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Access to HPV vaccination for boys in the United Kingdom

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Abstract

Human papillomavirus (HPV) is a common sexually transmitted infection. There is a well-established link between HPV and the development of cervical cancer, but HPV infection is also associated with vaginal and vulvar cancer, head and neck cancers as well as anal cancers in both sexes and penile cancer in men. Despite this, since its introduction in 2008, the United Kingdom has included only girls in its vaccination programme and, in 2017, suggested that it was not cost effective to extend the vaccine to adolescent boys. Men-who-have-sex-with-men (MSM) have been offered the HPV vaccine in the United Kingdom since 2016. A number of countries (21 to date) have implemented a universal HPV vaccination programme, with many countries arguing that female-only vaccination programmes protect males via herd immunity and that MSM will be protected via targeted vaccination programmes, although these may be limited in their effectiveness. Following an advocacy campaign to extend the HPV vaccination programme to boys in the United Kingdom, in July 2018 the Joint Commission for Vaccination and Immunisation recommended that boys should be included alongside 12/13-year-old girls in a school-based programme. Given that this decision has been delayed by many years, it is imperative that the UK Government and Department of Health implement this vaccine programme as quickly as possible and by September 2019 at the latest, that a catch-up programme for boys is introduced and, given the feminisation of HPV, that information materials on HPV vaccination that are targeted at boys, their parents and teachers are made widely available.

Keywords

Human papillomavirus, vaccine, vaccination, men's health, cancer

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Human papillomavirus

Human papillomavirus (HPV) is one of the most common sexually transmitted infections (STIs), so predominant and so easily acquired that nearly all sexually active men and women will be exposed to the virus at some point in their lifetime. There are over 100 different types of HPV, and varying degrees of risk are associated with persistent infection with each type. Many HPV infections are clinically insignificant, but the International Agency for Research on Cancer (IARC) has classified 13 types of HPV (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68) as known carcinogens,[1] responsible for a sizable burden of disease. During 2013–2014, the prevalence of high-risk HPV was 22.7% among adults aged 18–59 in the United States (25.1% among men and 20.4% among women).[2] In women, cervical cancer has been linked to HPV, with only a small fraction of cervical cancers being HPV negative.[3] However, HPV has also been associated with cancers that affect both men and women, specifically

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oropharyngeal cancer (OPC) and anal cancer. The incidence of oropharyngeal squamous cell carcinoma is rising globally.[4,5] In Scotland, the fastest growing cancer is OPC, especially among men.[6] In the United States, the rate of HPV-related OPCs per year will soon surpass the annual number of cervical cancer cases.[7] In addition, men are twice as likely to develop HPV-OPC as women;[8] in Canada, in 2012 the incidence rate of HPV-OPC was more than 4.5 times higher in males than in females.[9] Similar to OPC, anal cancer incidence has increased rapidly in recent years in both sexes.[10] Since the early 1990s, anal cancer incidence rates have increased by 56% in the United Kingdom, with rates projected to rise by a further 43% by 2035.[11] Men who have sex with men (MSM) are disproportionately more likely to develop anal cancer (15:1 compared with heterosexual men).[12] HPV infection in men may also increase the risk of acquiring HIV infection[13] as it may increase the penetrability of the genital lining to HIV infection.[14] Consequently, anal cancer incidence rates are significantly higher in HIV-positive men than in HIV-negative men (70–100 versus 35 per 100,000 person years).[15] Globally, 570,000 cases per year in women and 60,000 cases in men are attributable to HPV, that is, 8.6% of all cancers in women and 0.8% of all cancers in men.[16] In Europe specifically, HPV is implicated in ~23,250 cases of cervical cancer each year, plus vaginal and vulvar cancer (3850 cases), head and neck cancers (15,230 cases) as well as anal cancers (4630 cases) in both sexes and penile cancer (1090 cases) in men.[17] In addition to cancer, infection with low-risk HPV strains (i.e. 6/11) is implicated in the development of genital warts (GW)[18] which cause a significant burden in both men and women, with a prevalence of approximately 160–289 per 100,000 and a peak in males between the ages of 25–29 years.[19] HPV infection can also be transmitted to a foetus by a pregnant mother, which could lead to recurrent respiratory papillomatosis (RRP).[12] There is a low prevalence of RRP (1–4 per 100,000), but it carries a high health and economic burden, given the many medical procedures required to treat each patient.[20]

