

# Extending the HPV vaccine to males



## Key points

- HPV is responsible for 5% of all cancers worldwide and rates of HPV-related cancers are increasing
- Since 2008 an immunisation programme has been in place in the UK for girls aged 12-13 years of age
- There is no vaccination programme for males
- Men who have sex with men (MSM) are offered no protection from the female vaccination programme and are particularly at risk of infection

## Calls to action

- Extend the vaccination programme to all 12-13 year old boys
- Negotiate a cost-effective HPV vaccine
- Provide males with a vaccination that protects against genital warts
- Absolute minimum that men who have sex with men (MSM) have free access to the HPV vaccine
- Explore using a range of settings and incentives to increase uptake of the vaccine
- Increase public awareness of the risk of transmitting or contracting HPV

## Background

About 130 types of human papillomavirus have currently been identified.<sup>1</sup> Of these, most are categorised as low risk (LR) types, however there are at least 13 high risk (HR) forms,<sup>2</sup> including HPV 16, 18, 31, 33, 35 and 45.<sup>1</sup> HR HPV is responsible for 5% of all cancers worldwide,<sup>3</sup> with types 16 and 18 causing 70% of cervical cancer and around 90% of anal cancer in both men and women. HPV types 16 and 18 have also been found to cause close to half of vaginal, vulvar, and penile cancers.<sup>4</sup> Oral cancers which have historically been linked to smoking and alcohol have also increased by 50% in the last 20 years,<sup>5</sup> and increasingly HPV is seen to be a contributing factor.<sup>6</sup>

HPV is generally spread through genital skin-to-skin contact, although not necessarily sexual intercourse, and nearly all sexually active men and women will contract some form of HPV at some point in their lives.<sup>7</sup> Most high risk HPV infections last 12-18 months before being cleared by the immune system.<sup>8</sup> Research remains inconclusive about the extent to which reinfection with the same HPV type is then possible following clearance.<sup>9</sup> Approximately 10% of infections, however, are not cleared and result in persistent infection. Persistent infection of a HR HPV type is the single most important risk factor for development of cancer.<sup>8</sup>

Vaccination programmes offering protection for girls against HPV have now been introduced in many countries around the world. A number of countries including Australia, the US, Austria and some parts of Canada have now extended the vaccine to boys as well.

In the UK, around 3,400 women are diagnosed with cervical cancer every year and in 2008 the Government launched a nationwide immunisation programme for 12-13 year old girls to protect against cervical cancer using the vaccine Cervarix which protects against infection by HPV types 16 and 18. The vaccine was subsequently changed to Gardasil in 2012 which in addition to types 16 and 18, offers additional protection against two strains of HPV that are responsible for 90% of genital warts, types 6 and 11.<sup>10</sup> Gardasil also protects against most anal cancers,<sup>11</sup> and while there is currently no data on the efficacy of the vaccine to prevent cancers of the penis, most HPV-related cancers of the penis are caused by the HPV types prevented by Gardasil. From September 2014 the vaccine schedule will move from three to two doses for 12-13 year old girls in the UK.<sup>12</sup> Another vaccine which has just completed clinical trials (nonvalent) has been found to offer even further protection against the four original HPV types (6, 11, 16, 18) in Gardasil, plus five additional variants linked to cervical and vaginal cancers.<sup>13</sup>

Overall uptake for the vaccination programme has been good. Data for 2012-3 suggests that around 86% of girls received all three doses of the vaccine in England<sup>14</sup> and 82% in Scotland.<sup>15</sup> Prevalence of HPV types 16 & 18 has significantly fallen since the introduction of the programme.<sup>16</sup> However, there has been concern that some groups have disproportionately low uptake. Research suggests that there is lower knowledge of HPV and lower acceptability of the HPV vaccine in non-white ethnic groups, and that this may also be linked to religion.<sup>17</sup> High levels of deprivation have also been linked to low HPV uptake.<sup>18</sup> Other research suggests that poor school attenders or those not in school at all, for example those from travelling communities, are at risk of missing the vaccination, particularly where schools do not have systems in place to stop these girls falling through the net.<sup>19</sup> One issue with uptake appears to be in the setting in which it is offered. School-led programmes of vaccination appear to be more successful than those offered through GP surgeries, and health services in Cornwall, where uptake has been particularly poor, are now moving their vaccination programme into the school setting.<sup>20</sup>

## What is the RSPH calling for?

- **Extend the vaccination programme to all 12-13 year old boys**

RSPH believes that vaccinating boys as well as girls before they become sexually active would provide the highest protection for the population against HPV and we are calling for the Joint Committee on Vaccination and Immunisation (JCVI) and Department of Health to extend the two-dose vaccination to all boys aged 12-13 years.

There is currently extensive debate in the UK over the cost effectiveness of extending the vaccination scheme and the JCVI is currently considering the implications of extending the programme.

Despite the overall success of the vaccination programme for girls, there is currently no immunisation programme for boys. While the vaccination for girls does offer herd immunity for boys, this doesn't take into account of transient populations and presumes that males remain within the herd.<sup>21</sup> Men may still contract HPV elsewhere (e.g. travelling abroad) or from females within the UK who have not had the vaccination (14% of 12-13 year old girls in England and 18% in Scotland did not have three doses of the vaccine in England in 2012/3<sup>14,15</sup>).

- **Negotiate a cost-effective HPV vaccine**

The decision as to which vaccine to use is based on a range of different factors, including cost-effectiveness and the impact on Quality Adjusted Life Years (QALYs). QALYs are based on the additional life expectancy that can be assigned to a particular treatment and the likely quality of life in these years. The higher the cost per QALY associated with a treatment, the less likely it will be paid for.

