RESPONSE TO JCVI CONSULTATION ON INTERIM STATEMENT ON EXTENDING HPV VACCINATION TO ADOLESCENT BOYS

Introduction

HPV Action (HPVA) welcomes this opportunity to respond to JCVI's consultation on its interim statement on extending HPV vaccination to adolescent boys.

HPVA is a partnership of 48 patient and professional organisations that advocates HPV vaccination for both boys and girls. Its members, which are listed at the end of this submission, come from a wide range of backgrounds including public health, cancer prevention, sexual health, men's health, gay men's health and oral health.

HPVA believes that the JCVI's interim statement has not reached the correct conclusion and therefore urges the Committee to reconsider its position before making a final decision. In our view, and in the view of many other organisations (including the BMA, Jo's Cervical Cancer Trust and Cancer Research UK) as well as individual clinicians and other experts in this field, the evidence points to a clear case for extending HPV vaccination to adolescent boys.

The modelling work

HPVA is concerned that the JCVI has not placed in the public domain the details of the modelling work undertaken by Public Health England (PHE) and Warwick University. We understand that this is because the modellers wish to submit their work for academic publication, an inevitably lengthy process. We believe that there must be full disclosure at this stage to enable stakeholders to understand, comment on and, if appropriate, critique the assumptions on which the JCVI's interim decision has been based. A public consultation in which the detailed modelling is withheld does not allow for proper scrutiny. It is also noteworthy that, as far as we can ascertain, the modelling work undertaken by PHE has not been peer reviewed and is therefore as yet unvalidated.

We therefore urge JCVI to reconsider this matter and to restore credibility to the consultation process by publishing full details of the modelling and allowing additional time for stakeholders to review and comment on it. We refer the

JCVI to the government's Consultation Principles 2016 which state that public consultations should 'facilitate scrutiny' and 'include validated assessments of costs and benefits.' A failure by a public body to follow a fair consultation process can leave it vulnerable to judicial review. The JCVI may also have a duty to disclose full details of the modelling under the terms of the Freedom of Information Act.

One further issue of particular concern to us is that JCVI may not have made a realistic assessment of the economic cost of the diseases caused by HPV and of the potential savings that would be achieved by vaccinating boys as well as girls. The JCVI should publish details of the various costs it has taken into account and the source of this information. The dates to which the costings apply is particularly relevant. We are also concerned that, because of the limited range of costs it normally considers in its cost-benefit analyses, JCVI will not have included the costs of welfare benefits, the costs to employers and the costs to individuals and their families. If the full economic cost of the impact of HPV-related diseases on males was taken into account, this would almost certainly make a significant difference to the modelling.

We note that JCVI does not appear to have assessed the option of vaccinating only boys. HPVA would not support this approach but, if the JCVI considers that a single-sex programme can provide adequate herd protection, boys-only vaccination should certainly have been considered. (This option has been mooted by Nobel Laureate Professor Harald zur Hausen.[1]) A male-only programme would potentially have a greater impact on HPV infection rates than a female-only programme because men generally have more sexual partners than women and because of the higher levels of infection in MSM in particular. It is also relevant that men have a poorer immune response to HPV infection than women, with HPV infection rates appearing to stay constant in men, independent of age, as opposed to women, among whom HPV prevalence is highest during 18–24 years of age and then decreases until middle age. We therefore recommend that the JCVI considers the option of a boys-only programme and, if it is rejected, provides a clear rationale for this decision just as there should be for a decision to reject gender-neutral vaccination.

Epidemiology

The JCVI's epidemiological data on cancer described in the interim statement appears to use very low estimates of the proportion of cases caused by high-risk HPV types. For example, JCVI suggests that 12.8% of oropharyngeal cancer cases in males are caused by high-risk HPV types. By contrast, the CDC puts the figure at 63% for males from HPV types 16 and 18 alone.[2] A UK-specific study of oropharyngeal cancer found that, between 2002 and 2011, the overall proportion of such cancers that were HPV-positive was 52% (and

[1] https://www.sgo.org/newsroom/news-releases/nobel-laureate-makes-strong-case-for-vaccinating-young-males-against-hpv-to-prevent-cervical-cancer-in-females/
[2] https://www.cdc.gov/cancer/hpv/statistics/cases.htm

98% of these cases were linked to 16/18 specifically).[3] The CDC figure for penile cancer is 48% (16/18) while the JCVI figure is 28.6%. We recommend that the JCVI reviews this aspect of its epidemiological analysis.

