British Association for Sexual Health and HIV

Statement on HPV vaccination and MSM

The British Association for Sexual Health and HIV (BASHH) advocates universal, gender neutral HPV vaccination of all children. However while this is being re-considered by the Joint Committee on Vaccination and Immunisation (JCVI), this position statement has been produced to provide guidance on a proposal to offer HPV vaccination in men who have sex with men (MSM).

Summary of recommendations

MSM up to the age of 26, or older if the evidence supports a continuing risk, should receive the three dose schedule of the quadrivalent HPV (qHPV) vaccine, although in the ideal situation that the vaccine is administered before sexarche in those aged 14 or less, a two dose schedule may be utilised.

The vaccine can be administered in tandem with hepatitis B vaccination, which is also recommended in this group.

GUM services should work with other stakeholders with an interest in the health and well-being of young MSM to ensure young MSM are aware of the availability of HPV vaccination, its efficacy and its potential benefits.

Background

This document has been developed to provide guidance to providers of sexual health services in the UK on possible provision of HPV vaccination in MSM. Two pieces of work are currently being undertaken in the UK which may lead to changes in policy in relation to HPV vaccination in men and boys: the JCVI re-consideration of the cost effectiveness of HPV vaccination in boys and the development of BASHH guidelines on the sexual healthcare of MSM. However given that neither will be completed imminently, BASHH is producing this guidance to support a proposal to deliver HPV vaccination to MSM attending sexual health services. MSM, unlike girls and heterosexual boys, will receive little if any benefit from the current policy of vaccination of girls, and therefore remain at high risk of infection, and associated morbidity and long term serious sequelae, such as anal cancer.

Reason for development and summary of the evidence

The successful introduction of HPV vaccination of girls in Australia has resulted in significant population health benefits in both girls and unvaccinated heterosexual boys (1-3). Similar benefits are expected to be seen in the UK following the introduction of a vaccination programme for girls, however evidence from Denmark (4) suggests that herd immunity may be less effective when the population is less self-contained, for example when compared to Australia.

MSM bear a significantly increased burden of HPV related disease and adverse outcomes compared to heterosexual men, which is even more marked in those with HIV infection, but have not benefited from the national vaccination programme. Equality of access on the basis of gender argues that the
vaccination programme should be extended to all boys (5), regardless of current or future partner gender and this would offer significant practical benefits in terms of ensuring coverage of all those at risk, and the optimal timing of vaccination at 12-13 years of age. However, the high risk of HPV related disease in MSM, and the consequent health inequity, supports the proposal to vaccinate MSM now.

In all men 80-85% of anal cancers, 36% of oro-pharyngeal and 50% of penile cancers are associated with HPV infection (6, 7). MSM experience higher rates of HPV infection and HPV related cancer, especially HPV 16-associated anal cancer (8, 9). Rates of anal cancer are 15 times higher in MSM compared to heterosexual men (OR 17.3; 95%CI 8.2 to 36.1) (10) and are comparable to the rates of cervical cancer in women prior to the introduction of the cervical cancer screening programme. Recently, there has been a dramatic, poorly understood increase in rates of oropharyngeal cancer (11), with the number of oral sex partners and HIV infection both being risk factors (12). Recent data from the Netherlands shows a high prevalence (9.4% and 23.9% in HIV negative and positive MSM; with median ages of 38 and 47 years respectively), incidence (8.1% 6 month incidence) and persistence (36.9%) of oral, high risk HPV infection in MSM (13).

Vaccination has been shown to be safe and effective in MSM, including those who have already been exposed to HPV and those with HIV infection. Vaccination is highly immunogenic, prevents new HPV infection, reduces persistent infection, incidence of genital warts and rates of AIN (14, 15). In MSM without evidence of previous infection qHPV vaccination resulted in seroconversion to the four relevant types in 89.7 – 97.4%. Vaccination is effective in preventing persistent infection of all four types: 78.6 -95.8% in the per-protocol analysis and 55.2-57.5% in the intention to treat analysis (15, 16).

The majority of evidence regarding the proportion of MSM who have not been exposed to HPV, and therefore for whom the vaccine is likely to have higher efficacy, indicate low levels of previous exposure: 4.9 -12.5% anal canal detection (HPV 16/18) (17); 19% seroprevalence (aged <35, HPV 16) (18). Data from Australia (19) showed a higher prevalence in young MSM with 23% aged 16 -20 having evidence of a vaccine preventable HPV type, which differed significantly based on the number of reported previous anal sex partners. The incidence of new infection with HPV is maintained throughout adulthood in MSM (18) and the vaccine is still effective in those with previous exposure, suggesting that vaccination is still of benefit in adult men.

