

The human papillomavirus vaccine

The virus, the diseases and the new HPV vaccine



This factsheet describes the human papillomavirus (HPV), the diseases that it causes and the vaccine that helps to protect against these diseases.

What is HPV?

HPV is a virus that infects the deepest layer of the skin or genital surfaces (epithelium). There are approximately 100 types of HPV, of which about 40 infect the genital area (McCance, 2004). The majority of all HPV infections resolve on their own and cause no clinical problems. Around 70% of new genital infections clear within one year and approximately 90% clear within two years (Ho *et al.*, 1998; Franco *et al.*, 1999). This factsheet focuses on those types of HPV that cause genital infections.

What diseases can HPV cause?

Genital HPVs can cause cancer, genital warts and other rarer anogenital cancers and cancers of the head and neck (Parkin *et al.*, 2006; Stanley, 2007).

Genital HPVs are classified as either:

- 'high-risk' or oncogenic types which cause cervical cancer and the early changes in the cervix associated with cervical cancer, or
- 'low-risk' types, which lead to the development of benign genital warts.

Cervical cancer

Infection by a high-risk type of HPV is necessary for the development of cervical cancer (see table 1). Over 99% of cervical cancers are caused by HPV infection. There are other cancers that can be caused by HPV but less than half of the total cases are attributed to HPV infection (see table 2). Most cases of high-risk HPV infection do not lead to cervical cancer. In some people, the infection can persist and, though the person is usually symptom-free, the virus can damage the surface of the cervix (the mucosa). Persistent infection can cause abnormalities of the cervix, which, if left undetected and untreated, can lead to cervical cancer. The time span between being infected by a high-risk HPV and the development of cervical cancer is, in most cases, many years (Moscicki *et al.*, 2006). While infection by genital HPV is most common among young adults (aged 18-28) (Koutsky, 1997), cases of cervical cancer peak in women in their late 30s. Two high-risk types, HPV 16 and HPV 18, are responsible for over 70% of all cervical cancers in Europe (Smith *et al.*, 2007). Other high-risk HPVs that cause cervical cancer include HPV types 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 66 (WHO IARC, 2007), (see table 1).

HPV type	Percentage of cervical cancer cases caused by HPV type	Cumulative total (%)
16	58.1	58.1
18	15.7	73.8
33	4.4	78.2
31	4.0	82.2
45	2.9	85.1
35	1.6	86.7
58	1.2	87.9
56	1.0	88.9
52	0.6	89.5
39	0.2	89.7
51	0.2	89.9
68	0.3	90.2
59	0.1	90.3
Other	1.4	91.7
No type identified	8.3	100.0

Table 1. Prevalence of the most common HPV types found in cases of cervical cancer in Europe

Adapted from Smith et al., 2007

Other anogenital cancers

The same high-risk HPV types that are associated with cervical cancer can also cause other anogenital cancers. These include cancer of the vagina, vulva, penis and anus. HPV is associated with 80–90% of all anal squamous cell cancers (Munoz *et al.*, 2006). HPV types 16 and 18 are found in most anal cancers (see table 2).

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Table 2. Types of cancer related to HPV and the percentage of these cases that are caused by HPV infection

Site	Percentage attributable to HPV infection	Percentage of which, HPV16 and/or 18	Reference
Cervix	>99	>70	Smith <i>et al.</i> , 2007
Penis	40	63	Rubin <i>et al.</i> , 2001
Vulva,vagina	40	80	Daling <i>et al.</i> , 2002 Iwasawa <i>et al.</i> , 1997 Trimble <i>et al.</i> , 1996
Anus	90	92	Daling <i>et al.</i> , 2004 Frisch <i>et al.</i> , 1999
Mouth	3	95	Kreimer <i>et al.</i> , 2005
Oropharynx	12	89	Kreimer <i>et al.</i> , 2005

Adapted from Parkin et al., 2006.

However, unlike cervical cancer, where over 99% of cases are caused by HPV infection, only around 40% of vaginal and vulval cancers are associated with HPV (Munoz *et al.*, 2006). The development of vaginal and vulval cancers is not well understood. Invasive cancers are usually preceded and accompanied by abnormalities, known as vaginal intraepithelial neoplasias (VaIN) or Vulva intraepithelial neoplasias (VIN). HPV 16 is the type most commonly associated with VIN lesions.

Genital warts

Genital warts are the most common viral sexually transmitted infection in the UK (Fenton *et al.*, 2004). Over 80,000 new cases were reported throughout the UK in 2006 (HPA, 2007). HPV types 6 and 11 cause 90% of all genital warts (Lacey *et al.*, 2006).

