



# Equality Analysis

## Human Papillomavirus (HPV) Vaccination

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# 1. Introduction

## Purpose

- 1.1 This document reviews equality issues related to HPV vaccination in England. It is intended to support consideration of JCVI's advice on the potential extension of HPV vaccination to adolescent boys.

## Public sector Equality Duty (PSED) analysis

- 1.2 The Equality Act 2010 imposes a number of obligations on public authorities. One of the most relevant to the Department is the Public sector Equality Duty which arises under section 149 of the Act. The PSED requires that when carrying out any functions ministers have due regard to the need to:
- a) eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;
  - b) advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
  - c) foster good relations between persons who share a relevant protected characteristic and persons who do not share it.
- 1.3 The relevant protected characteristics are; age, sex, sexual orientation, gender reassignment, disability, pregnancy and maternity, race, and religion or belief.
- 1.4 The PSED does not necessarily require ministers to achieve these three goals, but to have due regard to these objectives and the desirability of promoting and achieving them when making decisions. In other words, these are three additional factors to be taken into account, along with all the other relevant factors, when making any decision.

## Intended outcome

- 1.5 This document considers equality issues in relation to the current HPV vaccination programme for girls and men who have sex with men (MSM) as well as potential HPV vaccination of adolescent boys. It is intended to support a ministerial decision on whether or not to extend the existing HPV vaccination programme so that it is 'gender neutral' for adolescents.

## Who will be affected?

1.6 A number of cohorts could be affected by the decision:

- a) adolescent boys - they are not currently eligible for HPV vaccination. Most receive indirect protection from the girls' programme. They would be offered direct protection if the programme was expanded to them;
- b) men who have sex with men (MSM) – from April 2018 an HPV vaccination programme started to roll out to MSM up to the age of 45 who attend sexual health clinics. If adolescent boys were vaccinated, MSM could potentially be protected from an earlier age and, in the longer term, a programme in sexual health clinics might no longer be needed;
- c) females – vaccination of boys would be expected to provide additional protection for girls over and above that provided from the existing girls' programme thus reducing even further their risk of developing cervical and other HPV-related cancers.

## 2. Background/Context

- 2.1 UK vaccination programmes are based on expert advice from the Joint Committee on Vaccination and Immunisation (JCVI). The JCVI bases its recommendations on a review of a wide range of scientific and other evidence, including from the published literature, and commissioned studies such as independent analyses of vaccine effectiveness and cost effectiveness. Cost-effectiveness is important because it is about how to fairly, consistently and robustly assess which interventions and treatments should be funded in a publicly funded health system.
- 2.2 Human papillomavirus (HPV) is the most common viral sexually-transmitted infection. Most sexually active women and men will be infected at some point in their lives and some may be repeatedly infected. Infection is most likely to occur in late teens and early twenties. Though most HPV infections clear spontaneously, in some people the infection can persist and this can cause abnormalities of the tissue infected which, if left undetected and untreated, can lead to cancer.
- 2.3 There are over 100 different types of HPV, thirteen of which are known to be linked with cervical cancer. Persistent infection by a high-risk HPV type is the most important causal factor for the development of cervical pre-cancerous and cancerous lesions. HPV is responsible for almost all cervical cancers, with two HPV types (16 and 18) responsible for about 80%<sup>i</sup> of all cervical cancers in the UK.
- 2.4 On the advice of the JCVI, an HPV vaccination programme for girls was introduced into the UK vaccination schedule in September 2008. The primary aim of the programme was prevention of cervical cancer. Around 3000 women are diagnosed with cervical cancer each year, with around 900 associated deaths.
- 2.5 At the time the original cost-effectiveness modelling was done for JCVI's consideration, it is understood that the available vaccines (a bivalent which protects against two HPV types [16 and 18] and a quadrivalent which protects against four HPV types [16, 18, 6 and 11]) were only licensed for use in females for prevention of cervical cancer and, in the case of the quadrivalent vaccine, genital warts also. There were vaccine trials in males underway and therefore the modellers considered the cost-effectiveness of potentially extending vaccination to males.
- 2.6 With respect to adolescent boys, the JCVI advised that vaccination was not cost-effective. This was mainly because high HPV vaccination coverage in girls would cause a decrease in the prevalence of infection thus generating herd protection and with high coverage in girls, vaccinating boys would provide little additional benefit to the prevention of cervical cancer, the aim of the programme. The JCVI

considered that there was insufficient evidence on the protective effects of the vaccine against non-cervical HPV related cancers (some of which could also affect males). They therefore noted that when more data became available, high-risk groups such as MSM would be considered. In addition, the Equality Impact Assessment<sup>ii</sup> issued by the then Department of Health in April 2008 noted that: 'Studies are now being carried out on the use of the vaccine to see if it is also safe in men to protect against genital warts and certain penile and anal cancers. The DH will consider the vaccine for boys and men if it becomes licensed and the intervention is cost effective.'