JCVI does not appear to have taken into account HPV-related cancers of the nasal and paranasal sinuses. According to Cancer Research UK, over 20% of such cancers are linked to HPV, especially type 16.[4] We recommend that these cancers are included in the modelling.

The JCVI has explicitly ignored predictive data on oropharyngeal cancer incidence even though this shows that HPV-related cases of this cancer are highly likely to increase significantly. We strongly recommend that predictive data for all HPV-related cancers is considered before a final decision is made.

We were surprised and concerned to note that the interim statement does not appear to have taken into account the incidence of recurrent respiratory papillomatosis (RRP). This may be a relatively rare condition but it affects males and females in roughly equal numbers, is very distressing to those affected and both difficult and costly to treat. We recommend that this omission should now be rectified.

Sexual behaviour

The JCVI's modelling does not include sexual contact between UK men and women from abroad because it would have added to the timeline for completion. JCVI has assumed that the impact of this contact would be small but has provided no robust evidence for this. We recommend that this issue should therefore be revisited. We wish to add that JCVI's concern that this additional modelling work would add to the timeline is somewhat ironic given that it has already taken JCVI some four years to review its policy on vaccinating boys.

The most recent sexual behavior data used in the modelling is from 2010-2012 (NATSAL-3). This may be the most recent robust data available but there is a strong possibility that behaviours will have changed enough to introduce a significant margin of error into the modelling. It is noteworthy that the reporting of anal sex with a partner of the opposite sex increased in men and women between NATSAL-1 and NATSAL-2 and then again between NATSAL-2 and NATSAL-3, a finding which suggests that heterosexual repertoires have expanded in successive birth cohorts and over time.[5] It is entirely possible that dating apps have had a significant impact on sexual behavior since NATSAL-3 (Tinder was launched in 2012, for example). One study found a robust association between using dating apps and having unprotected sex with a casual sex partner, implying that using dating apps is an emerging sexual risk

[3] http://cancerres.aacrjournals.org/content/early/2016/11/03/0008-5472.CAN-16-0633
[4] http://www.cancerresearchuk.org/about-cancer/nasal-sinus-cancer/risks-causes
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3899021/

factor.[6] There is also growing evidence that men who identify as heterosexual are sexually 'fluid' (ie. have same-sex relationships)[7] and are in fact increasingly embracing a significantly more inclusive, tactile and emotionally diverse approach to their relationships with other men[8] which may well increase the risk of male-male HPV transmission. We recommend that JCVI acknowledges and takes account of the evidential uncertainties in this area.

Men who have sex with men (MSM)

JCVI is almost certainly over-optimistic about the impact of the MSM vaccination programme. In our view, and in that of our members whose work focuses on the sexual health of MSM, the programme offers too little too late because most MSM at high risk of HPV infection will probably have been infected before their first visit to a GUM clinic (the average age of first attendance for MSM is 31/32 years). The immune response to vaccination is also known to be stronger at a younger age.

We are concerned that that sexual health services in England and Wales may lack the capacity to offer an effective HPV vaccination service to MSM. The Local Government Association (LGA), which represents more than 370 councils in England and Wales, has stated that sexual health services are at 'a tipping point' after demand increased by a quarter in the past five years while funding has been cut.[9] The King's Fund has found clear evidence that pressure on GUM services has increased over the past few years and that patient care in some parts of the country has suffered as a result.[10] Total local authority spending on GUM services fell by 3.5% between 2014/15 and 2015/16.

We also note that the evaluation of the pilot programme in England has not yet been completed and, in any event, this review will not be independent (PHE is reviewing its own programme) and will not be able to assess the impact on HPV-related disease (because the timeframe is too short).