MSM show moderate levels of self-reported willingness to be vaccinated (20, 21), but high uptake when it is offered; 96% in one study (19).

The JCVI is currently re-considering whether the UK vaccination programme should be extended to include all boys. The cost effectiveness of this approach has not been demonstrated in the UK setting. The original analysis which led to the introduction of vaccination in 2008 only considered cervical cancer endpoints, and the 2011 update did not re-examine the issue of male immunisation, although it did include oropharyngeal cancers. The cost-effectiveness of vaccination of MSM is now being examined. Recent US modelling data has demonstrated cost effectiveness of MSM qHPV vaccination; which is high in MSM aged 12 and remains cost effective even when the scenario is vaccination up to age 26 with HPV pre-exposure levels of 50% (22).
National policy in the US and Australia now includes vaccinating all boys and young men, and in the US, MSM up to 26 years. The US recommendation follows from the much lower uptake in girls than achieved in the UK, making male vaccination more cost effective, but also includes recognition of the particular needs of young MSM. Australian policy appears to derive from a combination of concern for equity for MSM, and benefiting from a low negotiated cost for the vaccine, enabling achievement of cost effectiveness.

In the UK, HPV vaccination coverage of girls is high at 85%, sufficient to provide indirect protection for heterosexual males but less protection for MSM. Coverage of vaccination in 12-13 year-olds shows little evidence of inequity by social determinants, although the catch-up programme did suffer from poorer uptake in more deprived areas (23) and amongst minority ethnic groups (24). This may result in less protection for heterosexual boys, depending on sexual mixing patterns.

**Vaccine eligibility**

Men aged up to 26 who identify as being gay, or whose sexual orientation is unspecified or who report having male sexual partners, presenting to sexual health services and who agree to an HPV vaccination course when provided with the relevant information. The recommended age range is based on the licence for the vaccine, but should be increased if evidence demonstrates a continuing risk in MSM above this age, and vaccination at older ages is shown to be cost-effective.

Vaccination should also be offered by services that deliver care in prisons, young offender institutions and to ‘looked after children’, as indicated above.

**Vaccination delivery**

The quadrivalent HPV vaccine is directed against HPV 6, 11, 16 and 18 (Gardasil, SPMSD) and is licensed for use in females and males aged 16-26 for the prevention of warts, female genital dysplasia and cancer and anal dysplasia and cancer.

The vaccination schedule for qHPV vaccination consists of three doses at time points 0, at least one month later, and then at least three months after the 2nd vaccination. This schedule would permit co-administration with the standard vaccination schedule for hepatitis B, which is also recommended in this group and has high levels of uptake in this setting. Efficiencies in delivery, cost and clinic capacity are added advantages of this approach. It may have an additional benefit of increased adherence and acceptability.

**Costs and supply of vaccine**

The cost of delivery of the vaccine will, in most cases, be small as it can be given at the same time as hepatitis B vaccination, or when attending for an STI screen. However additional follow-up attendances will be required for some patients attending sexual health clinics, the cost of which should be met by existing commissioning arrangements.

The major cost is the vaccine. It would be much more cost-effective to the NHS if the vaccine is procured as part of national process, as part of a national vaccine programme. It is therefore proposed that sexual health services should be given access to the same supply mechanism used for
the national adolescent vaccine programme. The funding for this element needs to be agreed as a public health initiative. Due to the wide variation in the proportion of MSM attending individual sexual health services, and in the absence of a tariff for this activity, the cost cannot be absorbed by ‘averaging out’ within existing funding mechanisms.

**Referrals and pathways and raising awareness**

Services should ensure local partners such as schools, primary care, youth services and community groups are aware of this guidance, and that information and clear pathways are made available in those settings.

The effective implementation of this programme will require both the opportunistic offer of vaccination at a clinic attendance and health seeking behaviour on the part of young MSM. Raising awareness through partner organisations and other stakeholders will be key to informing young MSM of the availability and benefits of vaccination. This can be expected to produce its own challenges and specific material will need to be developed and shared.

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**References**

1. Read TRH, Hocking JS, Chen MY, Donovan B, Bradshaw CS, Fairley CK. The near disappearance of genital warts in young women 4 years after commencing a national human papillomavirus (HPV) vaccination programme. Sex Transm Infect 2011; 87:544-7


Appendices

Patient Information Leaflet - To be developed

Guidance for missed/late 2nd and 3rd vaccinations - link