Successful HPV vaccination in females in combination with adequate screening programmes has resulted in the reduction and prevention of cervical cancer in many countries; in the United Kingdom, Public Health England data recently highlighted how the national vaccination programme had significantly reduced HPV prevalence in young women, providing encouragement for future reduction in cervical cancer mortality;[21] disappointingly, less progress has been made for HPV-related cancers affecting both sexes.

HPV vaccination

Three HPV vaccines are licensed for use: a bivalent vaccine which protects against the two high-risk HPV types (HPV16/18), a quadrivalent vaccine protecting against HPV 16/18, GW and RRP (by eliminating the maternal reservoir for HPV) (twHPV6/11), and a nonavalent vaccine that protects against nine of the most common virus types (HPV6/11/16/18/31/33/45/52/58). As the vaccine was initially approved for cervical cancer prevention in females, there are fewer studies of the vaccine's preventive effect in males.[22] However, the HPV vaccine has shown a good safety profile and efficacy in younger (aged 9–15)[23–25] and older males (aged 16–26).[26] Furthermore, immunogenicity of the nonavalent vaccine in males was shown to be similar to that in same-age females.[27] Pinto et al.[28] demonstrated that HPV antibodies in the oral cavity in males can be generated through vaccination. However, it will take many years before research will be able to ascertain the effectiveness of HPV vaccination on male cancer outcomes.

Since April 2009, the World Health Organization (WHO) has recommended that HPV vaccination for females be included in national immunisation programmes.[29] To date, HPV vaccination has been introduced in approximately one third of the countries worldwide.[30,31]

There is evidence that female-only vaccination programmes have resulted in a reduction in the number of males with GW.[32,33] The additional benefit of extending the vaccine to males appears to be reliant on vaccine uptake in females: the lower the vaccine coverage in girls, the easier it is to demonstrate the benefit of vaccinating boys. A high coverage in females may promote herd protection; however, even if herd protection is achieved, men who have sex with women are not protected as soon as they move outside of the 'herd'. Men will live and work in other countries where females are not vaccinated, or where female vaccination rates are low, and as a result will likely become infected with HPV. It is important to highlight that even with an 83% female uptake (the current rate in the United Kingdom), 17% of females are unprotected from HPV. There is increasing evidence to suggest that unvaccinated women demonstrate more risky sexual behaviour, for example, multiple sexual partners, anal intercourse and a smoking history.[34] These unvaccinated females have the highest attributable risk for HPV-related cancers and are at a higher risk of STIs and thus cervical and pre-cervical cancer. However, even though girls in the United Kingdom/Ireland may receive the vaccine through a publicly funded HPV vaccination programme, current levels may be inadequate to confer herd immunity. The most recent figures indicate that uptake in the Republic of Ireland (ROI) dropped to 51% in 2016/2017[35] and it would appear that Northern Ireland (NI) vaccine rates may also be decreasing (from 88.1% to 74.6%, 2017 figures).[36] This drop in uptake (particularly in the ROI) has been linked to a vocal anti-vaccine campaign on the island of Ireland.[35] However, in 2017, the Irish National Immunisation office and the HPV Vaccination Alliance (a group of 35 organisations in the

ROI) launched a media campaign of support for HPV vaccination, along with unvaccinated girls being offered another opportunity to be vaccinated; this has reversed the downward trend in Ireland, with an estimated coverage in 2017/2018 at 61.7%.[35]

