

Human Papilloma Virus (HPV) Vaccination Programme:

Factsheet for healthcare
professionals



Public Health
Agency

Background

In 2018, the Joint Committee on Vaccination and Immunisation (JCVI) recommended that the HPV vaccination programme be extended to include boys aged 12 to 13 years, as well as girls (School Year 9).

HPV vaccines protect against certain cancers caused by Human Papilloma Virus (HPV) infection, including cervical cancer, other anogenital cancers and oropharyngeal cancers. The purpose of extending the HPV vaccination programme to include all 12 to 13 year olds is to prevent more cases of HPV related cancers that affect both boys and girls, including various anogenital and oropharyngeal cancers, and to strengthen herd protection.

What is HPV?

HPV is a double-stranded DNA virus that infects the squamous epithelia, including the skin and mucosae of the upper respiratory and anogenital tract. There are approximately 100 types of HPV, of which about 40 infect the genital tract.

What diseases can HPV cause?

Although most HPV infections are asymptomatic and self-limiting, genital infection by HPV can be associated with certain cancers and genital warts in men and women.

HPV strain types are described as either:

- high-risk types (also referred to as oncogenic) associated with development of cancer and early cancerous changes;
- low-risk types associated with development of genital warts.

High-risk types

HPV is a causative factor for cervical cancer in women and persistent infection by high-risk HPV types is detectable in more than 99% of cervical cancers. Of these, HPV type 16 is responsible for around 60% and HPV type 18 for more than 15% of all cervical cancer types in Europe. A further 11 high-risk types have also been described.

In Northern Ireland, there are around 81 cases of cervical cancer diagnosed every year, with an average of 20 women dying each year. In addition, 1,125 cases of cervical cancer in-situ are diagnosed on average per year*. Studies show that receiving the HPV vaccine reduces the risk of getting cervical cancer by over 80%.

High risk HPV types are also associated with less common cancers, including cancer of the vulva and vagina, cancer of the penis and cancers of the anus and oropharyngeal tract. Anal and genital cancers can occur in both males and females.

* <https://www.qub.ac.uk/research-centres/nicr/FileStore/OfficialStats2019/Amendments/CervicalCancer/Filetoupload,1233975,en.pdf>

Whilst not as common as cervical cancer in females, high-risk HPV subtypes are associated with more than 80% of all anal cancers. HPV related cancers of the oropharyngeal tract are also increasing in the UK, particularly in men and younger people.

Low-risk types

Genital warts are the most commonly diagnosed viral sexually transmitted infection in the United Kingdom. HPV types 6 and 11 are responsible for the majority of cases. More information can be found in *Sexually Transmitted Infection Surveillance in Northern Ireland* www.publichealth.hscni.net/directorate-public-health/health-protection/sexually-transmitted-infections

How is HPV infection spread?

HPV infections are spread primarily by sexual contact with an infected partner, particularly through sexual intercourse, but also by non-penetrative genital contact and oral sex.

Risk factors for acquiring HPV infection are related to sexual behaviour. Risk increases with number of new sexual partners, the sexual history of partners and the number of previous sexual partners. Infection commonly occurs soon after sexual debut and almost 40% are infected within two years of this.

Non-sexual routes of HPV transmission include transmission from mother to baby in the period immediately before and after birth, and hand to genital contact may explain some infections in childhood.

Will safe sex protect against HPV infection?

No. The use of condoms reduces but does not eliminate the risk of sexual transmission. HPV can spread by skin-to-skin contact and can be transmitted without penetrative sex.

Can HPV infection be treated?

Although HPV infection itself cannot be treated, the diseases it causes can often be treated successfully.

HPV vaccination programmes

Who is eligible for the HPV vaccine programmes in Northern Ireland?

HPV vaccination is offered by two national programmes:

- universal programme to all adolescents aged 12-13 years of age;
- targeted programme for men who have sex with men (MSM) up to and including 45 years of age.

What is the purpose of the universal HPV vaccination programme?

To reduce the burden of HPV infection, and thus HPV-related cancers in the UK, by protecting those who are at increased risk of disease.

Why is the universal programme offered to adolescents aged 12-13 years?

The vaccine has been shown to induce a better immune response in young people between 9 and 15 years of age compared with older teenagers and young adults (aged 16–26 years). The vaccine will protect the adolescent before adulthood and the likely exposure to HPV.

Why was the programme extended to boys?

In June 2018 a JCVI HPV sub-committee met to consider the association of HPV with non-cervical cancers that affect men as well as women. Following this meeting, JCVI recommended that the HPV vaccination programme for girls should be extended to boys, as vaccinating adolescent males would provide clear health benefits, including:

- direct protection for vaccinated boys against HPV infection and associated disease such as anogenital warts, anal, penile and oropharyngeal cancers
- Optimising protection against HPV for MSM by offering them vaccination before their sexual debut.
- Providing indirect protection for non-vaccinated girls and boys.

