

# Questions and answers about HPV

Information for health  
professionals



## About introduction of the vaccine

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Which countries have introduced the human papillomavirus (HPV) vaccine?

Over 100 countries have licensed one or more HPV vaccines, and as of 9 August 2017, globally 74 countries (including 33 countries in the WHO European Region) have added HPV vaccination to their national immunization programme for girls, and 11 countries also for boys.<sup>1</sup>

Has the introduction of the HPV vaccine been a success?

Yes.  
Countries with high uptake of HPV vaccines are seeing a clear decline in the rate of HPV infection and cervical abnormalities; a resulting drop in cervical cancer is expected to become visible in the next few years. Countries are also seeing a dramatic, over 90%, decrease in the prevalence of genital warts.<sup>2</sup>

What impact has the HPV vaccine had so far?

HPV vaccination is having a clear impact in reducing the spread of HPV. The immediate signs of this are reductions in the number of women with cervical lesions and a dramatic drop in the number of men and women suffering from genital warts. Whenever HPV transmission is reduced, this will be followed over a period of several years or decades by a drop in cases of cervical and other HPV-related cancers.

Studies conducted so far demonstrate that the vaccine is very effective. Rapid reductions up to 90% in HPV infections and genital warts in teenage girls and young women were demonstrated in Australia, Belgium, Germany, Sweden, United Kingdom, United States and New Zealand. Subsequently, as vaccinated cohorts began cervical screening, reductions in cervical abnormalities became apparent. For example in Australia and Denmark where HPV vaccine was introduced early and programmes achieved high coverage, studies showed reductions of 80% for high-grade cervical abnormalities, which are likely to lead to cancer if left untreated.

Is there any proof that the vaccine reduces incidence of cervical cancer?

Yes.  
After 10 years of use and over 270 million doses administered, there is now ample proof that HPV vaccination is very effective in preventing the chronic infections that can lead to cervical cancer. A reduction in cervical cancer cases is expected within the next few years, as the first group of girls who were vaccinated as young teenagers reach the age during which cervical cancer begins to appear.

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Why do different countries give the vaccine to girls at different ages?

WHO recommends that two doses of an HPV vaccine be given to 9–14-year-old girls as a first priority. Each country makes its own decision about who should be given the HPV vaccine, based on the national context. In some countries the HPV vaccine is available to girls and boys. Some countries offer vaccines to the recommended age group of girls only, while others encourage and pay for immunization of all girls and women up to age 26 as a “catch-up” immunization.

Why are boys not given the vaccine in most countries?

The primary goal of HPV vaccination is to prevent cervical cancer. Investing in high coverage among girls of the recommended age (9–14) is considered by WHO to be the most effective use of resources to achieve this goal. However, HPV vaccination has additional benefits for both women and men, and if countries have the resources they may choose to offer the vaccine to boys as well as girls.

Why have some countries added HPV vaccination to their routine immunization schedules?

Countries that have added the HPV vaccine to their routine immunization schedules see protecting their population against cervical cancer and other diseases caused by HPV as a high priority. In making the decision to introduce the vaccine, they have considered the burden of HPV disease, the pattern of the infection in their country and the efficacy, cost-effectiveness and affordability of the vaccine.

WHO recommends that all countries add HPV vaccine to their routine vaccination programme.

Why is HPV vaccine offered free of charge only to a specific age group of girls?

All countries have a national immunization programme, and the vaccines given under that programme are usually given free of charge to the recommended target group for each vaccine. The national immunization programme in each country determines which groups should get the vaccine and whether the government will pay for it. Ministries of health, with the help of independent committees of experts on immunization, decide who should be vaccinated based on the pattern of disease in that country, how much vaccine the country can afford, and whether it is cost-effective for the government to pay for vaccination.

