Human Papillomavirus (HPV) Vaccination for Men who have sex with men (MSM)

An update for Practitioners including vaccination details for Registered Healthcare Practitioners

May 2017
Key Messages

- Men who have sex with men (MSM) have a significantly increased burden of HPV related disease and adverse outcomes compared to heterosexual men.
- A targeted HPV-MSM vaccination programme is being introduced in Scotland from the 1st of July 2017.
- The aim of the programme is to provide direct protection against HPV infection, HPV associated cancers and genital warts to the MSM population up to, and including the age of 45 years.
- The vaccine will be offered opportunistically through existing appointments at local sexual health and HIV services.
Aims of the Resource

• To support Practitioners involved in discussing HPV vaccination with men who have sex with men (MSM) by providing evidence based information

• To raise awareness of the current epidemiology of HPV and the important role of vaccination in the MSM population

• To provide Registered Healthcare Practitioners with guidance on the administration of the vaccine including recommended dosage and schedule, contraindications, precautions and potential adverse reactions
Learning Outcomes

After completing this resource Practitioners will be able to:

• **Describe** the aetiology of HPV

• **Understand** the rationale and evidence base for a targeted HPV-MSM vaccination programme to those aged up to and including 45 years and their role in delivering it

• **Discuss** the benefits of vaccination against HPV with their eligible MSM clinic attending population

• **Safely** administer the vaccine (Registered Healthcare Practitioners only)

• **Identify** sources of additional information
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Human Papillomavirus (HPV)

- DNA virus
- Infects skin and mucosal sites (squamous epithelium) through skin-to-skin contact
- HPVs are a large group of related viruses. Each virus in the group is given a number, which is called an HPV type
- HPV infections are often asymptomatic
- Can resolve spontaneously:
  - 70% new high-risk infections will clear within a year
  - 90% new infections clear within 2 years
- Persistent infection can cause cell changes leading to lesions including warts, ano-genital and some oropharyngeal cancers
Human Papillomavirus (HPV) (contd.)

- Main oncogenic HPV types that affect genital areas
  - 16,18,26,31,33,35,39,45,51,52,53,56,58,59,
  - 66,68,73, and 82
- Main HPV types that cause genital warts
  - 6 and 11
- Those above shown in red are vaccine-specific
- Those above shown in green are genetically related to HPV 16 and 18 and reduced through cross-protection (Cervarix®)

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Human Papillomavirus (HPV)

• Of the 200 different types of HPVs
  - Over 40 types affect genital area
  - High risk types (16,18) cause cancer
  - Low risk types (6,11) cause genital warts

HPV16: Together account for 80% all cervical cancers – remaining 20% due to 13 other HPVs.
HPV18: Also cancer of the anus, penis, mouth & throat, vagina & vulva
HPV :6
HPV :11 90-95% of cases of genital warts are due to HPV 6 and 11
Transmission

- HPV is one of the most common sexually transmitted infections in the UK
- Nearly all sexually active people get infected with HPV at some point in their lives
- The risk of acquiring infection increases with:
  - The number of previous sexual partners;
  - The introduction of a new sexual partner
- HPV can still be present many years after an individual has been sexually active

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Why vaccinate MSM?
HPV Vaccination

• The National HPV Immunisation Programme began in September 2008 (throughout the UK)
  • Targeting 12-13 year old girls and catch up programme up to age 18
• Cervarix ® : 2008-2012
  • HPV types 16/18
  • Evidence of some cross-protection
• Gardasil ® since September 2012
  • HPV types 6/11/16/18
  • Direct protection against warts and cervical cancer caused by HPV16/18.
HPV vaccine uptake in Scotland—routine cohorts

S2 in School year

Uptake (%)

0 10 20 30 40 50 60 70 80 90 100


Dose 1
Dose 2
Dose 3

Two-dose regime

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Impact of vaccine on HPV prevalence among 20 year old screened females in Scotland
Results from Australia
(Note: Quadrivalent HPV vaccination programme started in 2007 for girls and 2013 for boys)
Proportion diagnosed with genital warts at Melbourne Sexual Health Centre (<21 year olds)
Indirect herd protection through reduced transmission

N=NOT VACCINATED

Y=VACCINATED

Vaccinating females at high coverage pre-sexual debut protects
✓ females through direct and indirect herd protection
✓ males through indirect herd protection
Indirect herd protection through reduced transmission

N=NOT VACCINATED

Y=VACCINATED

Much reduced

Some reduction

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Herd protection in males

Proportion of Australian-born women, heterosexual men, and men who have sex with men (MSM) diagnosed as having genital warts at Melbourne Sexual Health Centre, from July 2004 to June 2014: stratified by (A) all age groups, (B) <21 years, (C) 21 – 32 years and (D) >32 years. The vertical line represents the implementation of the national HPV vaccination programme for girls in 2007. In 2013 the national HPV vaccination programme for boys was introduced.
Why vaccinate MSM against HPV?

