

WELSH HEALTH CIRCULAR



Llywodraeth Cymru
Welsh Government

Issue Date: 13 January 2017

STATUS: ACTION

CATEGORY: PUBLIC HEALTH

Title: HPV vaccination for men who have sex with men.

Date of Expiry / Review N/A

For Action by:

Immunisation Leads, Health Boards/Trusts
Sexual Health Leads, Health Boards/Trusts
HIV Leads, Health Boards/Trusts
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Medical Directors, Health Boards/Trusts
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Dear Colleague,

Introduction of a HPV vaccination programme for men who have sex with men

From 1 April 2017, a new targeted human papillomavirus (HPV) immunisation programme will be offered in sexual health clinics to men who have sex with men (MSM).

The programme is based on advice from the Joint Committee on Vaccination and Immunisation (JCVI), the UK's independent committee of immunisation experts.

Background

Since the introduction in 2008 of the HPV vaccination programme against cervical cancer for adolescent girls, evidence has emerged that HPV immunisation is likely to provide protection against a wider range of HPV-related diseases such as penile, anal and oropharyngeal (head and neck) cancers.

The JCVI has recognised that MSM are a group at high risk of HPV infection and associated disease who receive very little indirect health benefit from the current HPV vaccination programme for girls. The full JCVI statement can be seen at:

<https://www.gov.uk/government/publications/jcvi-statement-on-hpv-vaccination-of-men-who-have-sex-with-men>

Programme Implementation

Service Delivery Arrangements

In Wales, health boards offer sexual health services through integrated sexual health clinics which incorporate GUM clinics as referred to by JCVI. HIV care is provided by sexual health clinics and infectious disease units.

The vast majority of MSM who are in regular contact with sexual health services in Wales are seen at consultant led (Level 3) sexual health clinics. It is considered that these specialist clinics are best placed to offer the HPV vaccine. The clinics currently offer Hepatitis B vaccinations and staff are trained in the administration of vaccine and management of anaphylaxis. Providing the vaccine at these clinics will allow high risk clients, who are attending for general sexual health services, to be vaccinated at the same visit.

Eligibility

Clinics may offer a full course of HPV vaccination to the following individuals when they are accessing services for sexual health care:

- All MSM up to and including 45 years of age.
- Based on case by case clinical assessment of the potential benefit of HPV vaccination, other groups recommended by JCVI may be offered vaccination including some MSM over 45 years, transgender men and women, HIV positive men who are not MSM, HIV positive women and sex workers. It is not intended that vaccination should be offered to all attendees in these groups but to those who may individually benefit.
- Sexual health services visiting prisons should offer HPV vaccine to MSM up to and including 45 years of age in the prison setting and other high risk individuals based on clinical judgment.

Clinics will not be required to arrange separate HPV vaccination sessions for eligible individuals who are not accessing services for sexual health care.

Clinics will not be required to proactively identify and contact eligible clients who have previously attended services.

The programme will not be offered via primary care services. Further consideration may be given to extending to other providers in future based on experience of the early programme roll out.

The vaccine

The vaccine offered will be Gardasil®. A course of three injections is needed for individuals who receive the first dose after their 15th birthday, ideally given at intervals of 0, 1 and 4-6 months. The first and third doses should be offered no more than 12 months apart but 24 months is clinically acceptable. For individuals receiving the first dose before their 15th birthday, a two dose course given a minimum of 6 months apart induces the same protection.

Further information is available in Annex A.

Vaccine supply

The vaccine supply will be procured centrally by Welsh Government.

A separate supply of Gardasil® vaccine for the MSM programme will be set up to order online via ImmForm. Supplies intended for the girls' school programme should not be used for the MSM programme. This arrangement has been applied at the UK level to help with national stock management.

Pharmacies and individual clinics that require to order vaccine for the MSM programme should contact Melanie Davies to provide customer account

information to enable access to the appropriate Immform screens to be arranged.

Funding

In line with arrangements for other new vaccination programmes, it is proposed that an annual top-up allocation will be made to health boards. This will comprise the cost of the vaccine and an administration allowance of £9.80 per dose. Allocations for 2017-18 are shown below.