WHO recommends that the HPV vaccine be given to 9–14-year-old girls as a first priority. Some countries follow this recommendation and offer HPV vaccination to girls in this age group at no cost to the individual. Others extend the offer to include boys and older adolescents or adults up to 26 years old. In some countries, the vaccine may be available at a cost to individuals not covered by the routine programme.

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## Why is the vaccine being introduced now?

HPV vaccination has been proven to be effective as well as cost-effective in reducing the human and financial burden of HPV infections.

Once a vaccine has been thoroughly tested and then approved, each country must decide whether it is feasible and affordable to add it to their immunization programme. An independent body of experts looks carefully at the rate of infection in the country, the effectiveness of the vaccine, who will be eligible and whether the country has sufficient resources available. The new vaccine must also go through a separate licensing procedure in each country, which can take several years. Introduction of a new vaccine within a country requires a lot of preparation to ensure that the public is aware of the benefits of the new vaccine and when it should be administered, and to ensure that enough vaccines are available to meet the demand.

More than 100 countries have licensed one or more HPV vaccines. The first countries introduced the vaccine in 2006, and as of 9 August 2017, globally 74 countries (including 33 in the WHO European Region) have added HPV vaccination to their national immunization programmes for girls. 11 of these countries globally have also introduced it for boys.<sup>3</sup> More countries plan to introduce the vaccine in the coming years.

## Why is only the bivalent or quadrivalent vaccine offered in my country? Why not one that covers more HPV types?

The choice of which vaccine to license in a particular country and when to introduce it into the national vaccination programme depends on several factors, including the time required to license a new vaccine, cost and the prevalent HPV types.

All three HPV vaccines in use are safe and effective in targeting the two most common HPV types (16 and 18) that are responsible for 71% of all cervical cancer cases globally. Two of the three vaccines also target types 6 and 11, which cause 90% of genital warts.

The newest of the three available HPV vaccines (approved for public use in 2014) offers protection against nine HPV types, which extends its protection to HPV types responsible for 90% of all cervical cancer cases.

Every vaccine must be licensed in a particular country before it can be used there; and the licensing procedure takes time. It may take several more years before the nonavalent vaccine (against 9 types of the virus) is licensed and available in each country that has chosen to introduce it.

## About the HPV vaccine

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**How long is the vaccine effective?**

Because the first vaccine was introduced in 2006, the full duration of protection is not yet known. New evidence shows that people vaccinated more than 10 years ago still have complete protection against the HPV types in the vaccine used, and are therefore still protected from developing pre-cancerous cervical lesions, genital warts and other diseases caused by these HPV types. There is no sign that this protection is decreasing in the currently vaccinated population and many experts believe the vaccine will prove to be effective for several decades.<sup>4</sup>

**Why is the vaccine not offered to children under nine?**

When the HPV vaccine was developed, the duration of protection was not known and the vaccine developers and health officials were concerned that if young children were immunized, the protection offered by the vaccine might not last long enough to protect them throughout the most at-risk period of sexual activity (up to age 25).

Recent evidence now shows that the duration of protection is at least 10 years and will most likely be much longer. Some scientists are therefore urging that research be done on the effectiveness of offering the vaccine to younger children.

**Is regular cervical cancer screening still necessary for women who have received the vaccine?**

Yes.

Women who have received the vaccine should still be screened for cervical cancer as recommended in their country. The vaccine protects against the HPV types that cause 71-90% of cervical cancers but it cannot prevent all potential cases. Also, it does not protect women against types with which they were already infected before receiving the vaccine. Cervical cancer screening programmes like PAP smears and visual inspections can find lesions caused by any HPV types early, so they can be treated before they become cancerous.

**Is there any evidence that the benefit of getting the vaccine is higher than the risk of potential negative side effects?**

Yes.