HPV infection in all men is linked to:
- 80-85% of anal cancers;
- 30-70% a subset of oro-pharyngeal cancer;
- 50% of penile cancer.

Also:
- MSM who attend sexual health and HIV treatment services experience higher rates of HPV infection and related cancers;
- HPV 16-associated anal cancer is far more common in MSM compared to heterosexual men;
- The incidence of anal cancer is also highest in HIV positive MSM;
- Some MSM have high risk sexual behaviour;
- Would benefit from direct effect of vaccine
A HPV-MSM immunisation programme should be introduced for MSM up to and including the age of 45 years who attend Sexual Health and HIV clinics, subject to procurement of the vaccine and delivery of the programme at a cost-effective price.
Why deliver the service through sexual health clinics?

- MSM accessing sexual health and HIV services are known to be at higher risk of HPV infection and disease
- More is known about MSM using these services, which allowed the evidence of the benefit from HPV vaccination to be assessed for this group
- Sexual healthcare and HIV services are also the services where MSM are most likely to present their sexual orientation
- Efficiencies in delivery, cost and clinic capacity are likely to be added advantages of this approach
- May have an additional benefit of increased adherence and acceptability
HPV MSM Vaccination programme
Aims of HPV-MSM immunisation

• To provide the HPV vaccine to MSM up to and including the age of 45 attending participating Sexual Health and HIV clinics

• To reduce the number of HPV infections and their onward transmission

• To reduce morbidity and mortality from HPV-related disease, including anal, penile and oropharyngeal cancers and genital warts
Vaccination against HPV
Information for Registered Healthcare Practitioners:
The use of Gardasil®
Programme Eligibility

• A full course of vaccination should be offered to all MSM up to and including 45 years of age attending Sexual Health or HIV clinics systematically, regardless of risk, sexual behaviour or disease status.

• Any eligible vaccinee up to and including 45 years of age who started, but did not complete, the schedule should complete the vaccination course.
The recommended vaccine: Gardasil®

**Brand name:** Gardasil®

**Generic Name:**
Human Papillomavirus Vaccine
[Types 6, 11, 16, 18]
Recombinant, adsorbed

**Marketed by:** Merck Sharp & Dohme Limited

**Approved for use:** in females and males aged from 9 years of age
HPV Vaccines

- Made from the proteins of the outer coat of the HPV Virus types
- Inactivated vaccine—cannot cause the diseases against which it protects
- Highly immunogenic
- Clinical trials show very high efficacy and well tolerated:
  - Over 99% effective at preventing pre-cancerous lesions associated with HPV types 16 and 18;
  - 99% effective at preventing genital warts associated with vaccine types in young women
  - A clinical trial of Gardasil® in men indicated that it can prevent anal cell changes caused by persistent infection, and genital warts
  - May boost immunity and prevent re-infection or reduce reoccurrences in people with established diseases
HPV Vaccines (Contd.)

- A course of 3 injections is needed for individuals aged 15 years of age and over.
- Recent studies indicate that for individuals under 15 years of age, a two dose course given a minimum of 6 months apart induces the same protection.
- Prior infection with one HPV type does not diminish the efficacy of the vaccine against other HPV types included in the vaccine.
- To get the best protection, it is important the full course of vaccination is received.
- Currently protection is maintained for at least 10 years although protection is expected to last longer.

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Safety of Gardasil® vaccine

- The safety of Gardasil® vaccine has been established through rigorous testing in clinical trials, followed by use of many millions of doses across the world.
- In the UK, since autumn 2012 more than three quarters of a million schoolgirls have received at least one dose of the vaccine.
- Some people may experience a side effect, but these are generally of short duration and are far outweighed by the expected benefits of the vaccine.
- The UK Medicines and Healthcare products Regulatory Agency (MHRA) have published extensive reviews of HPV vaccine safety ([www.mhra.gov.uk/HPVvaccine](http://www.mhra.gov.uk/HPVvaccine)).
- The US health authorities have also posted very clear advice on their website supporting the safety of HPV vaccine ([http://www.cdc.gov/vaccinesafety/Vaccines/HPV/index.html](http://www.cdc.gov/vaccinesafety/Vaccines/HPV/index.html)).
Postural Orthostatic Tachycardia Syndrome (POTS)

- Recently in the UK and other European countries parents and pressure groups have raised safety concerns linking the HPV vaccine to a condition called Postural Orthostatic Tachycardia Syndrome (POTS).
- In June 2015, the JCVI concluded that it had no concerns about the safety of the HPV vaccine.
- The European Medicines Agency independent review concluded evidence does not support a causal link between the vaccine and the condition.
Ordering & Storage of Gardasil®

Gardasil® should be ordered from NHS Board vaccine holding centres.