When the HPV vaccination was introduced to boys in Australia, given that the vaccination was already available to girls the relative gains were less than for girls and the Australian Government managed to secure a reduced cost per dosage of the vaccine for boys. RSPH would call on all parties involved in securing the cost per dosage in the UK to take into account this precedent and ensure a similar arrangement is adopted.

Given that the vaccination schedule will move from three to two doses for girls, one could argue that the potential cost savings associated with this could contribute to extension of the vaccine to boys.

- **Provide males with a vaccination that protects against genital warts**

The type of vaccination that is offered should also take into account the relative protection provided by the vaccine. While Cervarix offers protection against HPV types 16 and 18 linked to certain cancers, Gardasil also provides additional protection against types 6 and 11, linked to genital warts. We would argue therefore that Gardasil should be the vaccination used in males.

Genital warts are the most frequently treated sexually transmitted disease in GUM clinics in England with 178,000 cases diagnosed in 2009.<sup>22</sup> This does not include the cases treated within general practice. Treating genital warts in England is estimated to cost £52.4million per annum, so this cost should be factored into any decision about which vaccine to use.<sup>23</sup>

Basing a decision purely on economics fails to appreciate the impact of genital warts on the individual. Research shows that many individuals with genital warts experience psychological distress including anxiety, embarrassment, anger, and shame and that infection can interfere with relationships.<sup>24</sup> While warts themselves can be treated, the underlying HPV infection cannot, and individuals who develop a persistent infection will continue to experience future outbreaks of genital warts. RSPH would therefore call on the use of Gardasil to protect all males from genital warts caused by HPV types 6 and 11.

- **Absolute minimum that men who have sex with men (MSM) have free access to the HPV vaccine**

While there is evidence of some protection for heterosexual men through herd immunity,<sup>25</sup> men who have sex with men (MSM) do not benefit from the current vaccination programme. HPV infection is high in MSM<sup>26</sup> and they are at greater risk of developing anal cancer than heterosexual men.<sup>27</sup> Rates of anal cancer are particularly high in individuals with HIV<sup>27</sup> and it has been stated that rates of anal cancer in HIV-infected MSM have reached epidemic proportions.<sup>28</sup>

There is a clear need to ensure that MSM receive protection from high risk HPV strains. Introducing the vaccine to all boys aged 12-13 would help address this, but if this is not agreed, at the very least MSM should be offered the vaccination as they do not benefit from herd immunity from girls. Supplying the vaccine before infection of a high risk HPV type is acquired is the best way to prevent HPV-associated cancers and this highlights the need to offer the vaccine ideally before first sexual contact. For many MSM this will not be possible, but even if persistent infection of one strain of HPV is already present, the vaccine can still offer protection against other strains.

- **Explore using a range of settings and incentives to increase uptake of the vaccine**

While general practice, GUM clinics and other healthcare settings could provide the HPV vaccination to MSM, there should be greater consideration of other settings that could be used to effectively access MSM. HPV vaccinations could be offered to all MSM as part of standard screening in GUM clinics, but by this stage an individual may be presenting with an STI and could well have been exposed to a strain of HPV.

If the HPV vaccination is not offered to 12-13 year olds within schools, a three dose vaccination will be required for those aged 14+. There is a risk that individuals will not complete all three doses. Given the potential for drop-out we would encourage broadening the settings in which the vaccination is offered to one in which individuals are likely to return to. We would therefore call for the vaccine to be offered in non-clinical or community settings, (which have the appropriate facilities to offer vaccinations), such as pharmacies, gyms (or even nightclubs and bars if individuals were appropriately screened).

Universities could also be used effectively to ensure that MSM are accessed in a timely manner with the vaccine. We call for Public Health England to work with Student's Unions and University Union LGBT Societies to raise awareness of the vaccine and ensure its free provision for MSM students within the university setting. Regional colleges could also be used to encourage uptake for young people not at university. Youth offender institutions could also raise awareness and encourage vaccine uptake in MSM.

In addition to exploring the setting in which a vaccination is offered, research on hepatitis B suggests that offering incentives, such as small amounts of cash and supermarket vouchers<sup>30</sup> can help encourage individuals to complete the full dose of treatment. These could also be appropriate for MSM accessing the HPV vaccine, along with additional incentives related to the setting. For example, those accessing the vaccine through a gym, could receive a free period of gym membership as an incentive to complete both doses; or students could be offered food vouchers to be used within the university.

## • Increase public awareness of the risk of transmitting or contracting HPV

Most sexually active people, regardless of their gender, will contract HPV at some point in their lives. Evidence points to the increasing prevalence of HPV-related illness in both genders and we believe increased awareness is needed surrounding the potential impact HPV can have on everyone. This is particularly vital for groups that are already less likely to take advantage of the HPV vaccination available, particularly those from deprived areas and non-white ethnic groups. There may also be a need for religious leaders to be informed about the importance of vaccination, as support from religious leaders, for example telling students that the Pope supports HPV vaccination, has been shown to help increase uptake in some groups.<sup>19</sup>

There may also be a role for Youth Health Champions in signposting and increasing awareness of the importance of the HPV vaccination with girls in the groups that need additional targeting.

If the decision is to roll-out the vaccination to MSM, once this has been made freely available, it will need to be accompanied by an awareness campaign so that there is a clear understanding that the best time to receive the vaccination is before first sexual contact and, if this is not possible, that the vaccine should be accessed as early as possible.

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