

# **Why not Boys? The Human Papilloma Virus Vaccine Schedule in the United Kingdom**

Janet Kelly

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# **Why not Boys? The Human Papilloma Virus Vaccine Schedule in the United Kingdom**

## **Introduction**

The aim of this paper is to explore the ethical issues on why boys are not currently included in the Human Papilloma Virus vaccination schedule in the United Kingdom (UK). There is a paucity of literature on the benefits of vaccinating boys (Hull and Caplan, 2009). The current vaccination schedule in the UK for the Human Papilloma Virus (HPV) offers a two dose quadrivalent vaccination (against HPV types 6, 11, 16 and 18) for adolescent girls between 11-13 years old. This is given as a school based programme and is only offered to girls (NHS Choices). Boys are currently not offered the vaccine and there are no current plans to do so.

## **Background**

The vaccine was first introduced in the UK in 2008 (Green Book, 2014) with the intention of preventing sexually transmitted disease in girls (Bennett, 2016). However, mass immunisation of girls raises ethical dilemmas that can affect boys, which this paper will address (Hann and Peckham, 2008). HPV is a group of viruses that affect the skin and moist mucus membranes in any sex (NHS, 2016). As a DNA virus the organs most at risk are the cervix in girls and the mouth in both boys and girls (Peate, 2009). There are over one hundred subtypes of HPV however there are four that are known to cause significant disease. Subtypes 16 and 18 are known to cause approximately 70% of cancers of the cervix. Subtypes 6 and 11 being the leading causative factor in the most common genital warts.

HPV is a very common virus, 80% of the adult population have genital HPV virus at some point in their life with over 80% of sexually active women being infected during their lifetime (Trottier and Burchell, 2009). HPV can develop after skin to skin (genital) contact and is not a result of penetrative sex only. The majority of people who become infected with HPV will

not have any symptoms; the immune system will clear the virus in the majority of healthy people. In some people, however, the immune system cannot clear the virus; this is more common in people who are affected by HIV/AIDS or who are immunosuppressed (Russell et al 2013). There are also people with no known immunological problems whose immune systems do not clear the virus although it is not known why this occurs (Green Book 2014). Brisson et al (2011) acknowledge that HPV causes a substantial burden of disease in females. However, they also describe the disease being problematic to males. In fact, there has been a rise in the incidence of oropharyngeal cancers, particularly in men (Ramqvist and Dalianis, 2010). Gillison et al (2012) report a significant increase in the incidence of oropharyngeal squamous cell carcinomas over the past 30 years with HPV has being cited as the underlying cause. Furthermore, the rate of anal cancer is increasing among both men and women (Palefsky et al 2011). In spite of this, boys are not covered by the national HPV vaccination programme. Kim et al (2007) suggest that this is due entirely to cost with Pearson et al (2014) reporting that herd immunity is best achieved by improving the coverage of vaccination of girls rather than vaccinating boys as individuals. However, HPV vaccination is a public matter for all and is ethically complex due to challenges that public health has on best practice versus economic resources and as such it raises significant ethical issues Baun et al (2007).

### **Ethical Issues**

Beauchamp and Childress (2013) describe four principles of biomedical ethics which are considered culturally neutral to enable practitioners to think and consider ethical issues in health care. The three principles that this paper will consider are: beneficence which is the action should be in the best interest of the patient or to do good; non maleficence is that the action should do no harm and justice and equality concerning whether the action is equal and fair.

## **The Duty to Do Good**

Beneficence concerns doing good and averting harm (Purtillo, 2005). It is well documented that the HPV vaccination has prevented common cancers including genital warts (Bennet, 2016) and is therefore effective and is of benefit to the target population (Munoz et al 2010). The vaccine efficacy is proven by the PATRICIA (PApilloma TRIal against Cancer in young Adults) trial (Lehtinen et al 2011). This was a large, double blind, randomised study to determine the vaccine efficacy at preventing cervical intraepithelial neoplasia (CIN). CIN is abnormal cells in the squamous epithelium of the cervix that are proven to be a precursor to malignant disease. The results of the trial were that high coverage of the target population may have the potential to significantly impact on the rates of cervical cancer as vaccine efficacy against CIN3+ (highest level) that was caused by HPV type 16 or 18 was 100%. This is supported by Markowitz et al (2013) as a result of their analysis of prevalence data of HPV in the pre and post vaccine eras. Their conclusion was that the vaccine effectiveness was estimated to be high as despite low coverage and the uptake of all doses being low the reduction in disease was 56%. These studies by Munoz et al, Lehtinen et al and Markowitz et al demonstrate that the vaccine is effective and in the best interests of the target cohort (girls aged 12-13) and as the risk of cervical cancer is significantly reduced.