- 2.7 Since the JCVI's original advice in 2008<sup>iii</sup>, there has been increasing evidence that HPV vaccines can protect against other anogenital cancers (e.g. anus, penis, vagina and vulva) as well as oropharyngeal cancers (e.g. mouth and throat).
- 2.8 The JCVI keeps the eligibility criteria of all vaccination programmes under review and considers new evidence as it emerges. In view of increasing evidence on the association between HPV infection and other cancers and the impact of HPV vaccination on HPV infection the JCVI reviewed whether or not the HPV vaccination programme for girls should be extended to males. They considered vaccination for adolescent boys as well as MSM.
- 2.9 In November 2015, the JCVI advised that an HPV vaccination programme for MSM should be introduced for those attending sexual health clinics as they are at particularly high risk of HPV infection and may receive little indirect protection from the current HPV girls' vaccination programme. Following a successful pilot in 2016-17, national roll out of an HPV vaccination programme for MSM aged 45 and under attending such clinics in England began in April 2018.
- 2.10 In July 2017, the JCVI issued an interim statement on HPV vaccination for adolescent boys. It indicated that extending the current programme to boys would not be a cost-effective use of health service resources in the UK setting. It consulted on this advice and issued its final statement in July 2018. This advised that:
- a) there is evidence of benefit in vaccinating boys and a gender neutral programme would provide resilience against short-term fluctuations in uptake as well as offer the prospect of better control of the main cancer causing types of HPV;
  - b) gender-neutral vaccination would provide optimal protection in MSM in the long term;
  - c) under standard economic methodology extending the HPV vaccination programme to adolescent boys would not be a cost-effective use of health

service resources in the UK setting and increasing the attributable fraction of HPV for oropharyngeal cancer does not alter this;

- d) it could be argued that a 1.5% discount rate could be appropriate to better take into account the longer term impact of HPV vaccination in cancer prevention. It is likely that HPV vaccination for boys would be cost-effective using this approach;
- e) if considering a cost-effectiveness analysis where a combined girls' and boys' programme is compared to no HPV vaccination, gender-neutral adolescent HPV vaccination is highly likely to be cost-effective.

## 3. Evidence

3.1 The JCVI considered all relevant scientific evidence in developing their advice. Evidence for this equality analysis was considered from the following sources:

- a) [JCVI's statement on HPV vaccines to protect against cervical cancer](#) - 18 Jul 2008
- b) [Equality Impact Assessment Report Outline \(HPV Immunisation for Girls\)](#) - Dec 2007
- c) [JCVI statement on HPV vaccination of men who have sex with men](#) - Nov 2015
- d) [JCVI Interim Statement on Extending HPV Vaccination to Adolescent Boys](#) - Jul 2017
- e) Extracts from JCVI Minutes and JCVI HPV sub-committee minutes
- f) Responses to JCVI's July 2017 consultation on their interim advice
- g) [JCVI's final statement on HPV vaccination for boys](#) - Jul 2018
- h) Correspondence, meetings, parliamentary debates and information from websites of interested stakeholders

## 4. The protected characteristics

- 4.1 All UK vaccination programmes have eligibility criteria. These are based on expert advice from the JCVI and ensure that programmes are targeted, for example, at those most at risk or who could benefit the most from the vaccination in question. The JCVI bases its advice on eligibility on a wide range of evidence.
- 4.2 This section considers the current eligibility criteria for HPV vaccination (girls aged 12-13 and MSM under 45) and potential introduction of HPV vaccination for adolescent boys alongside each of the protected characteristics outlined in the PSED. These protected characteristics are: age, sex, sexual orientation, gender reassignment, pregnancy & maternity, disability, race and religion or belief.

### Age

#### HPV vaccination for girls and boys

- 4.3 When it was introduced in 2008, the JCVI recommended a universal HPV vaccination programme for girls aged 12 to 13 years with a two-year 'catch up' vaccination programme for girls aged 13 to 17 years. The programme in England is now focused on girls aged 12 to 13 years although girls remain eligible until the age of 18 if they miss vaccination for any reason. The age criterion takes into account three key facts:
- a) the HPV vaccines which are currently licenced are prophylactic (i.e. effective at preventing HPV infection);
  - b) that 'infection is most likely to occur in late teens and early twenties<sup>iv</sup>' – this indicates that the best time to vaccinate is before sexual debut.
  - c) that 'the vaccines produce higher antibody titres in individuals aged 10 to 14 years compared with those who are 15 to 24 years old<sup>v</sup>' – this means that the immune response to HPV vaccination is better in younger age groups and therefore greater protection is likely to be provided if the vaccine is given at a younger age.

There has been no recent evidence to suggest that the above position has changed.

- 4.4 It is arguable that the current policy has a negative impact in relation to elimination of discrimination as the programme is not extended to women over the age of 18.

Routine vaccination of girls aged 12 to 13 is likely to be before sexual debut and therefore before risk of contracting an HPV infection, it is also likely to produce greater immune response and therefore better protection than vaccination at an older age although girls remain eligible for vaccination up to 18. This age criterion was, and continues to be, justifiable. Also, the girls' vaccination programme provides indirect protection to boys and so seeks to advance equality of opportunity between girls and boys of a similar age. It is considered to have neutral impact on fostering good relations between girls and boys of a similar age.

- 4.5 If HPV vaccination was to be extended to boys, an age criterion would be used as for all national vaccination programmes. The JCVI's final statement does not include a suggested age criterion. It does note that HPV vaccine generates comparable immunogenicity to that seen in girls and that, as for girls, maximum benefit results from vaccination before sexual debut. Also, modelling work considered the same age eligibility as for girls. Introducing vaccination for boys aged 12-13 and having them remain eligible for vaccination up to 18 would reduce any perceived discrimination from the current programme and advance equality of opportunity within adolescents.
- 4.6 When the girls' HPV vaccination programme was introduced, there was a catch-up programme to vaccinate girls aged 13-17. As the HPV girls' programme has been in place for ten years and has and will continue to provide indirect protection to older boys alongside the MSM selective programme which will offer direct protection to older men at particularly high risk, a catch-up programme is not essential although it would provide the maximum advancement in terms of equality of opportunity. It is considered neutral in terms of fostering good relations.