Extending the HPV vaccine programme to boys aged 12 to 13 will prevent more HPV-related cancers and reduce the overall burden of these cancers sooner than a girls only programme would do.

A programme for boys and girls will also provide resilience against any short-term fluctuations in vaccine uptake and will contribute to better control of the main cancer causing types of HPV.

Will there be a catch-up programme for boys?

Older boys will not be offered the vaccine.

When the girls' programme was introduced in 2008, there was no population protection from HPV. So, although the programme was aimed at girls aged 12 to 13, a catch-up programme for older girls was introduced to accelerate protection. High uptake of HPV vaccine among girls over the last ten years has reduced the prevalence of the types of HPV that the vaccine protects against. The risk of unvaccinated boys and girls coming into contact with HPV viruses, and passing them on, is now lower than before 2008.

The number of diagnoses of genital warts has also fallen in both girls and boys since the programme started, which also suggests that boys are benefiting indirectly from the girls' programme through 'herd protection'.

This means there is not as strong a case for a catch-up programme for older boys as there was for the girls and there would be limited additional benefit.

Should people wait and get the vaccine when they are older?

No. Before the vaccination programme, over 70% of people caught HPV and rates increased rapidly after 15 years of age. Vaccination of younger adolescents is more effective and offers protection prior to any exposure to the virus.

If an individual from an eligible cohort does not receive the vaccine at the routine age, they are still eligible to receive the vaccine up to 25 years of age. Prior infection with one type of HPV does not mean that the vaccine will not offer protection against other types of HPV.

Are older people still at risk of contracting HPV infection?

All individuals who are sexually active are at risk of contracting HPV. Risk of a new HPV infection decreases quite markedly for most people over the age of 25 years, by which time many people will already have become infected and/or change sexual partners less frequently.

Sexually active older women should participate in the Cervical Screening Programme (to detect disease caused by existing infection) as this remains the best way to protect themselves against cervical cancer.

Why is the HPV vaccine routinely offered to men who have sex with men (MSM) up to and including 45 years old?

In November 2015, JCVI recommended that the HPV vaccine should also be offered to MSM up to and including 45 years of age who attend Genitourinary Medicine (GUM), and/or HIV services as MSM have received little or no indirect protection from the girls HPV programme and also are at higher risk of HPV-related cancers.

Since October 2016, all MSM up to and including 45 years who attend sexual health and HIV services are offered the HPV vaccine in Northern Ireland.

Programme delivery

How is the programme delivered to adolescents?

The universal HPV vaccine programme for adolescents is delivered through a school-based programme. Evidence from implementation of other immunisation programmes shows that schools-based programmes provide a very effective means of reaching and delivering important health interventions to school-aged children, ensuring good uptake.

Health and Social Care Trust School Health Teams work with individual schools to offer the vaccine to those in School Year 9. They will obtain parental consent and agree a date for vaccination sessions at the school. If someone misses the vaccine in school, they will be offered the opportunity to receive the vaccine in School Year 10.

How is the programme delivered to men who have sex with men (MSM)?

The HPV vaccine is offered to MSM up to and including 45 years old who attend GUM and/or HIV clinics across Northern Ireland. The vaccine is administered during routine clinic appointments.

Do females who have been vaccinated still need to attend for cervical screening?

Yes, it is very important that females who have received HPV vaccine still attend for cervical screening at the recommended age as the vaccine only protects against seven out of ten cervical cancers

Do males have to attend for screening for HPV-related cancers?

There are no screening programmes for other HPV-related cancers. If an individual becomes worried about any symptoms, they should contact their GP.

The HPV vaccine

What HPV vaccines are available?

Two HPV vaccine products will be available for use in Northern Ireland 2022. Gardasil® 4 has been the HPV vaccine used in the Northern Ireland vaccination programme since 2012. This will switch to Gardasil® 9 in 2022 but supplies of Gardasil® 4 can continue to be used until supplies are used up.

- Gardasil® 4 protects against four high-risk HPV types (6, 11, 16 and 18 – quadrivalent vaccine);
- Gardasil® 9 protects against nine high-risk HPV types (6, 11, 16, 18, 31, 33, 45, 52 and 58 – nine valent vaccine).

The two vaccines are considered interchangeable by the JCVI and vaccination should not be delayed waiting for supply of an alternative vaccine. For those individuals who started the schedule with Gardasil® 4, the course can be completed with Gardasil® 9.

Are the vaccines live vaccines?