- Store between +2 and +8°C
- Store in original packaging
- Protect from light

- Effectiveness cannot be guaranteed for vaccines unless the cold chain has been maintained and vaccine has been monitored as per national recommendations
- Refer to local NHS board policy on vaccine storage and handling

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Vaccine Stock Management

All Sexual Health and HIV clinics offering the vaccine should:

✓ Review available fridge space to ensure adequate storage capacity before ordering new vaccine.
✓ Do not over-order – 2 weeks of stock is usually adequate
✓ Have local protocols in place to reduce vaccine wastage to a minimum and protect vaccines in the event of a cold chain incident.
✓ Report any cold chain failures in line with local NHS board arrangements.

• Small percentage reductions in vaccine wastage will have a major impact on the financing of vaccine supplies.
Administration of Gardasil®

• The vaccine comes as pre-filled suspension that must be shaken before use to form a white suspension

• Two separate needles are available with the pre-filled syringe.

• Given by **intramuscular** injection into the **deltoid region of the upper arm**

• For individuals with a bleeding disorder, Gardasil® should be given by deep subcutaneous injection to reduce the risk of bleeding

• Can be given at the same time as Hepatitis B or other national schedule vaccines
Gardasil® dosage and schedule

**Individuals 15 years of age and older**
- Gardasil® should be administered as a 3 dose schedule of 0.5 ml
- Second dose should be administered at least 1 month after the first dose
- Third dose should be administered at least 3 months after the second dose
- All three doses should ideally be given within 12 months
- 24 month period is clinically acceptable.

**Individuals under 15 years of age**
- Gardasil® can be administered as a 2 dose schedule of 0.5 ml
- Second dose should be administered at least 6 months after the first dose
- 6-24 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
Administration of Gardasil®

Gardasil® should only be administered using a:

✓ Prescription written manually or electronically by a registered medical practitioner or other authorised prescriber;

✓ Patient Specific Direction;

✓ Patient Group Direction
Administration of Gardasil® with other vaccines

• HPV vaccines can be given at the same time as other vaccines such as Td/ IPV, MMR, Influenza, MenC and hepatitis A and B

• The combined hepatitis A and B vaccine (Twinrix®) should be offered to MSMs in conjunction with the HPV vaccine if they have not had this vaccine(s) already due to the higher likelihood of infection from these viruses and the ongoing outbreak of hepatitis A in MSMs in the UK, as per JCVI recommendations

• The vaccines should be given at a separate site, preferably in a different limb. If given in the same limb, they should be given at least 2.5cm apart
Contraindications and Precautions

Contraindications

Gardasil® should not be administered to those who have had:

- A confirmed anaphylaxis to a previous dose of the vaccine; OR
- A confirmed anaphylaxis to any component or excipient of the vaccine.

Please note: Yeast allergy is not a contraindication to the HPV vaccine. Even though Gardasil® is grown in yeast cells, the final vaccine product does not contain any yeast.
Immunosuppression and HIV Infection

• Individuals with human immunodeficiency virus (HIV) infection in the eligible cohort should be given HPV vaccine regardless of CD4 count, antiretroviral therapy use or viral load
• HPV vaccines are known to be safe and immunogenic when given to individuals infected with HIV
• The immune response to this vaccination and its effectiveness may be less than that observed among those who are non-HIV infected
Possible Adverse Reactions

Most Common

• Erythema (redness), pain, swelling at the injection site
• Headache, myalgia, fatigue and low grade fever
• These adverse reactions are usually mild or moderate in intensity
Reporting Suspected Adverse Reactions

Yellow card scheme

• Voluntary reporting system for suspected adverse reaction to medicines/vaccines
• Success depends on early, complete and accurate reporting
• Report even if uncertain about whether vaccine caused condition
• [http://mhra.gov.uk/yellowcard](http://mhra.gov.uk/yellowcard)
• See chapter 8 of Green Book for details
The key role of Registered Healthcare Practitioners is to:

- To provide clear and concise information regarding vaccination against HPV
- To emphasise the importance of completing the full course of vaccines to ensure full protection and encourage timely uptake of doses
- To safely administer the vaccine to MSM in the eligible cohort

Every effort should be made by registered healthcare practitioners to maximise the success of the HPV-MSM programme and promote the uptake of the HPV vaccine in the Sexual Health and HIV clinic setting.
Resources


4. NHS Health Scotland- public information leaflet, The HPV Vaccine for men who have sex with men (MSM) , to support the programme. This can be accessed at: www.immunisationscotland.org.uk/vaccines-and-diseases/hpvm msm.aspx


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