## HPV vaccination for MSM

- 4.7 The JCVI noted in their statement of November 2015 that the majority of evidence on the sexual behaviours, incidence and risk of infection in MSM is limited to those MSM who attend genitourinary medicine (GUM) and HIV services. However they also noted that these are the most accessed sexual healthcare services by self-declaring MSM and that MSM accessing these services are known to be a high-risk group within the MSM population in terms of risk behaviour and sexually transmitted infection (STI) transmission.
- 4.8 JCVI's HPV sub-committee had advised in their meeting of June 2015 that a programme to vaccinate MSM aged up to 40 years old who attend GUM and HIV clinics was highly likely to be cost-effective, subject to procurement of the vaccine and delivery of the programme at a cost-effective price. It was also noted that sexual behaviour data becomes sparse for MSM after the age of 40 years and that it is difficult to extrapolate much beyond that age group. The sub-Committee was

of the view that sexual behaviour of MSM would not change significantly between the age of 40 and 45 but information beyond the age of 45 was more uncertain.

- 4.9 Based on the HPV sub-committee's advice, the JCVI advised an HPV vaccination programme for MSM attending sexual health services up to the age of 45 if it could be delivered at a cost-effective price. Following a successful pilot, the MSM programme is in the process of being rolled out across England.
- 4.10 Some stakeholders have expressed concern that 45 is an arbitrary age limit, noting for example that an older person could come out of a long term relationship and then have multiple partners. Although there is an upper age limit, clinicians are able to offer vaccinations outside of the national programme on a case by case basis based on clinical judgement. An MSM over the age of 45 attending sexual health services could therefore potentially receive HPV vaccination if a clinician deemed it clinically justified.
- 4.11 This age criterion was, and continues to be, justifiable. It is considered neutral in terms of eliminating discrimination, advancing equality of opportunity and fostering good relations for the reasons outlined in paragraph 4.10 above.

## Sex

- 4.12 This protected characteristic (alongside sexual orientation) is the most likely to be considered relevant when considering if there are equality issues in providing a girls-only adolescent HPV vaccination programme (supplemented by an MSM programme) when compared to providing HPV vaccination for both adolescent boys and girls.
- 4.13 As referred to earlier (see paragraph 2.4), the primary aim of the HPV vaccination programme for girls when it was introduced in 2008 was to protect against cervical cancer. As boys do not have a cervix they cannot develop cervical cancer. However, they did and continue to receive indirect protection from the programme. Reducing the circulation of HPV infection reduces the risk of boys becoming infected by HPV and therefore developing diseases attributed to HPV. Boys therefore receive some indirect protection from the HPV vaccination programme over and above its overall aim to prevent cervical cancer.
- 4.14 Since the girls' programme was introduced there has been increasing evidence that non-cervical HPV-related cancers can be protected against by HPV vaccination. Some of these are male specific cancers (e.g. penile cancer) and others are cancers seen in both men and women (e.g. anal and oropharyngeal cancers). Protection against non-cervical cancers is therefore a beneficial by-product of the existing programme established to protect against cervical cancer.

- 4.15 HPV is responsible for almost all cervical cancers. There is less certainty about the proportion of non-cervical HPV related cancers that are attributable to HPV and this is complicated by other risk factors, for example, alcohol and smoking which can cause head and neck cancers. However, even with this uncertainty the level of HPV-attributed non-cervical cancers is not insignificant. For example:
- a) estimates for HPV-related oropharyngeal cancers are between 31% (Conway and Anatharanan - unpublished) and around 60%.
  - b) around 77% of anal cancers are caused by HPV types 16, 18 and 33 (as modelled by Public Health England and based on International Agency for Research on Cancer review).
- 4.16 Proportionality is a consideration. For example, JCVI's interim statement in July 2017 stated that in England in 2014, there were 2,590 diagnoses of cervical cancer, and 726 deaths. Over 99% of cervical cancers are caused by HPV. In the same time period there were 2,380 new cases of oropharyngeal/oral cavity cancer and 479 deaths. In its July 2018 statement on HPV vaccination, JCVI considered estimates of the proportion of oropharyngeal/oral cavity cancers attributable to HPV range between 31% and 60%. Other cancers have fewer cases and/or a smaller proportion are likely to be caused by HPV; in 2014 there were 359 deaths from vulvar cancer (12.7% of cases attributed to HPV), 103 deaths from penile cancer (28.6% of cases attributed to HPV) and 281 deaths from anal cancer (77.0% of cases attributed to HPV). However, there is evidence that some cancers, particularly oral and anal cancer, are increasing and evidence of the proportion attributable to HPV is still emerging. Some stakeholders noted that anal and oral cancer are generally diagnosed late and thus have poor outcomes and the treatments can result in severe loss to quality of life so prevention would be particularly beneficial.
- 4.17 It will take a number of years before we will have direct evidence of the impact that the current HPV vaccination programme is having on HPV-related cancers and therefore the scale of indirect protection for boys against such cancers. Given the increasing evidence that a range of non-cervical cancers are preventable by HPV vaccines, it is reasonable to assume that the existing HPV vaccination programme will have some impact for males and females in terms of non-cervical HPV related cancers. One option would be to await evidence of the scale of indirect protection the girls' and MSM programmes offer to boys before considering whether or not to take action now to expand the programme further. The other is to expand the programme to boys now to increase the chances of similar levels of protection for both sexes. The addition of the MSM programme will have a positive impact in terms of advancing equality of opportunity in relation to levels of protection for males, albeit the direct protection would be largely limited to older MSM attending

sexual health services. However, the greatest advancement would be gained from vaccinating adolescent boys too.