HPVA had understood that JCVI's decision on the vaccination of boys would be made without reference to the outcome – positive or negative – of the MSM vaccination programme. Because of the very uncertain impact of this programme, we recommend that the JCVI does not take it into account when making a final decision on vaccinating boys.

---

[6] https://www.ncbi.nlm.nih.gov/pubmed/27634663

[7] https://www.researchgate.net/profile/Lisa_Diamond4/publication/309694747_Sexual_Fluidity_in_Male_and_Females/links/587ade7908aed3826ae7bd88/Sexual-Fluidity-in-Male-and-Females.pdf

[8] https://link.springer.com/article/10.1007/s11199-017-0768-5

[9] https://www.local.gov.uk/about/news/sexual-health-services-tipping-point-warn-councils

[10] https://www.kingsfund.org.uk/sites/default/files/field/field_publication_summary/Understanding%20NHS%20financial%20pressures%20-%20report%20summary.pdf

Vaccine confidence

The interim statement does not recommend male vaccination because of the current high uptake in girls. This position appears complacent about the possible impact of vaccine safety scares in the UK. No doubt health officials in Denmark and Ireland, where uptake in girls has fallen sharply in recent years, were as convinced as JCVI is now that their vaccination programmes were resilient. There was a vaccine safety scare story in The Sun[11] on 8 May 2017 and in The Daily Mirror[12] as recently as 30 July 2017, for example, and the anti-vaccination lobby in the UK, led by Time for Action, is becoming much better organized.[13] A recent paper on HPV vaccination stated: 'There remains the ever-present risk that a vaccine scare will have an impact on uptake and, therefore, individual and population health. … the UK knows only too well of the damage done due to the … prolonged negative media coverage in relation to the MMR vaccine.'[14] We therefore recommend that the JCVI takes account of a possible fall in vaccine confidence in the UK.

Equality issues

The interim statement notes that JCVI is required to show 'due regard' to equality issues.

Section 149 of The Equality Act 2010 states that public bodies, when carrying out their functions, must have due regard to three needs. These are the needs to:

• Eliminate unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Act;

• Advance equality of opportunity between people who share a protected characteristic and people who do not share it; and

• Foster good relations between people who share a protected characteristic and people who do not share it.

More specifically, the courts have determined that 'due regard' means that public bodies should:

- Consciously consider the duties and their impact on the decisions to be taken.[15]

[11] https://www.thesun.co.uk/living/3507121/mum-claims-hpv-vaccine-has-left-her-football-loving-teenage-daughter-wheelchair-bound-like-an-old-lady-in-a-teenagers-body/
[12] http://www.mirror.co.uk/news/uk-news/teenage-girl-exhausted-go-school-10899400
[13] http://timeforaction.org.uk/
[14] https://www.nature.com/articles/s41541-017-0004-x.pdf
[15] http://www.bailii.org/ew/cases/EWHC/Admin/2007/3064.html

- Consider each of the aims of the Equality Duty and then whether and how they should be applied to the decision that is being made.[16]

- Consider the effect of each of the aims of the Equality Duty and how they should be applied. It is not a matter of considering the duty and then immediately dismissing it without properly considering the potential effects. Nor is it sufficient to note that a decision may have a detrimental effect if the public body does not go on to consider whether the decision should be changed in order to reduce or remove any adverse effects.[17]

- Treat the Equality Duty as an essential preliminary to a decision and not as a rearguard action following a concluded decision. This means that the Equality Duty should be considered at the time the decision is taken.[18]

- Recording the process of consideration and how decisions have been reached to help demonstrate that the aims of the Equality Duty have been considered.[19]

- Give particularly careful consideration to the Equality Duty when a decision clearly affects a considerable number of people with protected characteristics.[20]

An examination of the minutes of the JCVI and its HPV Subcommittee suggests that equality issues may not have been appropriately considered and/or recorded. The interim statement states that JCVI should 'show due regard to equality by identifying potential issues for further consideration.' This is, in our view, not sufficient to comply with the legislation. We would therefore recommend that the JCVI takes full and proper account of equality issues before making its final decision and to publish evidence that it has done so. In the absence of such action, the JCVI could be vulnerable to legal action.