Uptake is difficult to estimate until the programme becomes established. In the first year of operation, the funding will be based on a notional 50% uptake of a three dose course for the number of individuals indicated below.

The number of eligible individuals is expected to fall in subsequent years as clients are immunised. Resources in 2018-19 and future years will be adjusted accordingly taking into account actual uptake.

| <u>Health Board</u> | <u>Estimated no. of eligible clients</u> | <u>Funding</u> |
|------------------------|--|----------------|
| Abertawe Bro Morgannwg | 728 | £32,650 |
| Aneurin Bevan | 848 | £38,050 |
| Betsi Cadwaladr | 476 | £21,350 |
| Cardiff and Vale | 921 | £41,340 |
| Cwm Taf | 234 | £10,500 |
| Hywel Dda | 293 | £13,150 |
| | 3,500 | £157,040 |

Training

Vaccination procedures will be familiar to clinic staff who are already delivering Hepatitis B vaccines. Training resources, including an e-learning package, to support the HPV programme will be made available from:

www.wales.nhs.uk/immslearning

Data Collection

Clinics will be required to record the vaccination status of eligible clients. SHHAPT codes already exist for the three doses of HPV vaccine:

| SHHAPT code | Description |
|--------------------|-------------------------------|
| W1 | HPV vaccination – first dose |
| W2 | HPV vaccination – second dose |
| W3 | HPV vaccination – third dose |

Public Health Wales will provide quarterly reports on uptake to service providers and Welsh Government.

Information Materials

Information on the HPV vaccine will be provided in sexual health clinics. A factsheet about the programme is attached. This will be available shortly to download from the NHS Direct Wales web site at:

<http://www.nhsdirect.wales.nhs.uk/doityourself/vaccinations/Leaflets/>

Vaccination record cards will also be available to order from February. The cards are credit card sized and have space to record vaccination dates. They will be available in boxes of 200 and should be obtained from:

hplibrary@wales.nhs.uk or telephone 0845 606 4050

The Green Book

The *Immunisation against infectious disease* ('the Green Book') chapter on HPV has not been updated as the MSM programme is not available across the UK. The Green Book does, however, include information about the presentation, administration, storage, etc. of the vaccine.

HPV vaccination for adolescent boys

The JCVI is reviewing the evidence on extending HPV vaccination to adolescent boys. It is anticipated that JCVI's advice will be available in early 2017.

The successful introduction of this new vaccination programme will contribute towards reducing the risk of HPV-associated cancers and genital warts.

I would like to take this opportunity to thank all who will be involved in delivering the programme for their efforts and continuing commitment to improving public health.

Yours sincerely,



Dr Frank Atherton
Chief Medical Officer / Medical Director NHS Wales

Recommendations for the use of the quadrivalent HPV vaccine (Gardasil®) in MSM

Administration

1. Gardasil® is administered into the upper arm (deltoid region). The vaccine is provided in a pre-filled syringe.
2. Prior to use, the pre-filled syringe should be shaken well to obtain a white, cloudy suspension. Gardasil® is supplied with a Blue 23 gauge 25mm needle and an orange 25 gauge 16mm needle. The blue needle has the correct width and length recommended for IM administration to most adults.
3. A small air bubble may be visible in the prefilled syringe. This is not harmful and should not be removed prior to administration. This small bolus of air injected following administration of medication clears the needle and prevents a localised reaction from the vaccination. To try to expel it risks accidentally expelling some of the vaccine and therefore not giving the patient the full dose.
4. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
5. Full guidance on administration is included in the relevant chapter of the “Green Book” and the Summary of Product Characteristics (SPC) for Gardasil®.

Dosage and schedule

6. Due to the flexibility in the Gardasil® summary of product characteristics (SPC), variable spacing options for the doses are possible. This will enable the administration of subsequent doses to be aligned with recommended clinic re-attendance.

Three dose schedule for individuals 15 years of age or older: three doses of 0.5ml.