Genital warts can be difficult to treat and patients may experience frequent recurrent episodes. Genital warts are not life threatening, but they can cause significant distress to the individual and substantial healthcare costs (Lacey *et al.*, 2006).

How is HPV infection spread?

Genital HPV infections are spread primarily by sexual contact, particularly through sexual intercourse but also by non-penetrative genital contact. Risk factors for acquiring HPV infection are related to sexual behaviour – risk increases with the introduction of a new sexual partner, the sexual history of the partner and the number of previous sexual partners. 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 (Cubie *et al.*, 1998).

What are the main factors that cause HPV infection to lead to the development of cervical cancer?

Persistent infection by one or more high-risk HPV types is the most important factor for the development of cervical intraepithelial neoplasias (CIN) cancerous lesions.

Several co-factors are likely to be involved in the development of cervical cancer. The incidence of invasive cervical cancer is increased by cigarette smoking, increasing number of full-term pregnancies, and HIV infection (WHO IARC, 2007; Vaccarella *et al.*, 2008). Some other factors, such as the use of the contraceptive pill, have been suggested to increase the likelihood of developing cervical cancer. But, as it is difficult to separate this factor from other linked factors such as sexual behaviour, the findings are inconclusive (Munoz *et al.*, 2006).

How does HPV infection lead to cancer?

HPV can cause changes in infected epithelial cells. In some cases, HPV DNA integrates into host (human) DNA in the cervical epithelial cells at the site of infection. It is this process that is likely to be involved in changes to these cells that can progress to cancer (Woodman *et al.*, 2007). The exact nature of this process and the role of other factors are not fully understood. A description of how precancerous lesions can develop into cervical cancer is shown in figure 1 (see pages 10 and 11).

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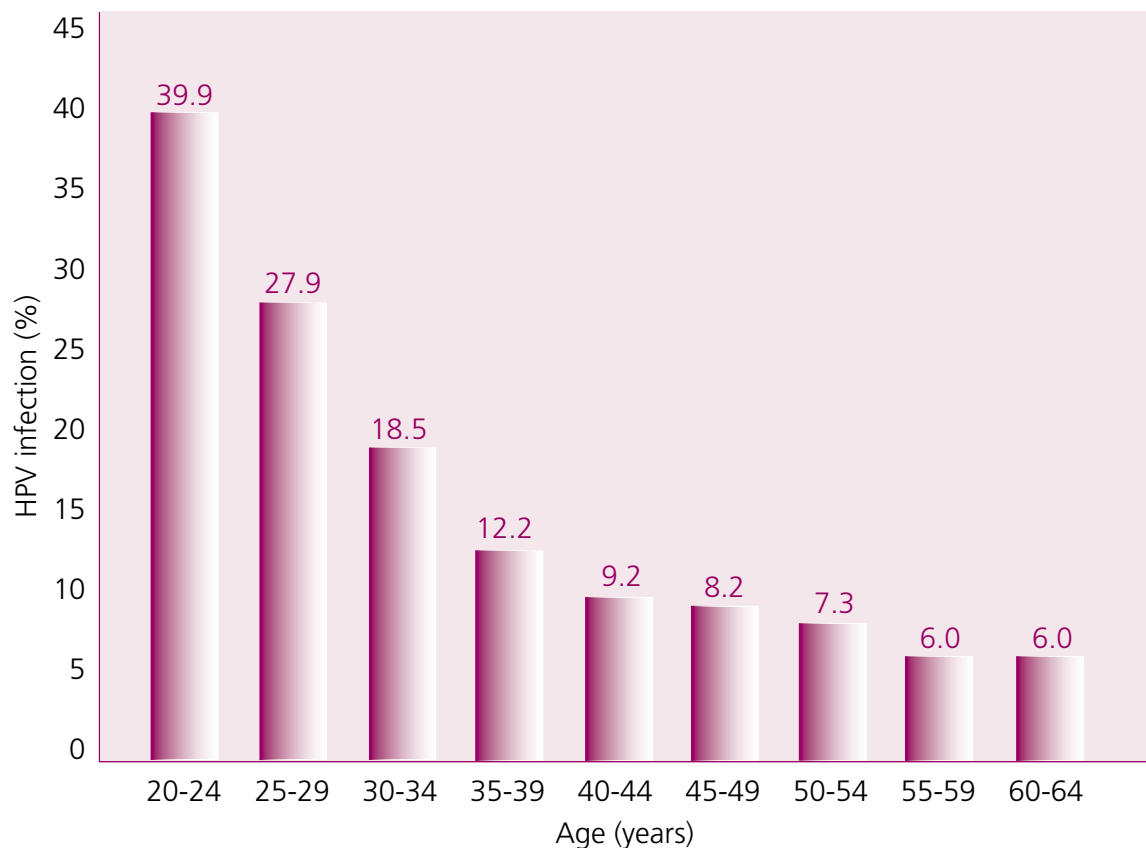


Figure 2. Prevalence of high-risk HPV according to age quinquennia. The graph shows that HPV infection is greater in 20- to 29-year-olds and decreases rapidly after age 30. Data taken from Kitchener *et al.*, 2006.