Causes of opposition to the HPV vaccine

Opposition to the HPV vaccine has not just been seen in ROI. While the benefits of HPV vaccination are difficult to overstate, there has been significant opposition and misinformation surrounding the intervention. An attempt to make the vaccine mandatory for young women in the United States resulted in political controversy, and ultimately the measure was not adopted. The US opposition displayed clear political polarisation, with parental rights frequently invoked.[37] Concerns that vaccination would elevate sexual activity in teenagers were frequently voiced,[38] with opponents of vaccination arguing for abstinence-based approaches rather than vaccination.[39–41] However, these concerns appear misguided, as evidence to date suggests that vaccinated cohorts exhibit no increase in sexual activity, relative to their unvaccinated peers.[42,43] Further evidence indicates that abstinence approaches are themselves ineffective, with teens subjected to such education commencing sexual activity at the same stage as their peers,[44,45] but being less likely to use contraception or condoms.[46]

Outside of the United States, safety concerns rather than the moral ones have proved a far greater barrier to implementation of HPV vaccination programmes. While the vaccine has a very favourable safety profile, the misconception that it has deleterious effects has taken root in several jurisdictions. Much of this has been disseminated through non-traditional media platforms, particularly online – analysis of HPV vaccine videos on YouTube found the majority to be negative in tone, casting doubt on safety and alleging pharmaceutical conspiracy.[47] The same study also indicated that negative videos regarding the vaccine were more widely favoured than positive coverage. Countering misinformation associated with vaccination has become increasingly challenging.[48] The Internet has become an especially potent vector for anti-vaccine views; anti-vaccine activists have been remarkably successful in exploiting it for rapid propagation of unsubstantiated information regarding the vaccine and its safety profile.[49–53]

The bulk of anti-HPV vaccination messaging pivots around profoundly conspiratorial beliefs, namely, the assertion that the vaccine is damaging and that negative effects on health are being ignored. This follows standard anti-vaccine messaging, where conspiratorial thinking is endemic. Those advocating scientific or medical consensus are deemed agents of some odious grouping committed to concealing the truth.[54] The psychological mechanisms behind such adamant belief in conspiracy theories are multi-faceted,[55] but they can certainly function as a defence mechanism to protect beliefs incompatible with evidence. Anti-vaccine sentiment tends to demonstrate numerous reasoning flaws, particularly reliance on anecdote over data.[56] Conspiratorial narratives around vaccines spread quickly and have detrimental effects on public intention to vaccinate.[57]

Unsubstantiated claims of harm appearing in media and from local political figures are especially potent in driving vaccine opposition; in Japan, HPV vaccination recommendations were suspended after claims of adverse reactions appeared in local media in 2013. Despite an investigation from the Vaccine Adverse Reactions Review Committee concluding that there was no link with vaccination, recommendations were not reinstated and a considerable vaccine gap has grown.[58] The coverage of adverse effects themselves had a strong impact on public perception, despite the finding that the vaccine had nothing to do with the reported symptoms.[59] Despite no evidence to support claims of harm, anti-vaccine groups pushed the mantra that the HPV vaccine was damaging young women. These claims received wide media coverage, pushing vaccination rates down from 70% in 2013 to less than 1% by 2017.[60]

Similar claims of the vaccine negatively impacting on health have arisen in Europe, most notably in Denmark and in ROI as described earlier. While lacking in any substance, claims of harm were widely covered in Danish media since 2014, after intensive lobbying by anti-vaccine groups, including a show on TV2, a Danish TV channel, which insinuated that the vaccine was damaging young women. Ensuing public concerns resulted in a precipitous drop in vaccine uptake, falling from 79% to 17% within 3 years.[61]

Previous studies have suggested that it can be incredibly difficult to sway vaccine-sceptical parents, despite the scientific evidence.[62] However, combatting uncritical spreading of anti-HPV activist claims is of paramount importance. In the face of emotive anecdotes (even unsubstantiated ones), repetition of facts and statistics alone is not always a useful approach. Some authors suggest that in such cases reframing the benefits of vaccination in an emotionally engaging way might be a more effective strategy to counter vaccine hesitancy and stave off the influence of anti-vaccine misinformation. Approaches such as story-telling techniques to demonstrate how vaccination saves lives may be effective.[63]

Crucially, most vaccine hesitancy is based on citizen fears in the wake of anti-vaccine sentiment and can be overcome by addressing their concerns.[64] Strong recommendations by physicians also have a marked impact on vaccination rates.[65] Addressing mistruths and concerns is of paramount importance in keeping female uptake high. Such interventions will become even more vital as universal vaccination becomes the standard, and pre-empting misinformation is an important step as vaccination is rolled out to males.

