 the JCVI issued a call for evidence to support an HPV immunisation programme review. In addition to questions relating to the existing strategy, the JCVI was also interested in the potential benefits of HPV vaccination for those not currently offered immunisation, e.g. MSM group. Subsequently, Health Protection Scotland (HPS) has responded to the secretariat of the JCVI stating, 'we have no Scottish data on the prevalence of HPV in MSM - however [the Scottish HPV Reference Laboratory] are looking to collaborate with University College London in relation to a project which incorporates genotyping of MSM attending an anoscopy service'¹¹. The JCVI plans to reconsider extension of the vaccination program in June 2013. The Scottish Government will be waiting on further advice arising from this meeting¹².

Scottish Parliament Action

Specific aspects raised within the petition have not been debated or discussed within the Scottish Parliament or its Committees. Three motions have been lodged to debate the extension of HPV vaccination provision (Motions: <u>S3M-00692</u>, <u>S4M-05613</u>, <u>S4M-06167</u>), though none have been debated.

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¹¹ Health Protection Scotland, personal communication, April 2013

¹² Scottish Government, personal communication, May 2013

amended to reflect subsequent changes.