How common is HPV infection in the UK?

In a study conducted in the UK, 40% of the cervical smears from 20- to 24-year-old women were positive for HPV DNA (indicating a current infection); (Kitchener *et al.*, 2006). Fifteen per cent of these women had recently been infected by HPV types 16 or 18. As individuals get older the likelihood of infection by HPV decreases (see figure 2) (Clifford *et al.*, 2003; Kitchener *et al.*, 2006). The Centers for Disease Control and Prevention estimate that at least half of all sexually active women are infected by genital HPV in their lifetimes (CDC, 2004). Infection is likely to occur in their late teens and early twenties. A study of antibodies to four types of HPV infection (16, 18, 6 and 11) showed that the proportion of females who have been infected by HPV increases rapidly from 14 years of age to 24 years of age (Jit *et al.*, 2007), (see figure 3).

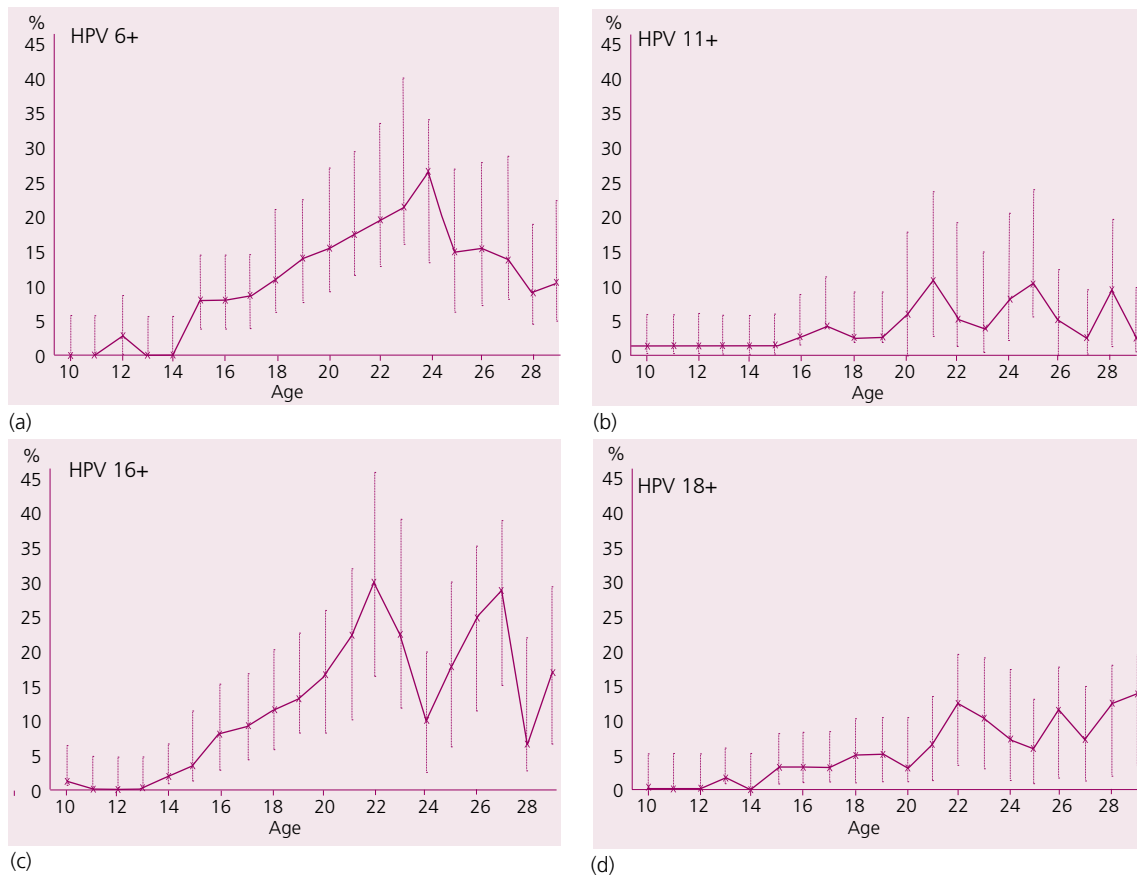


Figure 3. The percentage of females aged 10 to 29 years who have antibodies to (a) HPV 6, (b) HPV 11, (c) HPV 16 and (d) HPV 18. The error bars indicate the upper and lower confidence intervals. The presence of antibodies is evidence of past HPV infection. The graphs show that infection by HPV has already occurred in some girls shortly after age 14 years. Data taken from Jit *et al.*, 2007.