- First dose of 0.5ml of Gardasil® HPV vaccine.
- Second dose of 0.5ml at least one month after the first dose.
- Third dose of 0.5ml at least three months after the second dose. (Where the second dose is given late and there is a high likelihood the individual will not return for a third dose after three months or if, for practical reasons, it is not possible to schedule a third dose within this timeframe, then a third dose can be given at least one month after the second dose).
- All three doses should ideally be given within one year, however a 24 month period is clinically acceptable.

Two dose schedule for individuals under 15 years of age: two doses of 0.5ml given at least six months apart.

- First dose of 0.5ml of Gardasil® HPV vaccine.
 - Second dose of 0.5ml six to 24 months after the first dose.
 - Any gap between doses of between 6 and 24 months is clinically acceptable. As long as the first dose was received before the age of 15 years the two dose schedule can be followed. However if the second dose is not given within the recommended 24 month period then the course should be completed as soon as possible after that time.
7. If the course is interrupted, it should be resumed, but not repeated, ideally allowing the appropriate interval between the remaining doses.

Contraindications

8. There are very few individuals who cannot receive Gardasil®. When in doubt, appropriate advice should be sought from a consultant with immunisation expertise, a health board immunisation co-ordinator or the local health protection team, rather than withholding immunisation.
9. Gardasil® should **not** be given to those who have had:
- a confirmed anaphylactic reaction to a previous dose of the vaccine, *or*
 - a confirmed anaphylactic reaction to any constituent or excipient of the vaccine.
10. For the composition and full list of excipients of the vaccine, please refer to the manufacturer's Summary of Product Characteristics (SPC).

Immunosuppression and HIV infection

11. Individuals with immunosuppression and human immunodeficiency virus (HIV) infection (regardless of CD4 count) **should** be given the vaccine in accordance with the routine three dose schedule above.
12. Only a three dose schedule should be offered to individuals in the eligible cohort who are known to be HIV infected.

Concomitant administration with other vaccines

13. Gardasil® is an inactivated vaccine and will not be affected by, nor interfere with other inactivated or live vaccines given at the same time as or at any interval from each other.
14. Where other vaccines need to be administered at the same visit, they should be given at separate sites, preferably in separate limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's health records.

Consent

15. See Chapter Two of *Immunisation against infectious disease* ('the Green Book'):

Storage

16. Vaccines should be stored in the original packaging between +2°C and +8°C (ideally aim for 5°C) and protected from light. Gardasil® should not be frozen. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

Vaccine stock management

17. You should ensure sufficient fridge space is available for the vaccines. A maximum of two weeks of stock is recommended at any one time.
18. Effective management of vaccines throughout the supply chain is essential to reduce vaccine wastage. Local protocols should be in place to reduce vaccine wastage to a minimum. Even small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.
19. Any cold chain failures or other stock incidents must be documented and reported to the local health board co-ordinator and recorded through the ImmForm website on the Stock Incident page found in the Vaccine Supply section.

Reporting of adverse reactions (ADRs)

20. For a detailed list of ADRs associated with Gardasil® please refer to the manufacturer's Summary of Product Characteristics (SPC) or the Patient Information Leaflet (PIL) that comes with each vaccine.
21. Any suspected ADRs to vaccines should be reported via the Yellow Card Scheme⁵ (<https://yellowcard.mhra.gov.uk/>). Chapter 9 of "the Green Book" gives detailed guidance which ADRs to report and how to do so. Additionally, Chapter 8 of "the Green Book" provides detailed advice on managing ADRs following immunisation.
22. Any reported adverse incidents, errors or events during or post vaccination must follow determined procedures.

Patient Specific Directions (PSDs)

23. Public Health Wales will provide a national Patient Group Direction (PGD) template for the programme. The usual method for the supply and administration of vaccines is via a Patient Specific Direction (PSD). The authorisation for this is usually the responsibility of the doctor or an independent nurse prescriber. Where a PSD exists, there is no need for a Patient group Direction (PGD).