Table 1. The United Kingdom HPV advocacy campaign.

- In the first 6 months of 2018, the Mail on Sunday published a series of articles making the case for vaccination for boys and was the first publication to break the story that the JCVI had changed its position and was recommending to ministers that universal vaccination should be introduced in the United Kingdom.
- Politicians from all parties were supportive of the campaign which successfully achieved backing from parliamentarians in both Houses for debates, early day motions and parliamentary questions.
- The chair of the All Party Parliamentary Group (APPG) on Cancer, the Conservative MP John Baron, was among those supporting a change in policy, as were the APPG chair on dentistry and the chair of the APPG on men's health.

HPV: human papillomavirus; JCVI: Joint Commission for Vaccination and Immunisation.

Universal HPV vaccination

Despite the impact of HPV on both sexes, few countries have implemented a vaccination programme for both adolescent boys and girls. To date, to our knowledge, 21 countries currently vaccinate boys or plan to do so. These include Argentina, Australia, Austria, Bahamas, Bermuda, Brazil, Canada, Croatia, Czech Republic, Germany, Israel, Italy, Liechtenstein, New Zealand, Norway, Panama, Serbia, Switzerland, Turkmenistan and the United States.

Australia was the first country to initiate government-funded universal HPV vaccination and began including boys in a national school-based HPV vaccination programme in February 2013.[66] The United States also recommends universal vaccination, with the Vaccines for Children (VFC) Programme funding HPV vaccination for children aged 9–18 years who are uninsured or underinsured.[67] From 2013 to 2018, Canadian provinces and territories extended their programmes to all males, and hence all HPV vaccination programmes are now gender neutral.[68,69] Austria was the first European country to commence a publicly funded universal programme in 2014.[70]

HPV vaccination in the United Kingdom

Since its introduction in 2008, the United Kingdom included only girls in its vaccination programme; in 2015, in response to calls to extend the vaccine programme to adolescent males, the Joint Commission for Vaccination and Immunisation (JCVI) recommended the HPV vaccine for MSM.[71] The justification for this was that MSM do not benefit from a female-only vaccination programme and are at higher risk of HPV infection.[72–74] The JCVI recommendation is targeted at MSM up to age 45 years who are already attending genitourinary medicine (GUM) and/or HIV clinics.[71] There can however be no certainty that this method will ensure enough of the MSM population will be reached – or reached at the optimal time – to assure herd immunity in this group. A targeted MSM HPV vaccination programme may be difficult to implement and may also have limited efficacy in preventing HPV-related disease, as the HPV vaccine is thought to be the most effective when given at a younger age (9–15 years), before exposure to HPV through sexual contact and when immunogenicity is at its highest.[75] In a study of young MSM (age range 16–24), the majority were sexually active, with an average of six partners over the past 12 months (range 1–25 partners), but participants had never discussed or been recommended the HPV vaccine by a healthcare professional; thus, the vast majority were unvaccinated, despite being sexually active with a wide range of sexual partners.[76] MSM are therefore likely to have delayed in their presentation to a healthcare provider (HCP; average age of the first visit in the United Kingdom is 32 years) and to have had multiple sexual partners with an increased risk of HPV acquisition before they attend a sexual health clinic.[76–79] There is evidence that once they do attend a GUM clinic, the majority of MSM will re-attend within 24 months, which could facilitate the delivery of the HPV vaccine programme.[77] However, there are also MSM who do not identify as gay or homosexual and will not disclose their sexual activity to an HCP, meaning that they will never be offered the vaccination.