There is also evidence to suggest that the vaccine also has value in preventing disease caused by HPV in males. A large randomised, double blind, placebo controlled trial was completed by Giuliano et al (2011) with the intention to determine whether quadrivalent HPV vaccination was as effective in males to prevent subsequent disease after becoming infected with HPV as it was in females. The results were that the vaccine did prevent infection with HPV and suggested that vaccine efficacy may be similar for the two sexes. Palefsky (2011) carried out a sub study of a larger double blind study to determine if HPV vaccine could be effective in reducing the rates of anal cancer in men who have sex with men. A reduction in the incidence of anal cancer in this sub group was observed.

The further studies by Giuliano et al and Palefsky demonstrate that the vaccine is of benefit to the population, not just the current target cohort of girls. The vaccine does reduce the incidence of CIN and therefore subsequent risk of malignant disease of the cervix. The vaccine also reduces the incidence of genital warts. This is further supported by Bauer et al (2011) who claim the vaccine *significantly* reduces the risk of genital warts in both males and females. The Nobel Peace Prize winner Harald Zof Hausen who won the prize in 2008 for his discovery in the 1980's that HPV causes cervical cancer has called for boys to be added to the current vaccination schedule. He theorises that vaccinating boys will protect them as individuals but also prevent transmission to unvaccinated partners. This approach demonstrates the clear benefit of vaccinating boys as well as girls (Branković et al, 2013). Therefore, the principle of beneficence which is further described by Fry and Johnstone (2008) as helping others gain what is beneficial to them and an action that will actively promote their wellbeing can be applied to the scenario of the HPV vaccine being routinely offered to boys. The evidence suggests that there is a clear benefit to boys as well as girls. Moreover, Luyten et al (2014) remark whether it is ethically justifiable not to vaccinate boys as well as girls. They argue that there is a duty not to harm others as those not afforded the opportunity to have the vaccine can clearly be harmful to not only themselves, but others whom they have sexual contact with who may not have had the vaccine also. Nonetheless, the status quo remains in the UK in that vaccination will be for girls only.

In the United States of America the HPV vaccination was offered to boys in 2011 (Sokley et al, 2014). The Centre for Disease Control and Prevention (CDC) state that HPV vaccination is recommended for boys at age 11-12; furthermore, they suggest that there will also be benefit to girls by reducing the spread of HPV (CDC, 2015). Australia followed by adding boys to their HPV vaccination programme in 2013 to protect the boys as individuals but also to improve herd immunity where vaccination uptake and coverage may be low (Australian department of Health, 2015). Arguably, both countries programmes are beneficial and are in the best interests of all of the population who are vaccinated. Furthermore, it has the

potential to improve herd immunity for the unvaccinated population. A view shared by Luyten et al (2014) who argues that vaccinating boys will have a significant impact on girls as they are more at risk of catching the disease.

### **The Duty Not to Harm Others**

Vaccination is an extremely effective public health intervention, second only to clean water for the impact there is on saving lives and promoting good health (Yarwood 2014). However, conversely, vaccinations are drugs and as with all drugs, there is always a risk that the vaccine has the potential to cause harm as well as do good. Accordingly, when any drug or vaccination is prescribed it must always be considered if the benefits outweigh the risk of harm. The duty of non-maleficence is a difficult principle to apply to vaccinations as the ethical duty to not cause harm, is seen to be stronger than the duty of beneficence which is to do good (Chonko 2012). Further, it is multifaceted with the aim to prevent disease and illness and at the same time promote health and well-being (Bennet, 2016).

Concerns have been raised that the HPV vaccination causes harm. Although rare, Haug (2009) documented that there were reports of anaphylaxis, Guillain Barre Syndrome, demyelinating diseases, pancreatitis and thromboembolic events after vaccination and suggested a causal link. In a recent study by Scheller et al (2015) it was acknowledged that reports have suggested a link between multiple sclerosis and other demyelinating diseases. However, these concerns have been disproved as there appears to be no increased risk in receiving the vaccine from the earlier research by Slade et al (2009). Adverse reactions are rare, often reversible and despite this the evidence strongly suggests that the HPV vaccine is safe and that the benefits far outweigh the minimal risk of harm (Kuehn, 2011).