Where a PSD is not available, a PGD may be used. A PGD is a written instruction that allows for the supply and/or administration of medicines to groups of patients who present for treatment where it offers an advantage to patient care without compromising safety. A template PGD will be made available for amendment by health professionals to administer the vaccine where a PSD is not available. More information is available from the Public Health Wales vaccine Preventable Disease Programme NHS Wales intranet site at: <http://nww.immunisation.wales.nhs.uk/guidance>

Hepatitis B (HBV) vaccination check

24. Please take the opportunity to check (and correctly code) patients' HBV vaccination status. Maintaining high vaccine coverage in MSM is important to avoid outbreaks of infection. Guidelines for HBV vaccination are detailed elsewhere:

<http://www.bashh.org/documents/New%20Viral%20Hepatitides%20FINAL%20DRAFT%20MAY15.pdf>

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/503768/2905115_Green_Book_Chapter_18_v3_0W.PDF.

(See points 27 and 28 in this guidance regarding concomitant administration).

HPV VACCINATION FOR MEN WHO HAVE SEX WITH MEN (MSM)

What is human papillomavirus (HPV) and what diseases can it cause?

There are over 100 types of HPV that infect the skin and mucous membranes. The majority of HPV infections do not cause any symptoms and infections usually resolve on their own.

HPV infections which persist can lead to cancers e.g. HPV types 16 and 18 cause the majority of HPV associated cancers, notably anal, throat and penile in men and cervical cancer in women.

Other types of HPV such as 6 and 11 cause genital warts.

How is HPV infection spread?

HPV is one of the most common sexually transmitted infections in the UK. HPV is spread mainly by skin to skin contact. Genital HPV infections are highly contagious, and usually associated with sexual contact. Nearly all sexually active people get infected with HPV at some point in their lives. The risk increases with the number of sexual partners you and/or your partners have.

Can HPV infection be prevented?

Condoms do not guarantee protection from infection. This is because HPV can be transmitted by skin contact with areas not covered by condoms.

The best way to protect yourself from HPV infection is to get vaccinated. The vaccine offered to MSM attending sexual health/HIVclinics is called Gardasil. It protects against the four HPV types 6, 11, 16 and 18 that are responsible for causing cancers and genital warts.

The vaccine is a course of 3 injections over 4-12 months if you have the first dose aged 15 years or older. If you have the first dose before 15 years of age, you only need two doses (6 months apart). Ideally, vaccine should be given before you become sexually active but the protection is still good even if you receive the vaccine later. To get the best protection, it is important you receive the full course of vaccination.

From 15 to 45 years of age:

1st dose

2nd dose

at least one month after the first dose

3rd dose

3 months after the second dose
and ideally within 12 months of the first dose

Who is being offered HPV vaccine at sexual health/HIV clinics?

The UK's expert panel on immunisation matters, the Joint Committee on Vaccination and Immunisation (JCVI), has recommended that HPV vaccine should be offered to all MSM up to (and including) 45 years of age when they attend sexual health/HIV clinics for sexual health services.

Other individuals may be offered HPV vaccination based on a clinical assessment of the potential benefit. These include some MSM over 45 years, transgender men and women, HIV positive men who are not MSM, HIV positive women and sex workers.

Why should MSM attending sexual health/HIV clinics be vaccinated?

The risk of anal cancer in MSM is higher than in heterosexual men. If you also have HIV, this risk is higher again. In addition, MSM are more likely to get genital warts.

In the UK, a HPV vaccine programme for girls aged 12-13 has been in place since 2008. Vaccinating the majority of girls in the UK, means that their future male partners get some protection too. However boys who become MSM will get far less of this protection.

HPV vaccination is a very effective way to reduce your risk of genital warts and your risk of developing HPV-associated cancer in the future.

Is the vaccine safe?

Gardasil is a very safe vaccine. The vaccine meets the rigorous safety standards required for it to be used in the UK and other European countries. It has been used in the UK since autumn 2012. It has been given safely to millions in Europe, the Americas and Australasia. HPV vaccine safety is taken seriously by the Medicines and Healthcare products Regulatory Agency (MHRA), and its safety is kept under continual review.

Does it have any side effects?

The most common side effects are similar to other common vaccines and can include tenderness, swelling and redness at the site of the injection and headaches. More serious side effects are rare.

For more information, speak to your clinic nurse or doctor