

Questions and answers about HPV vaccination

Information for parents
and caregivers



Q&A: Information for parents and caregivers

About the Human papillomavirus (HPV)

What is HPV?

HPV stands for human papillomavirus. This is a group of viruses that infect the skin or various mucous membranes (such as in the mouth or cervix). The majority of infections are not harmful, but common types of HPV can cause genital warts, cervical cancer and other diseases.

About 80% of people will be infected with one or more types of the virus at some time in their lives.

Is the human papillomavirus dangerous?

Yes, the virus can be dangerous.

12 sexually transmitted types of the HPV virus are known to cause cancer of the cervix, anus, vulva, vagina, penis or throat. Each of these HPV types is easy to contract and pass on to others. In most cases infection with these types does not cause any symptoms, so the person does not know he or she is infected. The infection usually lasts 1-2 years and will go away on its own.

However at least 1 out of 10 of such infections becomes longer-lasting, and can develop into precancerous growths. If these growths are not detected and removed on time they can develop into cancer.

How does a person get the virus (HPV)?

HPV is spread through direct, skin-to-skin, contact with an infected area. About 30 types of HPV are transmitted through sexual activity (out of a total of more than 200 types). This can be any intimate contact with an infected area, such as during sexual intercourse or genital touching.

In rare cases the virus can be transmitted during childbirth from an infected mother to her newborn. This type of transmission can lead to a rare but serious disease of infants called Recurrent Respiratory Papillomatosis (RRP).

HPV is not hereditary: a person's risk of becoming infected with the HPV virus is not influenced by their genes or family history of the disease.

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How common is the virus (HPV)?

HPV is the most common sexually transmitted disease. About 80% of men and women will become infected at some point in their lives, and it is especially common among sexually active men and women up to age 25.

Cervical cancer is the most common type of cancer caused by HPV, and the fifth most common cancer in women in the WHO European Region. Early detection and treatment of precancerous growths through improved screening programmes help to prevent cervical cancer in women, but more than 28 000 women still die from the disease every year in the European Region.

Several sexually transmitted HPV types can also lead to cancer of the anus, vulva, vagina, penis or throat, or genital warts, a painful and difficult-to-treat condition affecting both men and women.

Other HPV types cause common warts, for example on the hands and feet.

What causes cervical cancer?

Virtually all cervical cancer cases start with a sexually transmitted HPV infection.

HPV is a very common virus that can infect skin and mucosal tissues, including the lining of the cervix in women. Most cervical infections clear up on their own within 1-2 years, but in 5-10% of infected women the infection continues, and can develop into a cluster of abnormal cells called a pre-cancerous lesion. Even at this stage a woman may have no symptoms and not even know she is infected, but if the lesion is not detected and removed it can slowly develop over years or even decades into cervical cancer.¹

Cervical cancer can be fatal or lead to long-term health problems such as infertility.

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Is it possible to get tested for HPV and cervical cancer?

Yes, regular testing is possible and very important.

There are three different methods of screening for HPV and cervical cancer:

- The HPV test is used to detect types of HPV that may cause cancer.
- The widely used PAP test is used to detect abnormal cell growth (precancerous or cancerous lesions).
- Visual inspection of the cervix may also be used to detect visible lesions.

These tests, combined with effective treatment of any precancerous cells they detect can prevent many women from developing and potentially dying from cervical cancer.

Unfortunately, screening programmes cannot detect or prevent all cases of cervical cancer. Even countries with an effective cervical cancer screening programme have significant numbers of cervical cancer deaths.

This is why *vaccination in combination with regular screening* offers the most effective way for women to protect themselves against cervical cancer.

Is it possible to avoid getting the virus (HPV)?

Sexually transmitted HPV types are transferred through intimate contact, so the only sure way to avoid the HPV infections that can cause cervical and other types of cancer is to never engage in sexual activity. Even if a person has only one sexual partner, that person could already be infected without knowing it because the virus often has no symptoms.

Using condoms and other barrier contraception methods can reduce the risk of HPV transmission. But these methods are only partially effective, because they may not cover all areas of infected skin.