The benefits of HPV vaccination are far greater than the very minimal risks. The benefits include prevention of infection with the HPV types that cause 71-90% of cervical and other HPV-related cancers and (in the case of the quadrivalent and nonavalent vaccines) also 90% of genital warts. The risks are mild side effects like pain and redness at the injection site usually lasting less than a day. There is no evidence linking serious side effects to HPV vaccination despite careful monitoring since 2006 and over 270 million doses of HPV vaccines administered so far.

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## Does the HPV vaccine work?

Yes.

HPV vaccination is having a clear impact in reducing the spread of HPV. The immediate signs of this are reductions in the number of women with cervical lesions and, depending on which vaccine is used, also a dramatic drop in the number of men and women suffering from genital warts. Whenever HPV transmission is reduced, this will be followed over a period of several years or decades by a drop in cases of cervical and other HPV-related cancers.

Rapid reductions up to 90% in HPV infections and genital warts in teenage girls and young women have been demonstrated by studies conducted in Australia, Belgium, Germany, Sweden, United Kingdom, United States and New Zealand.

## What is in an HPV vaccine?

Vaccines are made up of virus-like particles that contain the protein coat of the virus, without any of the genetic materials from the virus itself. By resembling the virus, the vaccine stimulates the immune system to produce protective antibodies against HPV.

To be as effective as possible, the vaccine also contains tiny amounts of adjuvants (substances that help enhance the body's immune response). These include mineral salts, water and materials such as aluminum sulfate (alum) – a substance we are already regularly exposed to through the air, food and cosmetics such as deodorants.

Contrary to some rumours, currently available HPV vaccines do not contain Thiomersal (an authorized and harmless preservative used in some other vaccines), nor any other form of mercury.

## What is the difference between the different kinds of the HPV vaccine?

Three different HPV vaccines are currently in use:

- *Gardasil*<sup>®</sup>, made by Merck Sharp & Dohme (sometimes called MSD or Merck) and licensed for use in 2006, is a quadrivalent vaccine, meaning that it protects against 4 types of HPV.
- *Cervarix*<sup>®</sup>, made by GlaxoSmithKline (sometimes called GSK) and licensed in 2007 is a bivalent vaccine (it protects against 2 types of HPV). The bivalent and quadrivalent vaccines also provide cross-protection against types of the virus not contained in the vaccines.
- *Gardasil 9*<sup>®</sup>, made by MSD and licensed in 2014, is a nonavalent vaccine (it protects against 9 types of HPV).

Each country's national regulatory authority decides which vaccines will be available in that country. All three vaccines are very effective in preventing infection with the most common HPV types responsible for cervical cancer and

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most other HPV-related types of cancer, as long as the recommended number of doses is taken. The quadrivalent and nonavalent vaccines also prevent genital warts. If more than one type of HPV vaccine is available in your country, you can discuss with your health care provider which vaccine is the best option for you or your child.

Immunization experts do not recommend getting more than one series of HPV vaccines.

## Which HPV types does the vaccine protect against?

There are many types of HPV - more than 200 have been discovered so far. The three available vaccines target the most common and dangerous types of the virus. The vaccines are classified as bivalent (protecting against 2 HPV types), quadrivalent (protecting against 4 HPV types) and nonavalent (protecting against 9 HPV types).

The following table shows which HPV types each of the vaccines protects against.

Name of vaccine	Valency (number of types in the vaccine)	Specific HPV types in the vaccine	Proportion cervical cancer cases caused by these types	Proportion of genital warts caused by these types
Cervarix®	Bivalent (2 types)	16,18	71%	No
Gardasil®	Quadrivalent (4 types)	6, 11, 16,18	71%	90%
Gardasil 9®	Nonavalent (9 types)	6, 11, 16,18, 31, 33, 45, 52, 58	90%	90%

About 30 separate types of HPV are sexually transmitted. Some are considered high risk for developing into cancers. Other types that are considered low risk for cancer are responsible for genital warts. All three vaccines protect against HPV types 16 and 18, which cause about 71% of cervical cancer cases and most other HPV-related cancers. The quadrivalent and nonavalent vaccines also protect against types 6 and 11, which cause 90% of genital warts. The nonavalent vaccine also protects against an additional five types (31, 33, 45, 52, 58), which together with types 16 and 18 cause 90% of cervical cancer cases.<sup>5</sup>

In addition, the bivalent and quadrivalent HPV vaccines provide some cross-protection against types not included in the vaccines.