- 4.18 In addition to protection against non-cervical HPV related cancers, HPV vaccination can provide protection against genital warts (depending on the vaccine being used). Prevention of genital warts is not the primary aim of the current HPV vaccination programme but an additional benefit resulting from the vaccine currently being used. This additional benefit is seen in both girls and boys. Girls aged 15-17 are receiving some direct protection as evidenced by a decline in the rate of first episode genital warts of 89% between 2009 and 2017<sup>vi</sup>. Boys are receiving indirect protection as evidenced by a reduction of the rate of first episode genital warts in young heterosexual males aged 15-17 years between 2009 and 2017 of 70%<sup>vii</sup>. This suggests substantial herd protection from the existing girls' HPV vaccination programme. However, the reduction in boys is slightly less than that seen in girls. As genital wart protection is not the aim of this programme but a welcome by-product and one that is dependent on the vaccine used for the programme (which is determined at each procurement round), it is not considered that the issue of genital wart protection in relation to this vaccination programme could be considered discriminatory. It is considered neutral in terms of promoting equality of opportunity and fostering good relations.
- 4.19 A programme that also vaccinates adolescent boys would provide all those vaccinated with direct protection against HPV infection, and associated disease including HPV related cancers and genital warts. As the JCVI noted in their final statement there are clear health benefits in vaccinating boys. For example, it:
- a) would potentially provide optimal protection for MSM by offering vaccination before the age of sexual debut; and,
  - b) would provide the greatest level of protection from HPV-related cancers not just for boys but for girls - it is predicted that by vaccinating boys as well as girls, additional cases of cervical and non-cervical cancer will be prevented in women and additional cases of non-cervical cancer will be prevented in males especially in MSM although the impact in terms of numbers of cases and proportion by each sex is dependent on a range of assumptions.
- 4.20 Without taking into account cost-effectiveness, an improvement to the health of the UK population from vaccinating boys over and above the benefits already seen and the future benefits predicted from the current girls' and MSM programmes is evident.
- 4.21 We have considered if maintaining the girls' programme in its current form (supplemented by a programme for MSM attending sexual health services) would amount to unlawful sex discrimination contrary to the Equality Act 2010 (the Act). It

is our view that it does not as an HPV vaccination programme could fall within the exception for single-sex services provided for at paragraph 27 of Schedule 3 to the Act.

- 4.22 A girls' only programme (supplemented by an MSM programme) could be considered a proportionate means to reduce cervical and other HPV-related cancers more generally. This would be considered proportionate for a range of reasons including the negligible additional health benefits of extending the vaccination programme to adolescent boys in the context of high coverage amongst adolescent girls and that much of the benefit from vaccinating adolescent boys would be the additional prevention of cervical cancer cases in women.
- 4.23 However, just because it is not unlawful to have a girls' only programme does not mean that vaccinating boys should not be considered. There are a range of equality-related arguments to consider particularly in view of the increasing evidence of association between HPV infection and non-cervical HPV related cancers and the additional benefits vaccinating boys would provide for the population. A number of issues have been considered including those raised by stakeholders both during the JCVI consultation on their interim statement and with DHSC directly. These are discussed below.
- a) The majority of health benefit from HPV vaccination is from vaccinating girls - this is primarily due to the substantial effects on reducing HPV related disease achieved by the high uptake of the girls' programme (through herd protection). The University of Warwick's analysis [as yet unpublished] determined that although there is some additional population health benefit to both males and females by extending the programme, the vast majority of benefits of vaccinating boys would be seen in unvaccinated girls and MSM. They noted that using the same number of vaccines to achieve 80% coverage in girls has a greater impact than vaccinating 40% of both boys and girls and greater overall benefit in sustaining and increasing the uptake in girls than in vaccinating boys<sup>viii</sup>. There is therefore a potential risk that extending HPV vaccination to boys could be detrimental overall if it diverts resource away from improving current vaccination uptake rates amongst girls especially in areas where uptake is lower than the wider population.
  - b) Direct protection for boys - HPV vaccination of boys would be expected to reduce the prevalence of HPV infection amongst the male population. This could reduce the rates of genital warts (subject to the HPV vaccine being used) to a lower level than a girls-only programme alone and also reduce the rates of some non-cervical HPV-related cancers. This would provide equality of opportunity to boys as they would be receiving direct benefit from the HPV vaccination programme rather than indirect benefit only.

- c) Greater protection for MSM – the MSM programme will most likely vaccinate most MSM after sexual debut and therefore after potential exposure to HPV infection. In addition, not all MSM will attend sexual health services although those at highest risk are expected to. The current girls' and MSM programmes will not provide the same level of protection to MSM as a gender neutral adolescent HPV vaccination alongside an MSM programme. Vaccinating all boys at an age that would generally be before potential exposure, regardless of their sexual orientation, would provide equal levels of protection to those adolescent boys who have sex with men or women in future. Vaccinating adolescent boys would therefore advance equality of opportunity. However, a gender neutral adolescent HPV programme would not provide protection to older individuals identifying as MSM, Provision of an MSM programme alongside a potential gender neutral programme until individuals who identify as MSM are already vaccinated through the adolescent programme when they begin attending sexual health services would maximise equality of opportunity.
- d) Advantage for girls of vaccinating boys - the main benefit of HPV vaccination for boys in terms of cancer is even greater protection against cervical cancer. Thus, by not introducing HPV vaccination for boys, the main disadvantage is for girls. One consideration is therefore whether it is acceptable to vaccinate boys mostly to provide more protection for girls. Given that boys will also receive some direct protection themselves over and above the level they receive indirectly from the girls' programme this would seem a reasonable situation. The campaign to extend HPV vaccination to boys is backed by a large number of charities and professional organisations which would indicate that such a move would be supported irrespective of whether the main beneficiaries would be males or females.
- e) Potential decline in coverage for girls' programme – the relative benefit of vaccinating boys would be much greater if the coverage in girls were considerably lower than at present (currently over 80%). The JCVI noted in their minutes of June 2017 that the sustained high uptake in the girls' programme together with the length of time it has been running provides considerable resilience to the programme in the event of any temporary fall in coverage. Uptake is currently high and stable and recent results from a PHE attitudinal survey give cause for optimism that this will continue. For example:
  - i) 97% of young people stated it was important to accept offered vaccinations; and
  - ii) 97% of parents thought it was important to be offered vaccination against cervical cancer.