In the United Kingdom, there has been a sustained advocacy campaign to extend the national HPV vaccination programme to include boys. This has been led by a collaborative partnership of (currently) 51 professional and patient organisations (HPV Action). These include organisations/individuals with an interest in cancer, sexual health, men's health, gay men's health, public health and oral health. The campaign commenced in 2014, soon after the JCVI began its assessment of vaccination for boys, and has focused on influencing scientific and medical opinion through journal articles and conference presentations, lobbying politicians and making the case for vaccinating boys directly to the officials supporting and advising the JCVI (see Table 1 for more details).

A sustained campaign of promotion/lobbying for universal HPV vaccination has also been conducted through the Northern Ireland Assembly (and in particular through its Health Committee and associated groups – see Table 2 for more details).

The Throat Cancer Foundation initiated legal proceedings in 2018 against the JCVI and the Department of Health and Social Care (DHSC), on the grounds that not vaccinating boys constituted sex discrimination under the terms of the Equality Act 2010. It also argued that the JCVI should have considered the equality issues as part of its assessment of the vaccination of boys, rather than asking the DHSC to conduct the equality analysis after it had

Table 2. Promotion of universal HPV vaccination in Northern Ireland.

- We (G.P. and M.L.) have spoken at the NI All Party Groups (on both Sexual Health and Cancer), while an All Party Round Table event was hosted at Parliament Buildings by the then Chair of the Health Committee on the importance of extending the current HPV vaccination programme in NI to adolescent boys.
- Meetings were conducted with both the NI Health Minister (Michelle O'Neill NLA) and ROI (Leo Varadkar TD) Health Minister to discuss the topic.
- May 2017: the topic was presented at the NI Assembly Knowledge Exchange Seminar Series.
- May 2018: contributed to the Westminster debate on extending the HPV vaccination to boys in the United Kingdom.

HPV: human papillomavirus; NI: Northern Ireland; ROI: Republic of Ireland.

made its recommendation to ministers. At the time of writing, the outcome of these proceedings is not known.

Cost effectiveness of universal HPV vaccination

The cost of a universal HPV vaccination programme continually features as one of the major arguments against implementation of HPV vaccination for both males and females, and it must be noted that a number of studies have concluded that vaccination of both males and females is not cost effective.[80] Indeed, initial economic evaluation of the HPV vaccination programme in the United Kingdom in 2008 concluded that the addition of males would not be cost effective,[81] while in 2017 the JCVI concluded that extending the vaccine to adolescent boys in the United Kingdom was unlikely to be cost effective. However, there has been mounting evidence that universal vaccination can be cost effective,[82] particularly when the costs associated with OPC[83] and GW treatment[84] are considered, and the vaccination dose schedules are changed from three to two doses, while preserving efficacy.[85] It has been proposed that considerations on the cost of universal HPV vaccination should be expanded to encompass the broader economic consequences and benefits to society. When universal vaccination is approached from the perspective of a lifetime cost–benefit analysis, wider economic benefits are demonstrated such as increased productivity, increased earnings and enhanced tax revenue.[86]

In the United Kingdom, the additional cost of vaccinating the UK boys would be £20–22 million a year at most, less than 0.02% of the National Health Service (NHS) annual budget (www.hpvaction.org). Comparing this figure to the cost of treating GW, an estimated £58.44 million a year in the United Kingdom, and the secondary care costs for HPV-related OPC (>£21 million a year) and anal cancer (£7 million per year) highlights the potential economic benefits that can ensue and complement the health-preserving impact of a universal vaccination strategy.