How common are cervical cancer and other anogenital cancers?

Cervical cancer

Cervical cancer is the second most common cancer of women worldwide with approximately 500,000 new cases and 270,000 deaths annually (Parkin *et al.*, 2006; Munoz *et al.*, 2006). In industrialised countries, routine cervical screening programmes and subsequent treatment have prevented many invasive cancers and deaths by detecting and preventing cervical changes at an early stage (Peto *et al.*, 2004).

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Figure 4. Number of cases of newly diagnosed cervical cancer in England, 2006 (source: National Statistics, 2008)

In England, 2321 new cases of invasive cervical cancer were diagnosed in 2006 (National Statistics, 2008). Most cases occur in women in their 30s. There is a second peak amongst women in their 70s to 80s who did not have the opportunity to be screened when they were younger (see figure 4).

Vaginal and vulval cancer

In the UK, cancer of the vagina accounts for less than 1% of all cancer cases (around 200 cases a year) (National Statistics, 2004). Cancer of the vulva affects around 1000 women a year and around 70% of both types occur in women over the age of 60 years.

Anal cancer

In the UK, there are around 800 cases of anal cancer diagnosed annually (National Statistics, 2004). Anal cancer is more common in women than in men.

How common are genital warts?

Genital warts are the most common viral sexually transmitted infection in the UK, with over 80,000 cases of new infection reported from GUM clinics in 2006 (HPA, 2007). In a survey of the UK population, 4% of adults aged 18 to 44 years reported that they had genital warts at some time in their life (Fenton *et al.*, 2001).

Can HPV infection be treated?

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

Cervical, anal, vaginal and vulval abnormalities are treated by removal, or by using cryotherapy, electrocautery and laser therapy.

The main type of treatment for cervical cancer (when the cancer is restricted to the cervix) is surgery. Surgery may also be used to treat anal, vaginal and vulval cancers, either alone or in combination with radiotherapy and chemotherapy.

In the UK, approximately two-thirds of women diagnosed with cervical cancer are alive five years after diagnosis (National Statistics, 2004).

There is a variety of treatments for genital warts. They can be treated using topical agents, cryotherapy and electrocautery, all of which may require repeated applications. None of these approaches treats the infection and treated individuals may continue to be a source of infection to other people, and may suffer recurrence of genital warts.

Can HPV infection be prevented?

Abstinence from any sexual activity greatly reduces the risk of genital HPV infection. For sexually active people, condoms reduce the risk of HPV infection, but they are not 100% effective (Koutsky, 1997). This is because HPV can be transmitted by skin-to-skin contact of genital areas not covered by condoms.

Can the development of cervical cancer be prevented?

The UK national cervical screening programme has led to a significant fall in the incidence and death rate from cervical cancer. Death rates in 2004 were approximately 60% lower than 30 years before, mainly due to the introduction of systematic screening (Peto *et al.*, 2004). Cervical screening does not prevent HPV infection nor does it prevent the early changes that may indicate the later development of cervical cancer.

Some groups of women are less likely to attend for cervical screening, for example ethnic minority groups and women born in a foreign country (Webb *et al.*, 2004; Thomas *et al.*, 2005). More recently, there has been a fall in the number of younger women taking up their invitations for cervical screening (Department of Health, 2007).

The HPV vaccine

Vaccines are available to protect against the two most common HPV types (16 and 18) that cause cervical cancer and the two most common HPV types that cause genital warts (6 and 11). They do not protect against disease if HPV infection is already established in the individual.

The vaccine used for the national immunisation programme (Cervarix®) protects against HPV types 16 and 18. Cervarix® does not protect against genital warts.

The following section provides information on the HPV vaccine that is part of the national immunisation programme.

How effective is the HPV vaccine in preventing cervical cancer?

Cervarix® is over 99% effective in preventing cervical abnormalities associated with HPV types 16 and 18 in women who have not already been infected by these types (Harper *et al.*, 2006).

Cervarix® has not been shown to protect against disease if a woman has an active HPV infection. However, it may protect a woman who has already been exposed to HPV infections and is no longer infected. The vaccines will protect individuals against infection by the HPV vaccine types they have not already contracted.

Cervarix® does not protect against all HPV types that cause cervical cancer. There is some evidence that the vaccine may offer some protection against other types (cross protection) (Paavonen *et al.*, 2007). Studies to determine the extent of cross-protection are ongoing.