However, some other countries have seen significant drops in uptake due to unfounded concerns about the safety of the HPV vaccine. Whilst there is no reason to believe our coverage would drop, it cannot be guaranteed that adverse publicity by anti-vaccine campaigners might not eventually damage confidence in the existing girls' programme. Extending HPV vaccination to boys would provide some resilience to the programme in the case of short-term fluctuations in uptake in girls. A substantial drop in the uptake of a girls' programme would increase the cost-effectiveness of vaccinating boys. This wider 'insurance' provided by offering HPV vaccination to both adolescent boys and girls is a legitimate consideration.

- f) Burden of vaccination - the health benefits of HPV vaccination inevitably come with some burdens, time taken to be vaccinated, a small risk of transient side effects (such as sore arms and fainting) and the responsibility for the overall health benefit. As adolescent girls currently receive the vast majority of HPV vaccinations, they hold the majority of the responsibility for protecting the population as a whole from HPV-related infections. This might not be considered equitable given that both men and women are susceptible to HPV infection, and could both be affected by the resulting diseases. A gender neutral adolescent HPV vaccination programme would effectively spread the responsibility for population health and any potential drawbacks of vaccination across both genders equally eliminating any perceived discrimination, advancing equality of opportunity and fostering good relations.
- g) Sex with unvaccinated girls – stakeholders have raised concerns that boys are not as well protected by the girls' programme as often contended. In particular, they note that boys could have sex with:
  - i) girls in the UK who were eligible for vaccination but have not been vaccinated – stakeholders note that 1 in 7 eligible girls are not vaccinated with some socio-economic areas worse affected and that in areas with high proportions of unprotected girls there is a higher risk for boys in those areas;
  - ii) older women who were/are not eligible for UK vaccination;
  - iii) women in countries with limited or no HPV vaccination programme.

These scenarios have been factored into the modelling that the JCVI has taken into account in terms of cost-effectiveness. JCVI have reviewed evidence that has shown that this is unlikely to impact on the conclusions regarding cost-effectiveness<sup>ix</sup>. In addition, the JCVI advised, as referred to above<sup>x</sup>, that there is greater overall benefit in sustaining and increasing the uptake in girls than introducing HPV vaccination for boys. However, the

greatest level of protection would be provided by a gender neutral adolescent HPV vaccination programme.

- h) Wider determinants of men's health – in general men have higher rates of premature mortality and lower life expectancy. More specifically, men are more likely to develop and die from cancer than females. Stakeholders have therefore raised concerns that a decision not to vaccinate boys would exacerbate poor health outcomes in males. It could be considered to have a negative impact on advancing equality of opportunity.
- i) Cost-effectiveness – although extending HPV vaccination to adolescent boys would provide the highest level of protection, it does not necessarily present the best use of NHS resources. For something to be 'cost-effective' it must not only deliver a health benefit itself, but deliver greater health benefits than would be realised if the money were spent elsewhere in the health system. The best way to protect the health of the population (men and women) is to put resources where they can do most good for all people/ patients. Basing spending decisions on robust cost-effectiveness analysis helps to do that. Using standard economic methodology, extending HPV vaccination to boys is not cost-effective and thus resources would have to move from funding something that would benefit more people than vaccinating boys. If a vaccination programme that is not cost-effective is implemented then overall it would be worse for the nation's health. This could potentially have a negative impact on people who share any protected characteristic as NHS resources will have been diverted to fund the HPV programme. The JCVI advise that more weight should be put on the benefits HPV vaccination can bring decades into the future by preventing cancers and indicate that if that is done HPV vaccination for boys could be considered cost-effective.

4.24 In summary, having HPV vaccination programmes for girls and MSM are not discriminatory to boys, however, vaccinating adolescent boys would reduce any perceived discrimination and advance of equality of opportunity providing boys with direct rather than indirect protection from the vaccination programme. The impact on fostering good relations would be broadly neutral.

## Sexual orientation

4.25 The current programme is available to all girls up to the age of 18 irrespective of their sexual orientation.

4.26 In November 2015, the JCVI advised that an HPV vaccination programme for MSM should be introduced for those attending sexual health clinics as they are at particularly high risk of HPV infection and receive less indirect protection from the

current HPV girls' vaccination programme. Following a successful PHE-led pilot in 2016-17, national roll out of an HPV vaccination programme for MSM aged 45 and under attending such clinics in England began in April 2018.