The best strategy is vaccination, if possible before becoming sexually active, in combination with periodic screening for cervical cancer for women. Vaccination against HPV will not protect against all types of HPV, but depending on which HPV vaccine is used, it will protect against the types that cause 71-90% of cervical cancer cases, and up to 90% of genital warts.

About HPV vaccines

Why get vaccinated against HPV?

Vaccination offers the best possible protection against serious diseases, including cervical cancer. Each vaccinated person also helps others by stopping the spread of the virus.

HPV is so common that about 80% of unvaccinated men and women will be infected at some time in their lives. Sexually transmitted HPV is especially widespread among young people up to age 25. A person who is vaccinated before becoming sexually active will be protected from the most common and dangerous types of the virus, and will not go on to spread the virus to others.

Cervical cancer is the most common disease caused by HPV. Over 67 000 women were diagnosed with cervical cancer and 28 000 died from the disease in the WHO European Region in 2012.² In that same year, about 266 000 women died of cervical cancer worldwide, accounting for 8% of all female cancer deaths. Unlike most cancers, cervical cancer is more likely to develop among young women aged 20–45 than among older women.

Vaccination protects young girls against the HPV types that are together responsible for up to 90% of cervical cancers at any age. However, regular cervical cancer screening is very important – for both vaccinated and unvaccinated women – because HPV vaccines prevent the majority of cervical cancers but not all of them. In combination, vaccination and cervical cancer screening programmes provide reliable protection against cervical cancer.

HPV is also linked to cancer of the vulva, penis, anus, head and neck and to genital warts. It is always better to prevent an HPV infection than to try and treat the diseases it can cause.

What does the HPV vaccine do?

The HPV vaccine contains particles that mimic the most common types of the virus. These particles are not live virus and cannot cause infection, but when the vaccine is injected into a person's body, his or her immune system responds as if it was the actual virus. By building antibodies against these particles, the body builds a defense system that will fight off the real virus if it ever appears. This system works so well that the vaccine is up to 100% effective in preventing any future infections with the types of HPV virus it contains.

See also the video "How the HPV vaccine works":
<https://www.youtube.com/watch?v=qF7pBzU4D20&t=4s>

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Do HPV vaccines 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 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.

Is there more than one HPV vaccine, and what is the difference between them?

Three different HPV vaccines are currently in use:

- *Gardasil*[®], 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*[®], made by GlaxoSmithKline (sometimes called GSK) and licensed in 2007 is a bivalent vaccine (it protects against 2 types of HPV).
- *Gardasil 9*[®], made by MSD and licensed in 2014, is a nonavalent vaccine (it protects against 9 types of HPV).

In addition, the bivalent and quadrivalent HPV vaccines are known to provide some cross-protection against types not included in the vaccines. 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 most other HPV-related types of cancer,

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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.³

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

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Why get vaccinated 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.

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 (in addition, the bivalent and quadrivalent HPV vaccines are known to provide some cross-protection against types not included in the vaccines). 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.

Is the vaccine effective for someone who is already sexually active?

This is possible, but effectiveness will depend on past exposure to the virus.

HPV vaccines target the most common and dangerous sexually transmitted types of the virus. The protection they provide is strongest for the HPV types in the vaccine that a person has not yet been exposed to. In general, people contract one or more these types of the virus soon after becoming sexually active. So to benefit fully from the vaccine, it is best to be vaccinated before initiating sexual activity.

Is vaccination the only way to prevent HPV infection and cervical cancer?

HPV vaccination combined with regular screening is the best strategy to avoid developing cervical cancer.

Everyone who is sexually active has a high risk of becoming infected with HPV. Some methods of barrier contraception (such as condoms) can help avoid infection, but they are not 100% effective because they may not cover all areas of infected skin.

HPV vaccination protects against the types of the virus that cause up to 90% of cervical cancer cases. In addition all women, including those who have been vaccinated, should be screened regularly. Screening can detect pre-cancerous or cancerous growths caused by HPV so they can be removed as early as possible.

About vaccination

Who should get the HPV vaccine?

WHO recommends as a priority the vaccination of girls at the age of 9 to 14 years. When the vaccine is first introduced in a country, it is recommended that all girls aged 9–14 be offered the vaccine, and if feasible all those up to 18 years of age. Most countries share this recommendation, but some recommend vaccination of all girls and young women up to the age of 26. Some countries also recommend the immunization of boys and young men.