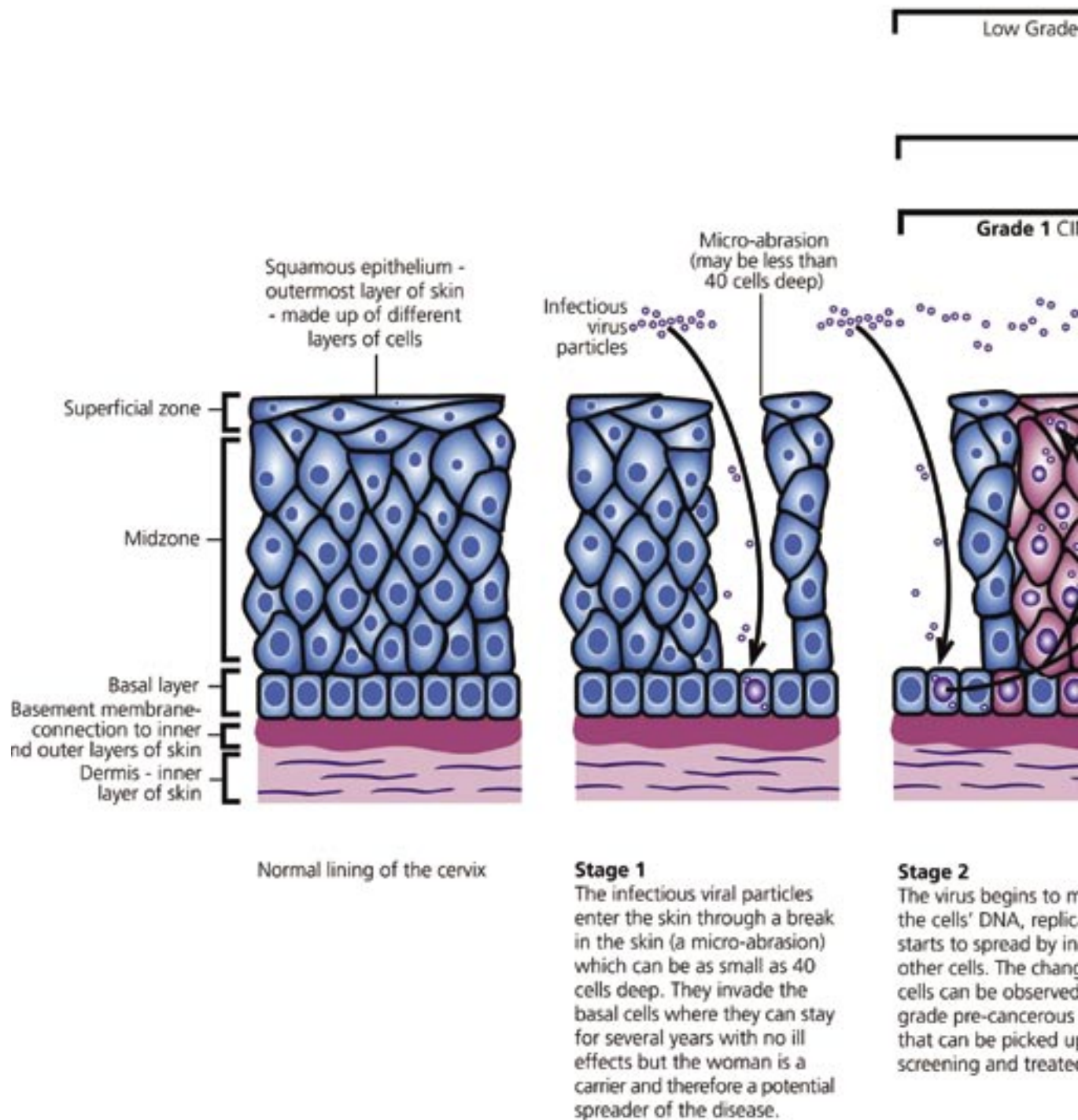
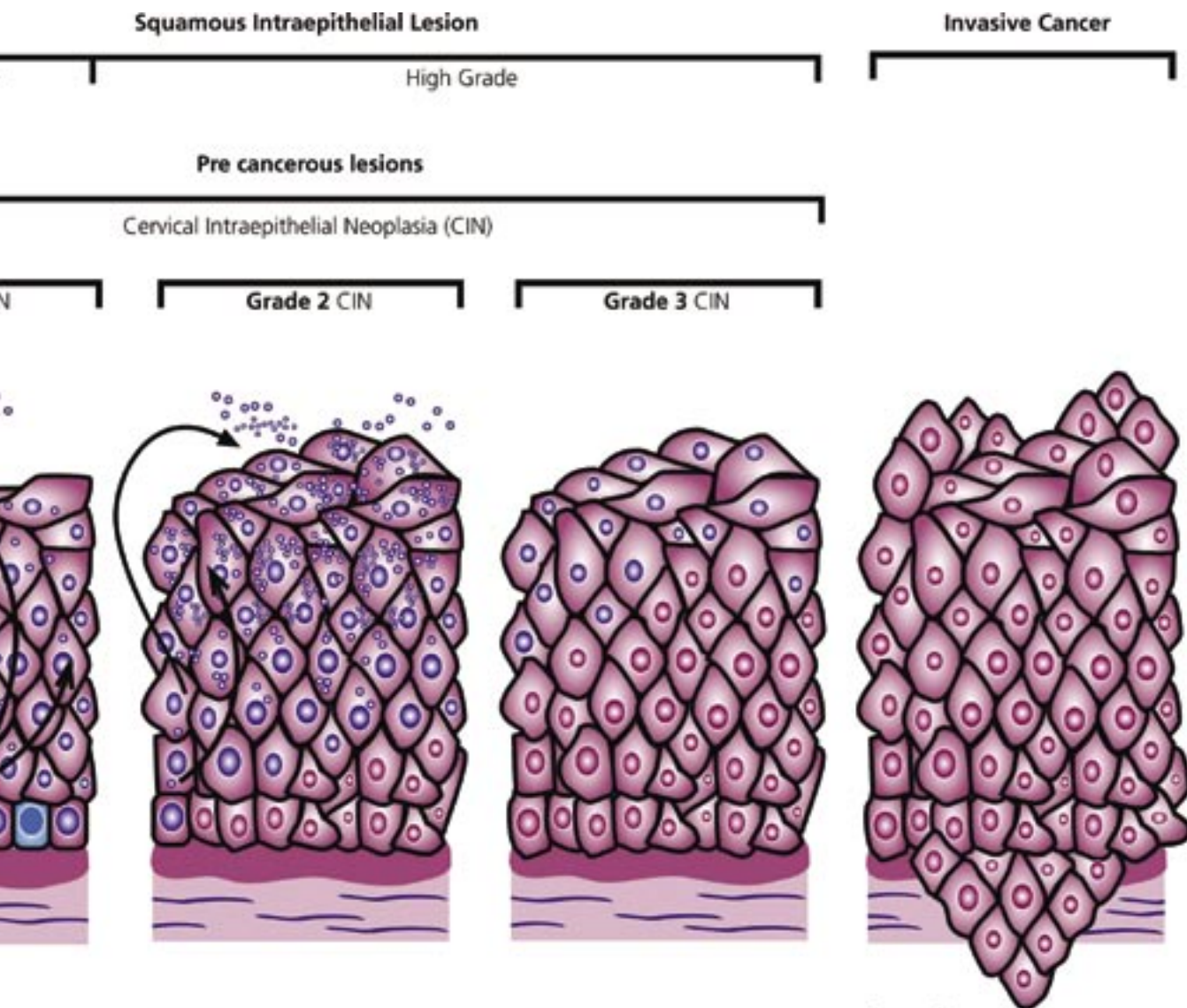