- 4.27 Stakeholders generally welcomed the addition of the MSM/HPV vaccination programme in England. It should bring benefits not only in terms of protection against genital warts (where MSM attending sexual health services are a particularly high risk group) but also a potential longer term impact on some HPV-related cancers such as anal cancer where there is an unequal burden in MSM.
- 4.28 Despite the general welcome, stakeholders also raised concerns that the HPV/MSM vaccination programme could amount to discrimination on the grounds of sexual orientation as the vaccine is not available to heterosexual males. Other concerns included that this programme did not provide satisfactory protection for MSM as they will generally have been sexually active for a number of years before attending a sexual health clinic and therefore already have been exposed to the HPV virus. Stakeholders argued that the best and easiest way to protect MSM is to vaccinate all boys before sexual debut. In the longer term this might mean that a dedicated HPV/MSM vaccination programme is no longer needed. It would also, ultimately, remove concerns that men at risk will not get vaccinated because of concerns about disclosing 'sexual status'. Stakeholders noted a general increase in 'sexual fluidity' where men declare themselves as heterosexual but will have sexual contact with men and thus could be at risk but not present to the HPV/MSM vaccination programme. They might of course receive some indirect protection from the MSM programme in this scenario if they were to engage in sexual contact with MSM who have been vaccinated.
- 4.29 A more general point that was raised by stakeholders was that the HPV/MSM vaccination programme requires a three dose course of vaccine (due to older age at vaccination) compared to a two dose course in boys which has logistical and financial benefit.
- 4.30 The JCVI noted in their final statement that:
- a) vaccinating boys would potentially provide optimal protection for MSM by offering vaccination before the age of sexual debut;
  - b) by vaccinating boys as well as girls, it is predicted that additional cases of non-cervical cancer will be prevented in males especially in MSM (although the impact in terms of numbers of cases and proportion by each sex is dependent on a range of assumptions).
- 4.31 In summary, having an HPV vaccination programmes for MSM attending sexual health clinics provides protection for those most at risk of HPV infection and

associated disease. However, vaccinating adolescent boys would eliminate discrimination and advance equality of opportunity as protection would be obtained irrespective of sexual orientation. The impact on fostering good relations would be broadly neutral.

## Gender reassignment

- 4.32 Under the current girls' programme, the vaccine is offered based on sex at birth. Individuals born as female would remain eligible until the age of 18 either through the schools programme or their GP. Transgender women are not systematically eligible for HPV vaccination as the aim of the programme is to prevent cervical cancer. However, for the school delivered programme, where possible transgender teenage girls should be offered the vaccine, as the programme aims to be inclusive and avoid stigma. In sexual health clinics, the eligibility of transgender women should be a case-by-case clinical decision based on a risk assessment that includes the woman's sexual behaviour and the sexual behaviour of her partners. Transgender women are eligible if their risk of acquiring HPV is considered equivalent to the risk of MSM eligible for the HPV vaccine. As with other men, transgender men are eligible if they have sex with other men, attend specialist sexual health or HIV services and are aged 45 and under. If they have previously completed a course of HPV vaccination as part of the girls' school year HPV vaccine programme, no further doses need be given.
- 4.33 Some stakeholders expressed concern that if the HPV vaccine was being given to transgender females then this was being done for social rather than medical reasons. They noted that the stated aim of the current programme is to prevent cervical cancer and as a transgender woman does not have a cervix then the provision of HPV vaccination is an inequality for boys between transgender groups.
- 4.34 Introduction of HPV vaccination for boys would have a positive impact on eliminating discrimination and advancing equality of opportunity as it would remove the need to distinguish between those of different gender identities as all adolescents would be offered HPV vaccine.

## Pregnancy and maternity

- 4.35 HPV vaccination is not advised during pregnancy. Following pregnancy, those under 18 would still be eligible if they had not already been vaccinated or completed their vaccination course.

- 4.36 People with this protected characteristic are not considered to be affected by a decision whether or not to introduce HPV vaccination for adolescent boys other than the fact that unvaccinated pregnant women might receive greater protection if their risk of being infected was reduced by the fact that the number of infected/unprotected males is reduced.

## Disability

- 4.37 The vaccine is offered to all those who meet the age and sex eligibility criteria (in relation to girls) and age and sexual orientation eligibility criteria (in relation to MSM) irrespective of disability. If a decision were made not to extend the programme to boys this would not change.
- 4.38 If the programme were to be extended to boys there would be no eligibility criteria to preclude those with a disability over and above any contraindications that might be in place for all sexes. Contraindications are medical reasons that mean the risk of a vaccine or medicine would outweigh any benefits.
- 4.39 We do not envisage any impact on people with this protected characteristic.

## Race

- 4.40 The current girls' HPV vaccination programme is offered to all eligible girls (in terms of age) irrespective of race.
- 4.41 There are some differences in HPV vaccination uptake rates amongst those in black and ethnic minorities, with some evidence of lower vaccination uptake among black and Asian women<sup>xi xii xiii</sup> and therefore ensuring high uptake of the HPV vaccination is important. Irrespective of the decision on HPV vaccination for adolescent boys, work needs to continue to identify and address reasons for lower uptake in some groups. This is an area where steps to advance the equality of opportunity would be beneficial.
- 4.42 If HPV vaccination were to be introduced for adolescent boys it would be offered to all eligible boys (in terms of age) irrespective of race. It is possible that such a programme could bring some benefits to black and minority groups where girls have lower uptake if boys from those same groups accept vaccination. However, overall, we would envisage only a negligible impact on this protected characteristic related to potentially culturally determined attitudes.

- 4.43 The HPV/MSM vaccination programme that is in the process of being rolled out in England is offered to all eligible men irrespective of race. It is too early to say whether there are differences in uptake rates on the basis of race.