No, the vaccines are not live and they do not contain the HPV virus and therefore, cannot cause the HPV infection. The vaccines do not contain thiomersal or any other preservative. For a full list of excipients, healthcare professionals should read the manufacturer's Summary of Products Characteristics (SPC) see <https://www.medicines.org.uk/emc/product/7330/smpc>

What is the current HPV vaccination schedule?

A two dose schedule of 0 and 6-24 months is recommended.

The full two dose course must be completed to ensure full protection.

What if an individual receives two doses less than six months apart?

Two doses given less than six months apart for Gardasil® 4 or five months apart for Gardasil® 9 should not be considered adequate to provide long term protection and a third dose should be given according to the guidance provided in the dosage and schedule section in the Green Book HPV chapter.

What happens if the two dose course is interrupted?

If the two dose course is interrupted, it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose and regardless of the age at which the individual presents. The Joint Committee on Vaccination and Immunisation (JCVI) has indicated that the interval between the first and second dose can be extended by a number of years without compromising protection or the boosting effect of the second dose.

What if an individual presents with incomplete immunisation status or started the course with Cervarix® but has not yet completed it?

Cervarix® was chosen for the initial vaccine supply. When this was reviewed in 2011, Gardasil® 4 offered the best value and so was chosen for the next contract.

There is no longer a supply of Cervarix® available in the UK. For individuals who started the schedule with Cervarix®, but did not complete the vaccination course, the course can be completed with Gardasil® 4 or Gardasil® 9. Any eligible individual who started but did not complete the routine adolescent HPV vaccination programme before reaching the age of 25 years should complete the vaccination course at the minimum interval.

For eligible individuals who may have started the schedule with an HPV vaccine that is no longer used in the Northern Ireland programme but did not complete the vaccination course, the course can be completed in Northern Ireland with the vaccine currently in use in the Northern Ireland programme.

How long does protection last for?

Efficacy studies have shown the vaccine to be effective for at least ten years, with no evidence of waning immunity. Data from clinical trials and ongoing research tell us that the protection provided by HPV vaccine is likely to provide life time protection from these viruses because the immune system develops antibodies to the virus after the vaccination.

How is HPV administered and where is it administered?

The vaccine will usually be given in the upper arm by intramuscular injection. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If in any doubt, consult with the individual's clinician.

Can the vaccine be administered at the same time as other vaccines?

HPV vaccines can be given at the same time as other vaccines such as Td/IPV (school-leaver booster), MMR, Influenza, MenACWY and hepatitis B. If multiple vaccines are to be administered, they 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. The site at which each vaccine was given should be noted in the individual's records.

What should I do if the vaccine was administered at less than the recommended dose?

In the event that the vaccine is administered at less than the recommended dose, vaccination will need to be repeated because the dose that the individual received may not be sufficient to evoke a full immune response. Where possible, the dose of vaccine should be repeated on the same day or as soon as possible after. In the event that the additional dose of vaccine cannot be administered at the same visit or day, arrangements should be made to administer the additional dose as soon as possible, thus not to delay future doses.

What are the benefits of the HPV vaccine?

HPV vaccines work extremely well.

Gardasil® 4 and Gardasil® 9 provide protection against HPV16 and HPV18 that can lead to cancer; and HPV6 and HPV11 that cause genital warts in males and females. Emerging evidence from evaluations of the programme around the world has shown that the prevalence of HPV 16 and 18 has reduced by over 80%. Gardasil® 4 has also been shown to be 99% effective at preventing genital warts associated with vaccine types.

For women:

The number of young women with pre-cancerous cervical lesions is also falling and in young women with no previous history of HPV infection, the vaccine has been shown to be 99% effective at preventing pre-cancerous lesions associated with HPV types 16 and 18.

Persistent infection with high risk HPV types 16 and 18 can cause cell changes leading to other anogenital cancers in females, including cancer of the vulva or vagina and some cancers of the head, neck, throat (oropharyngeal tract) or cancer of the anus in either sex.

These vaccines do not protect against all HPV types that cause cervical or other cancers. However, there is evidence of some protection against some of these types that are not in the vaccines (cross protection).

For males:

HPV-associated cancers in males are relatively rare compared with cancer of the cervix (and other sites) in females. Gardasil® 4 and Gardasil® 9 vaccines protect against high-risk HPV types 16 and 18, which are strongly implicated in ano-genital cancers in males (ie cancer of the penis and anus). These vaccines also protect against cancers of the head, neck, throat (oropharyngeal tract) related to these high-risk HPV types.

Vaccine safety

How do I know the HPV vaccine is safe?