Figure 1. How the human papillomavirus affects the surface of the cervix and produces a cancerous growth.

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Stage 3

The cells become more damaged and disorganised – resulting in a high grade lesion.

Stage 4

The high-grade pre-cancerous lesion grows and occupies almost the entire thickness of the skin.

Stage 5

All the cells have been infected and are completely disorganised producing an invasive cancerous growth or tumour that can break through the basement membrane into the inner layer of the skin and spread to other parts of the body.

How does the vaccine work?

The vaccine is made from the proteins that make up the outer coat of the virus types. These proteins assemble into small spheres that are called virus-like particles (VLPs). The VLPs are not infectious and cannot cause cervical cancer or genital warts.

When a person is vaccinated, their immune system mounts a response against these VLPs. If the person is exposed to the real virus infections, the body's immune system reacts quickly to stop the infection.

Who will receive this vaccine?

The vaccine will be offered to girls aged 12 to 13 years (school year 8). Starting in September 2008, older girls under the age of 18 years will receive the vaccine through a catch-up campaign.

How will the vaccine be given?

The vaccine will usually be given in the upper arm by intramuscular injection. Three doses of HPV vaccine are given over a period of six months. If a dose is missed, then the course should be completed within 12 months. It is important to complete the course.

How long does protection from HPV vaccination last?