People who are older than the recommended age in their country and already sexually active may still get the vaccine. This will protect them against any HPV types contained in the vaccine that they have not yet come in contact with.

When should my child get vaccinated?

The best time for a child to be vaccinated is from 9 to 14 years of age. The vaccine gives the strongest immune response at that age, and it is most effective if given before a person becomes sexually active.

The vaccine has not been tested and is not licensed for children under 9.

Would it be better to wait until my daughter is older?

No.

There is no reason to wait until your daughter is older than the recommended 9–14 years of age to get the vaccine. The HPV vaccine produces a stronger immune response at this age than later in life and it is most effective if given before a person comes in contact with the targeted HPV types. HPV is most prevalent among women younger than 25 years of age, so many become infected within just a few years of starting sexual activity. This is true even for women who have only one sexual partner.

If a girl does not start the 2-dose series of HPV vaccination before turning 15, she will need a third dose to ensure she is fully protected. This is because the immune response is best at the recommended age.

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Is a health check needed before getting the vaccine?

No, a health check is not necessary.

There is no need for a person without existing health issues to get a health check before getting an HPV vaccine. However, be sure to discuss with the health provider whether getting the vaccine is advised if your child:

- is scheduled to receive the second dose of an HPV vaccine but had an allergic reaction after receiving the first dose;
- has a known allergy.

The health care provider can advise whether your child's allergy is relevant for the specific vaccine being given.

HPV vaccines have not been tested among pregnant women, so they should delay getting vaccinated or finalizing their vaccination schedule until after the pregnancy.

Is a health check needed after immunization?

No, there is no need for a health check after immunization.

However, women who receive the vaccine should still participate in routine cervical cancer screening as recommended in their country. This is because HPV vaccines can prevent most, but not all HPV types that can lead to cervical cancer. Also, a person who receives the vaccine after becoming sexually active may have already become infected with one or more types contained in the vaccines.

How common is cervical cancer among those who don't get vaccinated?

Cervical cancer is the fourth most common cancer in women worldwide, and the fifth most common in the WHO European Region. Over 67 000 new cases and 28 000 deaths caused by cervical cancer were reported in the WHO European Region in 2012.⁴

I did not have the vaccine, and I do not have cervical cancer. Why should my daughter be vaccinated?

Cervical cancer is not a genetic disease. If no one in your family has had cervical cancer this does not mean that your child will not develop the disease. Most sexually active people (about 80%) will become infected with one or more HPV types in their lifetimes. WHO recommends that all girls be vaccinated against HPV and that all women be routinely screened to detect HPV infection that could lead to cervical cancer.

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What will happen if my child is not vaccinated?

Anyone who is not vaccinated has a high risk of becoming infected with HPV and passing the virus on to others. HPV infections can cause genital warts or lead to several types of cancer.

Over 80% of people who are not vaccinated before they become sexually active will become infected with at least one type of HPV in their lifetime. The most common infection for women occurs in the cervix. Most of these infections (about 90%) clear up on their own, but those that do not can develop into pre-cancerous lesions and over time lead to cervical cancer. HPV infections outside the cervix can develop into cancer of the vagina or vulva. Infections in men can develop into cancer of the penis, anus or throat. Certain types of HPV cause genital warts among both men and women.

It is vitally important for both vaccinated and unvaccinated women to obtain regular cervical cancer screening so that any pre-cancerous lesions can be detected and removed before they can develop into cancer.

Can I choose not to have my daughter vaccinated?

Some countries allow children and parents to refuse HPV immunization. People should understand that by choosing not to vaccinate, they are exposing their daughter/son to the risk of developing HPV-related diseases.

Why is the vaccine often only given to girls?

Cervical cancer is the most common disease caused by HPV. Protecting women from this potentially fatal disease is therefore the main aim of HPV vaccination programmes. WHO and national authorities in most countries recommend that vaccination against HPV be offered to girls aged 9–14 as the first priority. Protecting girls from HPV also indirectly protects their future partners, and this community protection or 'herd immunity' has shown to be very effective in impeding the spread of the virus.