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Why vaccinate if the vaccine only covers some of the circulating HPV types?

HPV vaccines protect against the HPV types which are most common and most likely to cause cancer and, in the case of two of the three available vaccines also genital warts. They also provide cross-protection against some types they do not contain.

The bivalent HPV vaccine protects against the two types (16 and 18), which cause 71% of cervical cancer globally. The quadrivalent vaccine protects against these same types, as well as two types which cause up to 90% of genital warts. The nonavalent vaccine protects against these four and another five types, which increases its protection to 90% of types that cause either genital warts or cervical cancer.

## Quality, safety and side effects

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Has the vaccine been properly tested?

Yes.

Each of the three available HPV vaccines was tested in extensive clinical trials before being licensed. The first HPV vaccine was licensed in 2006, and since then more than 270 million doses of HPV vaccines have been distributed in 74 countries.

Does the available evidence justify the introduction of this vaccine into routine immunization?

Yes.

WHO, professional societies, and the health ministries in 74 countries supported by independent expert groups on immunization have examined the evidence on effectiveness, cost-effectiveness and safety of HPV vaccination and have concluded that routine introduction of an HPV vaccine is justified and strongly recommended.

Is there any evidence available to support a link between HPV vaccination and Postural Orthostatic Tachycardia Syndrome (POTS)?

No.

There is no evidence to suggest a link between Postural Orthostatic Tachycardia Syndrome (POTS) and HPV vaccination.

POTS is a condition that causes lightheadedness or fainting and a rapid increase in heartbeat upon standing. The cause is unknown, but doctors think POTS may be associated with a number of medical conditions including: a recent viral illness, prolonged physical inactivity, chronic fatigue syndrome and nervous system problems.

In 2014–2015 rumours in Denmark that HPV vaccines caused POTS seriously harmed the Danish HPV immunization programme. The data related to vaccination and to the

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syndrome were reviewed by the European Medicine Agency and the WHO Global Advisory Committee on Vaccine Safety, and data from the United States were reviewed by the United States Centers for Disease Control and Prevention (CDC). In November 2015, the European Medicine Agency completed a detailed review of available POTS data from young women who received HPV vaccines. The review found that the evidence does not support a causal link between HPV vaccines and POTS.<sup>6</sup> The risk of developing POTS was not increased by HPV vaccination.

About 80 million doses of HPV vaccine were administered in the United States in the period from June 2006 through September 2015. CDC monitoring in this period through the Vaccine Adverse Event Reporting System (VAERS) again did not detect any increase in incidence of POTS following HPV vaccination.<sup>7</sup>

Is there any indication that vaccination causes autism?

No.

Many small and large-scale studies have looked for a link between any vaccination and autism, but no link has ever been found. Moreover, studies have shown that autism does not occur any more frequently in infants born to mothers who have received the HPV vaccine than in mothers who have not received the vaccine.<sup>8</sup>

Is there any indication that the HPV vaccine may affect fertility?

No.

HPV vaccination does not affect fertility. Clinical trials before the first HPV vaccine was licensed in 2006 and safety monitoring and studies since its introduction have confirmed that the vaccine does not cause any reproductive problems in women.<sup>9</sup>

In fact, the HPV vaccine helps to protect fertility by preventing pre-cancerous cervical lesions and cervical cancer. Surgical treatment of pre-cancerous cervical lesions during pregnancy can lead to premature labour and loss of a foetus, and treatment for cervical cancer (removal of the cervix and uterus, chemotherapy and/or radiation) leaves a woman unable to bear more children.

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