### **Fairness and Justice**

This principle ensures that individuals should be treated equally and fairly (Beauchamp and Childress 2013). This can be interpreted as a right of every individual to be able to access

available resources based on their health care needs within the area they live. There should not be any cost disadvantages for the less well off (Malmqvist et al, 2011). In the following this principle, according to Gorin et al (2011) it is unfair for boys not to enjoy the same benefits as girls who are routinely vaccinated. Boys have equal health needs as girls as they are equally at risk of developing disease from HPV infection; there should not be any health disparity between sexes (Bakir and Skarzynski, 2015). Arguably, they should therefore receive equal health resources such as the HPV vaccination, which is currently only afforded to girls (Fry and Johnstone 2008). Clearly, however, this does not happen in the UK and that boy and girls are not treated the same regarding the HPV vaccine. Justice alone therefore fails to take into account whether implementation is politically feasible or acceptable by a particular community (Malmqvist et al, 2011). Gorin et al (2011) further mention, although the vaccine is effective, it is costly and therefore it can be seen as a financial barrier to counties offering it to boys as well as girls.

Conversely, Brisson et al (2011) argue that health needs between boys and girls are not equal; where HPV causes a substantial burden of disease in girls it does so to a much lesser extent in boys. Although, boys and girls are both at significant risk of disease from HPV the evidence suggests that the risk is greater for girls. Mortensen (2015) comments that girls have a more direct benefit in having the vaccine than boys to prevent cervical cancer as opposed to boys who have more of an indirect benefit. However, an aspect of justice is fairness, whether an action is fair to all concerned. In this situation whether it is fair that boys are currently only protected from HPV by proposed herd immunity. Protecting boys from HPV by herd immunity alone may not entirely represent fairness (Branković et al, 2013). Boys as individuals have a right to their own protection from HPV. However, arguments tend to focus on boys having the vaccine to protect girls as opposed to protecting themselves from cancers such as penile or anal cancer, which is perhaps unbalanced, not truly informative and unfair (Foresta, 2009). This view is supported by Professor John Ashton CBE, President of the Faculty of Public Health who stated that although the decisions about

protecting children and adults against cancer should be made on the evidence and not on moral judgements, it is not acceptable to withhold effective health interventions from males simply on the grounds of gender (Ashton, 2016).

This question of men who have sex with men can also be raised. There is no herd immunity available for this group of males. Anal cancer rates are increasing in both males and females but particularly in men who have sex with men (MSM) (Palefsky et al 2011). However, the Joint Committee on Vaccination and Immunisation (JCVI) released an interim statement in November 2014 reporting that the HPV vaccination for MSM is to become available but not for boys. The programme will be targeted at 16-45 year old males who identify themselves as MSM, via genitourinary medicine and HIV clinics. The problem that arises from protecting males in this manner is that it is very difficult to ascertain when a man knows he is gay. If a man realises he is gay and receives the vaccination prior to any sexual contact, this programme would be successful for that cohort; however, it can be argued that sexual contact with another male may be what determines for the male that he is gay/bisexual, by which time it is potentially too late to protect against HPV.

Optimal protection from HPV vaccination only occurs if it is administered before first sexual contact (HPV Action 2016). Men who have sex with men do not benefit from the current vaccination schedule, the vaccine is available to them on an individual basis. However this would be unnecessary if adolescent boys were routinely offered the vaccination. It would remove gender health inequalities and place the responsibility for good sexual health with the individual rather than with just females or men who have sex with men (HPV Action 2016).

The option is available for an adolescent boy to access the HPV vaccination privately at the request of and paid for by his parents or guardians, this is available at over 40 clinics in the UK (What Clinic, 2016). This promotes further health inequalities between richer and poorer



social groups, which HPV Action (2016) raise the concern that existing inequalities in cancer will be further exacerbated. This is clearly not just, equal nor fair.

## **Conclusion**

The risks that males could potentially develop disease relating to infection with HPV are well documented and are considered significant (Brisson et al 2011 and Palefsky et al 2011). The evidence suggests that the benefit of being protected from HPV by vaccination clearly outweigh any risk that the vaccine may carry; therefore vaccinating boys can be considered as beneficial (Scheller et al 2015) (Arnheim-Dahlström et al, 2013). However, health needs of males and females are not equal; females are at greater risk of developing disease related to HPV but even so, the risks to males are significant enough to demonstrate that males also need protecting from the virus (Cancer Research UK 2012). The evidence suggests that the differences in risk are not substantial enough to justify not including boys in the HPV vaccination programme merely due to their gender. There is potential that adding boys to the UK schedule would improve herd immunity, offer protection for unvaccinated women and place the burden of ensuring good sexual health equally between males and females (HPV Action 2014). The current programme which is based on cost effectiveness and suggests that boys will receive protection by herd immunity is not satisfactory as there are pockets of society where vaccination levels are low therefore herd immunity is not available to males or females in these areas.

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