## Religion or belief

- 4.44 The girls' and MSM HPV vaccination programmes are offered to all eligible people irrespective of religion or belief.
- 4.45 There is evidence from local commissioners of the HPV vaccination programme, that some faiths, for example the Orthodox Jewish community, are less supportive of HPV vaccination given its association with sexual health and it is likely that uptake is lower in those communities because immunisation providers are not allowed to go into those faith based schools to vaccinate girls. Girls who wish to take up the vaccine may still do so through alternative service provision, for example their GP, but it is unlikely that they would pursue this independently of their family. In terms of ingredients there is no impact in terms of religion or belief as the HPV vaccines available do not include any animal derived products in the final formulation, which may have potentially limited its use in certain faith communities<sup>xiv</sup>.
- 4.46 If HPV vaccination were to be introduced for adolescent boys it would be offered to all eligible boys (in terms of age) irrespective of religion or belief. We do not therefore envisage any impact on people with this protected characteristic. If there was an impact it would likely be negligible related to potentially culturally determined attitudes.

## 5. Wider considerations

### Carers

- 5.1 HPV vaccination is not offered specifically because someone is a carer and there would be no plans to change this if HPV vaccination for adolescent boys were to be introduced.

### Home schoolers or those who may miss days at school

- 5.2 The girls' HPV vaccination programme is primarily delivered in schools although GPs are contracted to provide HPV vaccination for those who were eligible and missed their school appointment. It would be expected that such a GP service would be negotiated so that it was provided for boys should the HPV vaccination programme be extended to boys.

### Migrants

- 5.3 Assuming migrants are school aged they would be eligible for the girls' programme if female and, if the programme were extended to adolescent boys, male migrants would also be eligible if the right age. A proportion of migrants are not registered with a GP and, as a result, this could impact on those that might miss HPV vaccination at school and need to 'catch-up' in primary care. There is work underway to understand better the barriers to accessing primary care that migrants can face more generally (i.e. not specific to vaccination).

### Different socio-economic groups

- 5.4 The HPV vaccine is available privately and there is anecdotal evidence of parents seeking private HPV vaccination for their sons as they are not eligible to receive it under the UK programme. The decision to pay privately for vaccines is a matter for individuals and there is no data available to Government from which to estimate the volume of private sales of HPV vaccine, whether it is for males or females, the age of the vaccine recipient or where in the country they live. Despite this lack of data, it is not unreasonable to assume that the cost of private vaccination (estimated to be in the region of £300 for a two dose course) would be prohibitive for many families and thus not providing HPV vaccination for boys could exacerbate inequalities.

## Marriage and civil partnership

- 5.5 The girls' and MSM programmes are offered to all eligible people irrespective of their marital/civil partnership status. If HPV vaccination for boys were to be introduced it would be offered to all eligible boys (in terms of age) irrespective of marriage/civil partnership status.

## 6. Engagement and involvement

- 6.1 The JCVI consulted on its interim statement about HPV vaccination for boys between 19 July and 31 August 2017. The JCVI received 38 responses and shared with DHSC those where issues of equality were raised. In addition, the Department has received a range of correspondence from parliamentary, professional and charitable stakeholders making points related to equality. Officials also held a meeting with HPV Action and some of its member organisations to hear their concerns and views to reinforce those that they had contributed in writing. This has been taken into account when developing this analysis.

## **7. Summary of analysis against the three arms of the PSED**

### **Eliminate discrimination, harassment and victimisation**

- 7.1 The HPV vaccination programme could be seen to be discriminatory on grounds of age, as the primary determinant of eligibility is the age of the person to be vaccinated. However, research supports vaccination before sexual debut and confirms that the greatest protection is gained by vaccinating between the ages of 10-14. The age criterion for the girls' programme is therefore based on clinical evidence and the programme is intended to have a positive effect beyond those who are vaccinated due to the indirect protection (herd protection) it provides. The MSM programme has an upper age limit of 45 but there is an element of clinical discretion if an MSM over this age is considered at high risk.
- 7.2 The HPV vaccination programme could also be seen to be discriminatory on grounds of sex. However, we do not consider that maintaining the girls' HPV vaccination programme would amount to unlawful sex discrimination contrary to the Equality Act 2010. It is our view that an HPV vaccination programme could fall within the exception for single-sex services provided for at paragraph 27 of Schedule 3 to the Act. In addition, the adolescent girls' programme supplemented by the new MSM programme is a proportionate means to protect the population (both males and females) from HPV-related cancers and, depending on the vaccine being used, genital warts. Extending vaccination to boys could however eliminate 'perceived' discrimination on the grounds of sex.

### **Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it**

- 7.3 There are clear health benefits to girls, boys and MSM from extending HPV vaccination to boys, over and above the benefits that can be delivered from the existing programmes. This includes a positive effect on the sexual health of the whole population, the greatest level of protection from HPV-related cancers and optimal protection for MSM (by offering vaccination before the age of sexual debut).

7.4 Although it is not discriminatory to have a girls' only HPV vaccination programme – there are equality considerations about extending this vaccination programme to boys that have been set out in this analysis. These indicate that introducing HPV vaccination for adolescent boys would be a means to advance equality of opportunity between people who share the following protected characteristics and those who do not:

(a) girls and boys (sex) – girls currently receive direct protection but boys only indirect protection;

(b) MSM and heterosexual men (sexual orientation) – MSM are starting to be offered direct protection but heterosexual men only receive indirect protection from the girls' programme.

7.5 The health budget is finite and it is important to consider the issue of cost-effectiveness. Using standard economic methodology extending the existing programme to adolescent boys is unlikely to be cost-effective. This means that the resources that would need to be used to deliver this expanded service would likely provide more benefits in other services. As a result, there is the possibility that by advancing equality of opportunities between sexes in relation to HPV-related disease greater inequalities could result elsewhere. Having said that, the JCVI have made a case that the standard methodology may not be appropriate for this particular programme. Unlike other vaccination programmes its primary aim is to prevent cancer. Cancers can develop many years in the future, and those which affect younger people can cause a loss of many years of life. JCVI put a case forward that an adjustment is reasonable to reflect that. If that is done the JCVI advise that extending the programme to boys is likely to be cost-effective.