Vaccines undergo rigorous safety testing as part of the licensing process. The safety of HPV vaccines was tested in thousands of volunteers before the vaccines were approved. Since the HPV vaccine was licensed in 2006 it has been strictly monitored and frequently reviewed by many national and international bodies including:

- Medicines and Healthcare Products Regulatory Agency (MHRA)

- European Medicines Agency (EMA);
- Global Advisory Committee on Vaccine Safety of the World Health Organization;
- Centre for Disease Control and Prevention (CDC) in the USA.

All international bodies have continually reported that HPV vaccines are safe with no known long-term side effects. The only known severe reaction to the HPV vaccines is a severe allergic reaction which occurs in about 1 in every million who are given the vaccine.

The WHO vaccine-preventable diseases monitoring system 2018 global summary listed 121 countries using HPV vaccine around the world. Over 10.5 million doses have been given in the UK since 2008, and more than 80 million people have been vaccinated worldwide. The HPV vaccine has a very good safety record.

Are there any side effects with the vaccine?

Like any vaccine or medication, HPV vaccines can cause side effects. Some people have mild side effects after getting the HPV vaccine including, pain, swelling, or redness in the arm where the vaccine was given; fever, headache or feeling tired, nausea, vomiting or stomach pain or muscle and joint pain. Occasionally an individual may faint after receiving the vaccine and should be observed for approximately 15 minutes after vaccine administration.

A detailed list of adverse reactions associated with Gardasil® 4 and Gardasil® 9 is available in the Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) for each vaccine, which can be accessed at www.medicines.org.uk/emc/medicine/19016 and <https://www.medicines.org.uk/emc/product/7330/smpc>

Suspected side effects should be reported to the Yellow Card Scheme www.mhra.gov.uk

Are side effects more frequently reported after HPV vaccination than for other vaccines?

No. To date, the number of reports to the MHRA of suspected side effects for HPV vaccines is not unusual. Over the past few years several studies based in different countries have found no evidence of a link between the HPV vaccine and a range of serious and chronic illnesses. Over 80 million people worldwide in countries like the United States, Canada, Australia and New Zealand have safely received the HPV vaccine. Not one of these people anywhere in the world has been medically proven to have had a long term side effect from getting the vaccine.

Concerns about complex regional pain syndrome (CRPS) and postural orthostatic tachycardia syndrome (POTS) following HPV vaccination have been raised in certain geographic locations. CRPS is a chronic pain syndrome affecting a limb, while POTS is a condition where the heart rate increases abnormally on sitting or standing up, together with symptoms such as dizziness, fainting and weakness, as well as headache, aches and pains, nausea and fatigue. In some patients they can severely affect the quality of life. Both syndromes have been known for many years, before the vaccine was introduced, and are relatively common in young adolescents.

The European Medicines Agency conducted an independent review concluding that available evidence does not support a link between the vaccine and CRPS or POTS.

Analyses conducted on the girls HPV vaccination programme suggest that there has been no change in the incidence of these syndromes in girls aged 12-20 years since the introduction of the vaccination, despite high uptake.

What are the contraindications for receiving HPV?

There are very few individuals who cannot receive HPV vaccine. The vaccine should not be given to those who have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine, or a confirmed anaphylactic reaction to any components of the vaccine. **Pregnant women should not receive the vaccine.** If an individual is acutely unwell, immunisation may be postponed until they have fully recovered.

Should a female receive the vaccine if she is pregnant or breastfeeding?

HPV vaccine is not recommended in pregnancy. This is not because of any specific safety concerns with giving the HPV vaccine during pregnancy but due to limited information on using the vaccine in pregnant women.

If a female is pregnant, she should be offered the vaccine as soon as possible after pregnancy. If a woman finds out she is pregnant after she has started a course of HPV vaccine, she should complete her pregnancy before finishing the two dose course. Routine questioning about last menstrual period and/or pregnancy testing is not required prior to HPV vaccination.

There are no specific safety concerns with a female receiving the HPV vaccine when she is breastfeeding.

What should happen if the HPV vaccine is inadvertently administered to a pregnant woman?

No specific safety concerns have been identified in either the outcome of pregnancy or foetal development in women inadvertently vaccinated whilst pregnant or shortly before becoming pregnant.

However, if a female finds out she is pregnant after she has started a course of HPV vaccine, she should discuss this with her GP who can then report this to the UK Health Security Agency (UKHSA) register directly by visiting this website: www.gov.uk/guidance/vaccination-in-pregnancy-vip

What if an individual is immunosuppressed or is known to be HIV infected?

There is no data for two dose schedules for immunocompromised individuals. Therefore a three dose schedule should be used for individuals known to be HIV infected, including those on antiretroviral Rx, or known to be immunocompromised at the time of immunisation. Re-immunisation should be considered after completion of treatment or recovery.

Specialist advice should be sought.



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