Because the HPV vaccine has been used for around seven years* in follow-up studies, we know that protection lasts at least this long. Antibody levels among the vaccinated group remained higher than those in unimmunised individuals who had developed immunity through natural infection.

This evidence suggests that long-term protection against the HPV types in the vaccine is being achieved. The long-term effectiveness of the vaccine will be carefully monitored.

Is the HPV vaccine safe?

There are no reports of serious side effects attributed to Cervarix®. The vaccine has also been found to be safe and well tolerated in clinical studies (Paavonen *et al.*, 2007). As with all vaccines, its safety will continue to be monitored as part of the national immunisation programme. HPV vaccine does not contain thiomersal.

*As at time of publication (Nov. 2008).

What side effects does the vaccine cause?

The most common side effects that were reported in clinical studies using Cervarix® were swelling, redness and pain at the site of injection, general muscular pain and headaches. Other mild side effects such as slightly raised temperature, sickness, diarrhoea, itching, rash, and joint pain were reported in less than one in ten but more than one in 100 people. A full list of potential adverse reactions can be found on the patient information leaflet that comes with each vaccine or can be found online at: emc.medicines.org.uk/emc/assets/c/html/displaydoc.asp?documentid=20207

Very rarely, some people have an allergic reaction soon after immunisation. This reaction may be a rash or itching affecting part or all of the body. Even more rarely, some people can have a severe reaction soon after the immunisation which causes breathing difficulties and may cause the person to collapse (anaphylaxis). This type of reaction is extremely rare and health professionals administering vaccinations are trained to deal with it.

Are there any reasons why individuals should not have this vaccine?

There are very few individuals who cannot receive HPV vaccine.

Immunisation is contraindicated only in persons who have had:

- a confirmed anaphylactic reaction to a previous dose
- a confirmed anaphylactic reaction to any part of the vaccine.

Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If a person is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid wrongly associating any cause of fever, or its progression, or other symptoms to adverse effects of the vaccine. Allergy to yeast is not a contraindication to immunisation.

Is HPV vaccine safe if it is given to a pregnant woman?

There is no known risk associated with giving HPV vaccine during pregnancy. HPV vaccine is an inactivated vaccine, which means that it does not contain any live organisms, and so cannot cause infection in either the mother or her baby. However, as a matter of precaution, HPV vaccine is not recommended in pregnancy. This is not because of any specific safety concerns with giving HPV vaccine during pregnancy but due to limited information on using the vaccine in pregnant women.

Although pregnant women were specifically excluded from the HPV vaccine trials and safeguards were in place during the trials to prevent pregnant women from receiving the vaccine some women were unknowingly pregnant when they were immunised, or were immunised just before becoming pregnant. The women who received HPV vaccine were no more likely to have problems with their pregnancies than women in the trials who did not receive HPV vaccine. There were no increased risks found for the babies born to women who had received the vaccine.

What should happen if HPV vaccine is given to a pregnant women?

If a woman finds out she is pregnant after she has started a course of HPV vaccine, she should discuss this with her GP. There is no evidence that it will harm her or her baby and there is no reason to believe that the pregnancy cannot continue safely. Once the woman has completed her pregnancy, she can finish the three-dose course of HPV vaccine.

Due to the relatively limited experience of using HPV vaccine in pregnant women to date, it is important to follow up women who have been given the vaccine during pregnancy. This is to provide further information on the safety of the vaccine when it is given in pregnancy. This follow-up is being conducted by the Immunisation Department of the Health Protection Agency Centre for Infections (www.hpa.org.uk) which is setting up a registry of such incidents.

What should be done if a pregnant woman is vaccinated or a woman became pregnant shortly after receiving a HPV vaccine?

If a woman is pregnant and has been immunised with HPV vaccine it is recommended that she discusses this with her GP who can then report this to the HPA registering directly by visiting the Health Protection Agency (HPA) website (www.hpa.org.uk) or by telephone (01788 540298 or 0208 327 7471). Additional details on the registry are available on the HPA website.

Can the vaccine be given to people who are immunocompromised?

Women and girls whose immune systems are compromised, due to either disease or medication, can still receive HPV vaccine. However, the immune response to this vaccination and its effectiveness may be less than that observed among those who are immunocompetent. Clinical trials to study the effectiveness of HPV vaccination in individuals who are immunocompromised are in progress.

Is HPV vaccination recommended in other countries?

The HPV vaccine that is being used in the UK - Cervarix® - has been licensed in a number of countries worldwide.

What about older girls – are they at risk and will they get the vaccine?