Final comments

JCVI should take account of the depth of support for the vaccination of boys as well as girls both internationally and within the UK. It is now difficult to find a health professional who does not support an extension of the vaccination programme. This was confirmed by a recent HPVA survey which found that 95% of dentists and GPs supported the vaccination of boys. It is also noteworthy that there is widespread support from politicians of all parties for the vaccination of boys including the chairs of the All Party Parliamentary Groups on cancer, sexual health, HIV/AIDS and dentistry.

[16] http://www.bailii.org/ew/cases/EWHC/Admin/2008/3158.html
[17] http://www.bailii.org/ew/cases/EWHC/Admin/2008/3158.html
[18] http://www.bailii.org/ew/cases/EWCA/Civ/2007/1139.html
[19] http://www.bailii.org/ew/cases/EWHC/Admin/2007/3064.html
[20] http://www.edf.org.uk/0002-r-on-the-application-of-hajrula-and-hamza-v-london-councils-2011-ewhc-861-admin-2011-ewhc-861-admin-2011-ewhc-151-qb/

HPVA believes that there are several steps that the JCVI should take before making a final decision. These are summarized in the box below. In any event, we consider that there are sufficient uncertainties and deficiencies in the modelling process to lead the JCVI to make a decision that would clearly be in the interests of better public health, greater equality and reducing human suffering: extending HPV vaccination to adolescent boys.

Summary of recommendations

HPVA recommends that the JCVI should:

- Publish full details of the modelling work and allow additional time for stakeholders to review and comment on it.
- Provide details of the various costs it has taken into account and the source of this information.
- Review its epidemiological analysis of the proportion of cancer cases caused by high-risk HPV types.
- Take into account HPV-related cancers of the nasal and paranasal sinuses.
- Consider predictive data for all HPV-related cancers.
- Take into account the incidence of recurrent respiratory papillomatosis (RRP).
- Include sexual contact between UK men and women from abroad in its modelling.
- Acknowledge and take into account the evidential uncertainties in the area of changing sexual behaviours since the publication of NATSAL-3.
- Not take into account the MSM vaccination programme when making a final decision on vaccinating boys.
- Take into account the possibility of a fall in vaccine confidence and uptake by girls in the UK.
- Take full and proper account of equality issues before making its final decision and to publish evidence that it has done so
- Consider the option of a boys-only vaccination programme and, if it is rejected, provide an explanation for this decision.
- Take account of the depth of support for the vaccination of boys as well as girls both internationally and within the UK.
- Make a final decision that would clearly be in the interests of better public health, greater equality and reducing human suffering: extending HPV vaccination to adolescent boys.

HPV Action members

ATL – the education union
British Association for Sexual Health and HIV
British Association of Dental Nurses
British Association of Dental Therapists
British Dental Association
British Society for Immunology
British Society of Dental Hygiene and Therapy
Brook
Cancer Focus Northern Ireland
Children's HIV Association of the UK & Ireland (CHIVA)
ENT UK
European Men's Health Forum
Faculty of General Dental Practice (UK)
Faculty of Public Health
Faculty of Sexual and Reproductive Healthcare
Family Planning Association
GMFA (Gay Men's Health Charity)
Herpes Viruses Association
HPV and Anal Cancer Foundation
Let's Talk About Mouth Cancer
London Cancer Alliance
London Friend
Men's Health Forum (GB)
Men's Health Forum Ireland
Mouth Cancer Foundation
National Aids Manual
National Association of Laryngectomee Clubs (NALC)
National Oral Health Promotion Group
National Union of Students
Northern Head and Neck Cancer Fund
Oral Cancer Foundation (USA)
Oral Health Foundation
Primary Care Urology Society
Rainbow Project
Reproductive Health Matters
Royal College of Obstetricians and Gynaecologists
Royal Society for Public Health
The School and Public Health Nurses Association
Sexpression:UK
Society of British Dental Nurses
Society of Sexual Health Advisers
Stonewall
The Swallows Head and Neck Cancer Support Group
Tenovus
Terrence Higgins Trust
Throat Cancer Foundation
The Urology Foundation
Wellbeing of Women

30 August 2017