It has been argued that a decision on whether or not to vaccinate boys should not solely be made on the basis of cost, but the psychosocial impacts of HPV-related disease must also be considered when calculating the benefit of male HPV vaccination. It has been reported that HPV-related cancers and GW significantly impair psychosocial wellbeing and health-related quality of life.[87] Patients with OPC experience profound visible, functional and psychological consequences from their disease and its treatment.[88] Withholding a vaccine from any group of individuals at risk of developing a vaccine-preventable disease is unethical. It is also unfair for females alone to be expected to carry the responsibility for HPV prevention through vaccination, particularly when HPV is a virus that is sexually transmitted and affects both sexes so prolifically. The burden of HPV-related diseases is now almost the same in men as in women. Unlike cervical cancer, there are no reliable and cost-effective screening methods to prevent cancers caused by HPV among men. Thus, a gender-neutral vaccination programme would achieve real herd immunity; without male vaccination, men who move outside of the herd, and especially MSM, remain at risk of HPV infection and life-threatening and life-altering HPV-related diseases.

Progress within the United Kingdom for universal vaccination

In July 2018, following a sustained advocacy campaign and in the light of the most robust evidence, the JCVI changed its position and recommended that boys should be included in the UK vaccination programme alongside 12/13-year-old girls in a school-based programme. This resulted from the JCVI adopting a different modelling approach that 'better takes in to account the longer term impact of HPV vaccination in cancer prevention and the life years lost to cancer'.[89] JCVI also suggested that including males in the programme would increase resilience in the population should vaccine rates drop, and recognised the need for optimal protection for MSM, and the inequality that failing to vaccinate boys introduced.[89]

Encouragingly, the English, Scottish and Welsh governments have announced that they will include boys in their vaccination programmes; NI has yet to comment on any specific plans for universal vaccination; a positive response is essential to avoid geographical disparities. There is now a need for a catch-up programme for adolescent boys across the United Kingdom (similar to that which was conducted for girls in 2008) to maximise protection from HPV disease in both males and females. Also due to the 'feminisation of HPV' as a result of a female-only vaccination programme, there is the need to educate the public on the importance of male HPV

Table 3. Road map for the implementation of universal HPV vaccination in the United Kingdom.

- Following on from Scotland, Wales and England, an immediate announcement by the Department of Health and Social Care Northern Ireland that 12/13-year-old boys will be included in the HPV vaccination programme.
- The timely publication of an implementation plan for a national rollout throughout the United Kingdom at the earliest possible opportunity (September 2019 at the latest).
- A catch-up programme for boys which parallels the vaccination programme available for girls. This would mean that any boy up to age 18 years can be vaccinated against HPV.
- The production of information materials on HPV vaccination that are targeted at boys, their parents and teachers.
- A national campaign aimed to maximise HPV vaccine uptake in both sexes with the aim of eliminating current variations in uptake between local authority areas.
- An early agreement on the procurement issues between the Department of Health and Social Care in each jurisdiction and the vaccine manufacturers.

HPV: human papillomavirus.