Each country makes its own decision about who should be given the HPV vaccine, based on the national disease burden and available funding. If they have enough capacity and funding, a country may decide to expand coverage to girls older than 14 and to boys. So far, 11 countries, including Austria, Switzerland and parts of Italy offer the vaccine to both boys and girls.

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Should boys also be vaccinated if they have access to the vaccine?

Although cervical cancer is the most common disease caused by HPV, boys can also benefit from receiving the vaccine.

HPV infection can cause several types of cancer and genital warts in men, and both men and women are likely to become infected with HPV soon after they begin sexual activity. The highest prevalence of HPV infection among men is among HIV-positive men who have sex with men.

Quality, safety and side effects

Is the vaccine safe?

Yes, all three HPV vaccines are among the safest and most effective vaccines ever licensed.

Each HPV vaccine was thoroughly tested for safety and effectiveness in clinical trials before being introduced to the general public. Monitoring has also continued since the vaccines were introduced; and after 270 million doses of HPV vaccines administered in 74 countries so far, the vaccines continue to have very good safety profiles.

The Global Advisory Committee for Vaccine Safety (GACVS) regularly reviews the scientific evidence on the safety of HPV vaccines provided by studies conducted around the world. Any serious event following immunization that could potentially be associated with the vaccine is investigated and the Committee looks at how often they occurred before and after introduction of the vaccine. In January 2016, the Committee concluded that there was no evidence to support any serious safety concerns related to the use of these vaccines. The European Medicines Agency also conducted an independent assessment and concluded that the vaccines are safe and effective.

How can I be sure this is a high-quality vaccine?

WHO, the European Medicines Agency, national regulatory authorities and many others take the safety of vaccines very seriously. Rigorous systems have been put in place to ensure the quality and safety of vaccines during all steps of testing, production, transportation and administration. These systems also ensure that any potential safety issue is reported and properly investigated.

Before any HPV vaccine is licensed, it is tested in clinical trials that carefully look for side effects. In clinical trials the vaccine is given to thousands of volunteers, and the outcomes for this group are compared to the outcomes for a group of people who did not receive the vaccine.

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After a vaccine is shown to be safe and effective, the WHO "pre-qualifies" the vaccine's manufacturer and its factories. WHO and national regulatory authorities inspect the manufacturing facilities and process, and test the consistency of vaccine batches to ensure that each batch is the same. Reassessments are carried out at regular intervals, and WHO follows up on any reported inconsistencies.

The high manufacturing and quality standards are the same in every country where HPV vaccines are produced.

How can I be sure the vaccine has not expired?

The expiry date of each vial of vaccine is printed on the label. Parents, caregivers or patients can ask their doctor to show them the label. Health care facilities have systems to make sure that all medicines, including vaccines, have not passed the expiry date and are safe to use.

Who produces the vaccine and where is the vaccine manufactured?

The quadrivalent and nonavalent vaccines (Gardasil® and Gardasil 9® respectively) are manufactured by Merck Sharp & Dohme (sometimes called MSD or Merck), whose corporate headquarters are located in the United States. The bivalent vaccine (Cervarix®) is manufactured by a company called GlaxoSmithKline, whose headquarters are in the United Kingdom.

These companies have manufacturing facilities in many countries worldwide, where the vaccines are produced. All factories that produce HPV vaccines are regularly inspected by national and international authorities, including WHO.

How long has the HPV vaccine been in use?

HPV vaccines have been available since 2006: The quadrivalent HPV vaccine (against 4 HPV types) was introduced in 2006, the bivalent (against 2 types) in 2007 and the nonavalent (against 9 types) in 2014.

How many people have received the HPV vaccine?

Since 2006, when the vaccine was first introduced, over 100 million people have been vaccinated with over 270 million doses of HPV vaccines around the world.⁵ HPV vaccination is part of the routine immunization schedule in 74 countries so far.

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Are there any long-term consequences of the vaccine?

10 years have passed since the first countries introduced routine immunization of girls against HPV. Protection against the virus is still strong among those who were vaccinated 10 years ago, and shows no signs of waning.