All women who are sexually active are at risk of HPV infection. Risk of a new HPV infection decreases quite markedly for most women over the age of 25 – by this time many women will already have become infected or exchange sexual partners less frequently. For sexually active older women who are already likely to have been infected by HPV, participation in the NHS Cervical Screening Programme (to detect disease caused by existing infection) remains the best way to protect themselves against cervical cancer.

What about boys – are they at risk and do they need the vaccine?

As boys do not suffer from cervical cancer, the benefits of HPV vaccination are less for boys than for girls.

The vaccination of girls will also reduce the transmission of infections to boys. This should lead to a reduction in the rarer forms of cancer caused by HPV in both boys and girls.

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Glossary

Abstinence To refrain, to stop doing something

Allergic reaction A reaction by your immune system to a substance that does not usually affect most people

Anal Of the anus which is the opening at the end of the digestive system where solid waste leaves the body

Anaphylaxis An immediate and severe allergic reaction which needs urgent medical attention

Anogenital Of the genital area including the anus

Antibodies Proteins produced by the body to neutralise or destroy toxins and disease-carrying organisms

Benign Refers to a condition that should not become life-threatening. In relation to tumours, benign means not cancerous

Cancer A group of diseases in which cells grow unrestrained in an organ or tissue in the body; can spread to tissues around it and destroy them or be transported through blood or lymph pathways to other parts of the body

Cervical cancer Cancer of the cervix (neck of the womb)

Cervical intraepithelial neoplasias (CIN) A cervical abnormality that can progress to cancer. CINs are classified as CIN 1, 2 or 3 depending on how much of the epithelium is affected

Cervical screening Cervical screening is a method of preventing cancer by detecting and treating early abnormalities which, if left untreated, could lead to cancer in a woman's cervix. The first stage in cervical screening is either a smear test or liquid based cytology

Cervical screening programme The NHS cervical screening programme was set up in 1988 when the Department of Health instructed all health authorities to introduce computerised call-recall systems and to meet certain quality standards

Cervix The lower part of the uterus (womb) separating it from the vagina

Chemotherapy The treatment of infections or cancer using drugs that act on disease-producing organisms or cancerous tissue

Co-factors Other factors that may influence an outcome

Contraindicated Contraindications are reasons not to use a particular treatment or medication. An aspect of a patient's condition that makes the use of a certain drug or therapy an unwise or even a dangerous decision

Cross-protection The ability of a vaccine that protects against one strain of a virus to provide protection against other, similar strains

Cryotherapy A treatment that uses extreme cold to freeze and destroy diseased tissue

DNA Deoxyribonucleic acid The molecules inside cells that carry genetic information and pass it from one generation to the next

Electrocautery The cauterisation of tissue using electric current to generate heat

Epithelium The layer of cells that covers the body and lines many organs

Fetal/fetus The unborn baby, from the eighth week of pregnancy until birth

Genital tract The organs that make up the reproductive system

Genital wart A growth on the skin in or around the vagina, penis, or anus, transmitted by sexual contact; can cause cancer of the cervix

Genito-Urinary Medicine (GUM) clinic Clinic for the diagnosis and treatment of sexually transmitted diseases

Immune response The body's response to an immunisation or infection

Immune system The immune system is one of the body's defence systems, which helps protect it from disease

Immunocompetent With a well-functioning immune system

Immunocompromised When the body's immune system does not work properly

Intramuscular Into the muscle

Laser therapy The use of a laser (a concentrated beam of light) to perform medical procedures, such as the destruction of tumours

Lesions A lesion is an abnormal change in an organ or body tissue because of injury or disease.

Oncogenic genes that, when altered by environmental factors or viruses, can cause abnormal cell growth

Pre-cancerous Describes a condition from which cancer may develop

Proteins One of the essential constituents of living organisms

Radiotherapy Treatment of a disease, such as cancer, using forms of radioactivity that damage or destroy abnormal cells

Thiomersal A mercury-based preservative used in some vaccines to prevent microbial contamination, or in the process of producing inactivated vaccines.

Treatment Medical care for an illness or injury

Tumour An abnormal growth of tissue

Vagina The muscular passage connecting the uterus to the outside genitals; a component of the female reproductive system

Vaginal intraepithelial neoplasias (VaIN)

A pre-cancerous condition that may progress into vaginal cancer. Like cervical intraepithelial neoplasia (CIN) it is classified as VaIN 1,2 or 3 depending on how much of the epithelium is affected

Vulva The female external genitalia

Vulval Of the vulva

Vulval intraepithelial neoplasias (VIN)

A pre-cancerous condition that may progress into vulval cancer. Like cervical intraepithelial neoplasia (CIN) it is classified as VIN 1,2 or 3 depending on how much of the epithelium is affected

Warts Small growths on the skin caused by the human papillomavirus



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