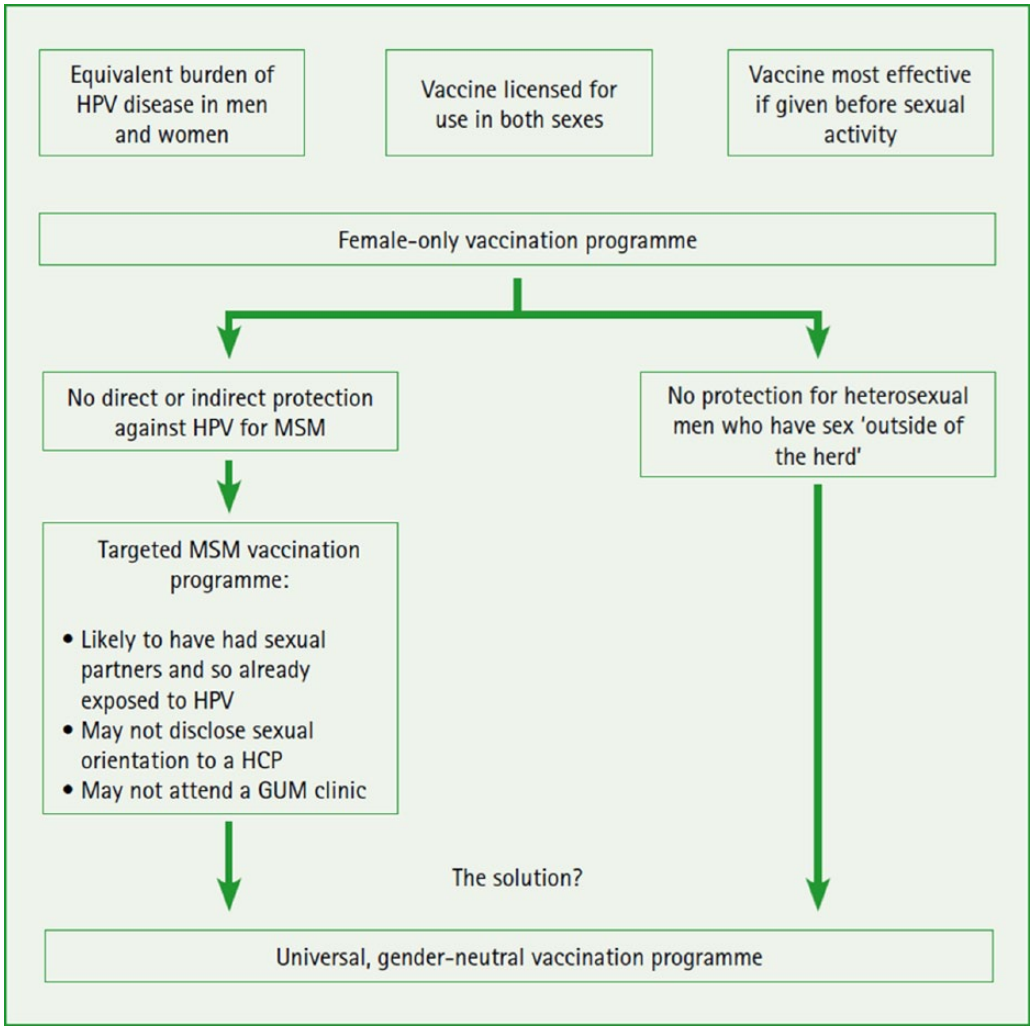


Figure 1. Rationale for universal HPV vaccination.

vaccination. In Table 3, we indicate a roadmap for the implementation of universal vaccination in the United Kingdom, following JCVI's landmark decision. Given the success of advocacy and lobbying in the United Kingdom, we also recommend a similar effort at a European level, in order to promote universal vaccination across Europe.

Summary and recommendations

- HPV vaccination is a highly successful cancer prevention strategy and has reduced the incidence of cervical cancer in women (see Figure 1).
- A significant proportion of the young women not being vaccinated are 'hard to reach', at risk of

making other 'poor life decisions' and at higher risk of STIs.

- Recent examples of a significant drop in female vaccination rates (in Ireland, Denmark and Japan as well as in particular regions in the United Kingdom) are of great concern, as they may lead to an increase in deaths from cervical cancer and a reduction in herd protection.
- Considering gender-neutral HPV-related cancers such as oropharyngeal and anal cancers, in addition to GW, it is now evident that there is an equivalent burden of HPV-related disease in men as in women.
- HPV-related OPC that affects both males and females is now among the most rapidly rising cancers in Europe.
- OPC will soon be more common than cervical cancer in the United States.
- The HPV vaccine is the most effective before sexual activity and offering it to 12/13-year-olds provides the best opportunity for maximum efficacy.
- To optimise the vaccine effectiveness in MSM, it should be offered to young MSM prior to sexual debut. Young MSM currently have low awareness of the vaccine.
- Vaccinating boys as well as girls is the only way to achieve comprehensive herd immunity.
- From an ethical perspective, to 'not fund' a vaccine for any group of individuals at risk of developing a vaccine-preventable disease is questionable; thus, including boys in vaccination campaigns is important to ensure equity in protection from HPV-related diseases.
- The landmark JCVI decision on universal vaccination must be rapidly implemented across the United Kingdom.

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