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Stuart Todd

Public Petitions Committee

The Scottish Parliament

Edinburgh EH99 1SP

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Re: Public Petition PE01477

I support the petitioners call to extend the HPV immunisation programme to boys in Scotland. My arguments in support of this are as follows:

Infection with a subset of human papillomaviruses, (HPVs) mainly HPV 16 and 18, is the cause of almost all cervical cancers in women. However, HPV is also the cause of cancers of the anus, tonsil and base of tongue and a major contributor to cancers of the vagina, vulva and penis. Altogether HPV is estimated to be the causal agent in 5% of all human cancers, with HPV 16 the major player and responsible for 60-90% of cases. HPV types 6 and 11 very rarely cause cancer but are the cause of nearly all genital warts, the commonest sexually transmitted viral infection with a lifetime risk of acquisition of 10%.

Highly effective prophylactic HPV vaccines are available. HPV immunisation is in the UK national immunisation schedule and the HPV vaccine Gardasil® that targets HPV 6, 11, 16 and 18 is delivered to year 8 schoolgirls (12-13 year olds) via a school-based programme. This programme is highly successful, particularly in Scotland, with uptake rates exceeding 90%.

The decision in 2008 to implement HPV vaccination to girls only was based on a public health outcome of a reduction in cervical cancer in females. In this scenario mathematical models indicated that male vaccination provided only a small added benefit and was not cost effective. However, the older, cost effective, health economic models on which these decisions were based, did not include the burden of HPV-associated disease (both warts and cancer) in men for which much more robust data is now available.

The burden of HPV-associated cancer in men in industrialised countries is now comparable to that in women. Cervical cancer, the major burden in women, is controlled in the UK both

by vaccination and by cervical cancer screening. Screening is either not routinely offered or not available for other HPV-associated cancers, particularly cancer of the anus and cancers of the mouth and throat. These cancers occur in both men and women and the incidence of both is rising.

Anal carcinoma is a rare cancer. In the over 50s, women have a higher incidence but men dominate in the 20-49 year age group. Incidence rates for this disease have risen by 2-3% per annum over the past two decades. Rates of anal cancer are particularly high (37 per 100,000) in men who have sex with men (MSM) and these rates double in HIV infected MSM. Rates of HPV associated oropharyngeal-associated squamous cell carcinoma (OSCC) have increased in both men and women over the past 2-3 decades. In industrialised countries, the USA, Europe, the UK, incidence of OSCC is higher in men than women and the rates continue to rise. In the USA the annual number of OSCC it is predicted will pass that of cervical cancer by 2020. Most of these cases will be in men.

HPV vaccine trials in men have shown efficacy against infection and disease of greater than 90%. Men make a poor immune response to natural infection with HPV, but an excellent immune response to the HPV vaccines and clearly will benefit from vaccination. The principal objections to extending male vaccination centre around cost-effectiveness. With a sexually transmitted infection, if one gender is vaccinated and vaccine coverage is high then with time, herd protection should develop and thus men who have sex with immunised women will be protected against disease. This is herd protection, not herd immunity. The latter requires a high percentage of the total at risk population to have protective immunity, as would be achieved with vaccination. With female only vaccination men, 50% of the population, remain at risk for HPV-associated disease. Furthermore, MSM receive little or no benefit from herd protection with female only vaccination and without immunisation remain vulnerable to preventable HPV infection and disease. They also maintain a pool of circulating virus within the population.

In the cost effectiveness models MSM represent too small a fraction of the population to justify general male vaccination but targeting MSM only would be cost effective. Implementation of an MSM targeted strategy would be challenging and discriminatory. For optimal vaccine impact MSM would need to be reached before their sexual debut in early adolescence, a quite unrealistic scenario. Sexual preferences are not firmly established in this age group and questioning the sexual orientation of boys would elicit parental outrage. If men in their teens and twenties are targeted, vaccine effectiveness will be reduced because this is a highly HPV exposed, sexually experienced population with high prevalence of infection and disease. Cost effectiveness is therefore also reduced. Targeting homosexual men as a special sub group would be a strategy that risks sexualising and stigmatising the vaccine in the perception of the public and could undermine the whole vaccine programme.

The cost effectiveness of the programmes is driven by vaccine costs per dose, delivery costs coverage and impact. National tenders in Europe and elsewhere have resulted in very competitive pricing for the commercial vaccines. USA and Australian mathematical models show that even with high female coverage, when vaccine costs are low, male vaccination

becomes cost effective. A final issue in the cost effectiveness debate is that in several countries, Switzerland, some Canadian provinces, Columbia, South Africa, Mexico and others, the immunisation schedule has been changed for adolescents under 14 years from 3 doses to 2. This issue is under consideration by the UK JCVI but a 2 dose schedule would significantly impact on the health economic models and cost effectiveness of gender neutral vaccination.

A female only programme for a sexually transmitted infection is highly discriminatory, discriminating both against women and men. Such a programme adds to the very heavy responsibility that women already have for sexual health and focuses attention only on girls and women and their behaviour with respect to this infection and disease. The burden of infection in men is the same as in women. In developed countries such as those in Western Europe, the burden of HPV associated cancers in men is now comparable to that in women. Cervical cancer, the dominant HPV related cancer in women, can be prevented through vaccination **and** screening. But there is no screening for anal cancer or OSCC. HPV associated cancers in these sites tend to occur in younger age groups (40-60 years), present at later stage with associated mortality and show significant morbidity with impaired quality of life after therapy. All men, irrespective of sexual orientation, carry a significant burden of HPV associated disease and this is increasing. By not vaccinating boys we are failing to gain maximum health benefit.

Margaret Stanley

Cambridge October 9th 2013