7.6 Under HM Treasury rules, cost-effectiveness analysis is performed on an incremental basis. In this instance this means analysing the cost-effectiveness of adding boys to the existing HPV programme. Some stakeholders have suggested that it is more appropriate to compare the cost-effectiveness of a gender neutral HPV adolescent vaccination programme to no HPV vaccination programme. Under such an approach the JCVI note that HPV vaccination for adolescent boys programme would be highly likely to be cost-effective.

## **Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.**

7.7 The introduction of HPV vaccination for adolescent boys could contribute to the fostering of good relations between those who share a relevant protected

characteristic and those who do not i.e. sex and sexual orientation but the overall impact is thought to be broadly neutral.

## 8. Action planning for improvement

- 8.1 There is a case that greater benefits could be made for both girls and boys by improving HPV vaccine uptake across the country for the existing girls' programme. Whether or not a decision is taken to continue with the current programme (i.e. girls and MSM) or to introduce HPV vaccination for boys the following actions should continue to be taken to secure improvements:
- a) maintaining high uptake in those areas that already have it and improving uptake where it is lower. Public Health England and NHS England will continue to work together to identify reasons for lower uptake in some areas and to put actions in place to address and improve this. Although this will not improve equality of access to the vaccine between sexes it will increase the protection afforded to boys through herd protection;
  - b) deliver full national rollout of the MSM programme as quickly as possible to ensure those males who receive little indirect protection from the girls' programme are protected;
  - c) continue surveillance of HPV infections and HPV-related cancers and the impact of HPV vaccination on these;
  - d) ensure that public information leaflets, posters, information on NHS Choices, training materials for health care professionals etc are updated to address the risks of HPV infection for both sexes;
  - e) continue to encourage eligible women to take up invitations for cervical screening and to address variations in uptake between different groups and geographical areas;
  - f) improve access to cervical screening in sexual and reproductive health services - Public Health England is convening an expert group of stakeholders including NHS England, local authority Sexual and Reproductive Health commissioners and providers to explore this.
- 8.2 The above actions would help to mitigate any risk from not introducing HPV vaccination for boys and would contribute to a proportionate public health programme.
- 8.3 If a decision was made to introduce HPV vaccination for boys, then the actions at para 8.1 would still be needed. In addition, building on the systems and processes

already in place, we would need to plan carefully to ensure that there was sufficient lead time in order to:

- a) secure additional vaccine supply;
- b) update public information leaflets, posters, information on NHS Choices;
- c) update training materials for health care professionals;
- d) expand data collections to monitor uptake in boys and the impact of the overall programme on both HPV-related cancers and genital warts;
- e) increase the capacity of the school vaccination teams to allow for additional workload.

## 9. Conclusion

- 9.1 This Analysis has considered equality issues related to HPV vaccination and in particular the potential impact of a decision to extend (or not) the current programme for girls and MSM to adolescent boys. The impact of both a decision to maintain the current programme or extend it to boys is neutral or negligible on the majority of protected characteristics. The characteristic with the biggest potential to be impacted is sex and to a lesser extent sexual orientation.
- 9.2 The current HPV vaccination programme is not considered discriminatory and a girls' only programme supplemented by an MSM programme is a proportionate response to advance equality of opportunity. It protects females and males from HPV-related cancers and, depending on the vaccine being used, genital warts also. Additional protection could be provided for both sexes by improving uptake for the girls' programme across the country and this would arguably have a bigger impact on protecting against cervical cancer (the reason the programme was introduced) and other HPV-related cancers (where there is increasing evidence of a link to HPV infection) than extending the programme to boys.
- 9.3 Vaccinating boys would, however, provide the optimal response in terms of advancing equality of opportunity and, arguably, fostering good relations between persons who share a relevant protected characteristic (most notably sex and sexual orientation) and those who do not. It would provide the greatest level of health protection although the greatest additional health benefit is likely to be experienced by women and MSM rather than boys. It would, however, provide boys with direct rather than indirect protection and would reduce the overall responsibility of girls in protecting the population's health.
- 9.4 More generally, extending HPV vaccination to boys would reinforce England's commitment to a world class vaccination programme as well as to cancer prevention and improved sexual health. HPV vaccination of boys and girls would put England in the strongest position to eliminate some HPV types and potentially some HPV-related cancers in the long term. It should certainly help to reduce the overall burden of HPV-related cancers sooner than a girls-only programme supplemented with an MSM programme could do. A programme that could prevent more of, and potentially eliminate, cancers is worthy of serious consideration especially if it would also contribute to advancing equality of opportunity. The contribution such a programme could make to improving men's health in general is also a relevant factor. In addition, vaccinating boys would provide some resilience for the programme if there were short-term fluctuations in uptake (as has been seen in other countries). This would ensure that protection levels are maintained for all relevant groups.

- 9.5 However, it is not clear that vaccinating boys would be cost-effective. It is not considered so using standard economic methodology. Introducing HPV vaccination for adolescent boys if it was not considered cost-effective would likely mean that more people overall would be disadvantaged than advantaged by the change. This could potentially have a negative impact on advancing equality of opportunities more generally across the wider health service.
- 9.6 It is a finely balanced decision whether or not HPV vaccination for boys should be introduced on equality grounds and either decision could be rationally justified.

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