Scandinavian countries and the United States periodically examine their computerized medical records of millions of people who have received the vaccine, to see if there are any unexpected negative health outcomes among women who have received HPV vaccines. They have not found any long-term negative consequences.⁶

Does the vaccine have any side effects and, if so, what are they?

Like other vaccines and medicines, the HPV vaccine often produces mild side effects. Redness, swelling or soreness in the arm where the injection is given is common. Some people also experience headache, mild fever, aches in joints or muscles or temporary nausea. These local reactions or side effects usually last less than a day and are not dangerous.

Occasionally, a person may faint when given a vaccine or other injection. This is more common when many young people are vaccinated as a group, such as in a school setting. This reaction is thought to be due to stress and anxiety, not to the vaccine itself.

About one in a million people who receive a vaccine of any kind will experience an allergic reaction (such as anaphylactic shock). Therefore, as a precaution a person receiving a vaccine should stay in the clinic for 15 minutes afterwards. If they feel light headed or have any changes in hearing or vision right after vaccination they should tell the health care provider.

Unfortunately rumors linking HPV vaccination to severe side effects or chronic health problems circulate on social media and among teenagers. Extensive studies and ongoing safety monitoring of the over 270 million doses administered so far throughout the world do not support any such links.

How many people experience side effects?

Reactions in the arm where the vaccine was given:

- Pain is felt by about 8 in 10 people.
- Redness or swelling is experienced by about 1 in 4 people.

Headache: About 1 in 3 people will develop a headache.

Fever:

- Mild fever (100° F/38° C) is experienced by about 1 in 10 people.
- Moderate fever (102° F/39° C) is experienced by about 1 in 65 people.

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These mild side effects usually last a few hours to one day.

About one in a million people who receive a vaccine of any kind will experience a strong allergic reaction (such as anaphylactic shock). For this reason, health care providers should ask about allergies before giving a vaccine and advise whether a known allergy is relevant to the specific vaccine being given. The person being vaccinated should stay in the clinic for 15 minutes afterwards for observation.

Can HPV vaccination cause an allergic reaction?

Yes, but only for people with very specific allergies relevant to the vaccine being given.

All medicines and vaccines (and some foods and insect bites) can cause allergic reactions. The most serious allergic reaction, called anaphylactic shock, occurs in about one in a million people who receive a vaccine of any kind.

Although allergic reactions to vaccines are very rare, patients and their caregivers should tell the health care provider about any known allergies before receiving any vaccine. The health care provider can then advise whether the allergy is relevant for the specific vaccine being given.

As an extra precaution, every person receiving a vaccine should stay in the clinic for 15 minutes afterwards for observation.

How can I be sure that my child will not experience any serious side effects?

It is very unlikely that your child will experience any serious side effects or anxiety-related reactions to HPV vaccination.

But there are several things a parent can do to help ensure that vaccination goes well for his or her child.

- Tell the health care provider if your child has an allergy before the vaccine is given. The health care provider can then advise whether the allergy is relevant for the specific vaccine being given.
- Make sure your child stays for 15 minutes in the clinic after receiving the vaccine, so the clinic staff can observe him or her and respond to any serious allergic reactions.
- After vaccination, you can expect the usual side effects (redness or soreness at the injection site) as well as possible fever or body aches. Reassure your child that these side effects are common, not dangerous and will resolve quickly.
- If anything unexpected occurs, report it to the doctor. All such reports will be taken seriously and investigated to see if the observed change is related to the vaccination or may have another cause.

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Will the vaccine influence my daughter's sexual behavior or choices later in life?

No, there is no evidence that the vaccine will impact future behavior.

Some parents worry that giving their children the HPV vaccine may lead them to have sex sooner or to have more partners, but there is no evidence supporting this. Studies show that girls who have received the HPV vaccine do not start having sex sooner and do not have more sexual partners than girls who do not get the vaccine.⁷ Giving a child the HPV vaccine reduces or eliminates the risk of cervical and other cancers, cervical lesions, and genital warts and is a positive step to improve your child's future health and wellbeing.

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

No.
HPV vaccination does not affect a girl or woman's chance of getting pregnant or in any way impact future pregnancies. It also does not affect the fertility of boys or men. Vaccination is an important first step to prevent the long-term consequences of HPV infection, which can include cervical cancer, infertility or even death.

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