About Vaccination against Human Papillomaviruses

Human papillomaviruses (HPV)
- Are the most significant cause for the emergence of cervical cancer (cervical carcinoma),
- Cause tissue changes, which are potential precursors of cervical cancer,
- Are responsible for malignant diseases of the external genitals (vulva; penis) as well as of the anus,
- Cause infectious warts (genital warts) of the external genitals,
- Can also cause tumours of the head and neck.

Papillomaviruses are widespread throughout the world and highly contagious. More than 40 virus types of human papillomaviruses (HPV types) are classified as sexually transmittable. Most sexually active people will contract HPV at least once in their lifetime. The highest infection rates are among young adults between the ages of 15 and 24. The majority of HPV infections are of a temporary nature and frequently remain without symptoms. However, HPV infections can also persist and lead to carcinomas of the cervix and in the pubic area (anogenital area), as well as in the oral cavity and in the throat years later through precancerous lesions. Most cases of cervical cancer are registered in women between the ages of 40 and 59. HPV types 16 and 18 alone cause more than 70 per cent of the cancers of the cervix; with the diseases resulting from HPV types 31, 33, 45, 52, and 58, this is approx. 90 per cent. HPV16 is often found in HPV-related head and neck tumours as well as in anal cancers. The genital warts (condylomas) on the external genitals in women and men are caused by HPV types 6 and 11 by more than 90 per cent.

In Germany, 4,600 women on average are currently newly affected by cervical cancer each year and some 1,600 die as a result. Additional HPV-related cancers, such as head-neck tumours or anal cancer affect both genders. Each year, approximately 2,300 HPV-related tumours in men alone are surmised in Germany – of these, approx. 250 are penile cancers.

Vaccine

There are currently two different HPV vaccines available, which are prophylactically effective either against 9 different HP virus types (9-valent vaccine: HPV 16, 18, 31, 33, 45, 52, and 58, as well as HPV 6 and 11) or 2 different HPV types (2-valent vaccine: HPV 16 and 18). These are biotechnologically manufactured, inactivated vaccines containing virus-like particles (particles that are very similar to the natural viruses, but are not infectious and not capable of reproduction). The vaccines also contain aluminium compounds to enhance the effect. The vaccines are approved for preventing cervical cancer and high-grade tissue changes (dysplasias) on the cervix. This is primarily caused by HPV types 16 and 18, as well as 5 other HPV types. Both vaccines are also approved for protecting against precancerous lesions on the external female genitals and of the vagina, as well as of the anus. The 9-valent vaccine also serves to protect against genital warts caused by HPV types 6 and 11.

As a reaction to the vaccine (immune response), the body develops antigens (antibodies). The immune response to the vaccine is many times higher than after a natural infection. The vaccination lasts for 10 years or more; additional findings regarding the duration of protection are expected in the coming years. There is currently no recommendation for a booster vaccination.

Your practitioner can inform you about the start of the vaccination as well as with which other vaccines the HPV vaccination may potentially concurrently be given.

Who should be vaccinated and when?

The HPV vaccination is recommended by the Standing Committee on Vaccination (STIKO) for all girls and boys aged 9 to 14 and should preferably be concluded prior to initial sexual contact. Catch-up vaccinations should be done by the age of 18 (by contrast, the vaccination in Saxony is recommended from 10 to 26 years of age by the Saxon Vaccination Committee). Even previously unvaccinated adults may potentially benefit from the HPV vaccination. Your practitioner can advise you in this regard.

The HPV vaccination is administered in the upper arm muscle. If the vaccination is started from the age of 9 through 14, a 2-dose schedule is applied. Here, the second vaccination dose is administered between 5 and 13 months after the first dose. If the minimum wait period of 5 months is not maintained, a third vaccination must be administered. If the vaccination series is only started as of the age of 15, the 0 - 2 - 6 or 0 - 1 - 6 month vaccination schedule must be applied (depending on the vaccine). The vaccination series should preferably be completed within 1 year for achieving full protection.

Note: It is also important that women who have been vaccinated against HPV never neglect their regular early cancer detection exams, as not all cancer causing HPV types are covered by the vaccination.

The vaccines are not suitable for treatment, but rather they serve exclusively as a prophylaxis.

Who should not be vaccinated?

Those suffering from an acute illness with fever requiring treatment should be vaccinated at a later point. Persons with a known hypersensitivity to a component of the vaccine should not be vaccinated as well. Persons suffering from a disease of the blood coagulation system should be vaccinated with particular caution, as a haematoma may occur on the vaccination site.

Pregnancy and Breastfeeding

There is no sufficient historical experience regarding the application during pregnancy. Thus, a vaccination should only be provided after the conclusion of the pregnancy. However, in general the vaccination may be administered in breastfeeding women.

Behaviour following Vaccination

Persons, who have received the vaccination, do not require any special care; however, unusual physical stress should be avoided within 3 days after the vaccination. For persons, who are inclined to have cardiovascular reactions or in whom immediate allergies are known, the practitioner should be informed of this prior to the vaccination. Due to the occasional occurrence of fainting spells, particularly youth should be vaccinated potentially in a reclined position and observed for 15 minutes following the vaccination.

Potential General and Local Reactions following Vaccination

As an expression of the normal interaction of the organism with the HPV vaccines, redness, swelling, and pain can frequently (> 10 per cent) occur within 1 to 5 days at the vaccination site; in a smaller percentage of those vaccinated, haemorrhaging (“bruise”), itching, sclerosis, dysesthesia or even swelling of nearby lymph nodes may occur.

Swelling and redness may increase somewhat during the second and third vaccination. A fever (> 38° C) frequently occurs (1 to 10 per cent).

As general reactions, headaches (even up to 15 days following vaccination), joint and muscle pain, fatigue and discomfort, gastrointestinal problems or dizziness are frequently observed. Fainting spells occasionally occur (0.1 to 1 per cent) immediately following vaccination as a reaction to the needle puncture, which may be temporarily accompanied by impaired vision, dysesthesia or involuntary movements during the recovery period (see also “Behaviour following Vaccination”).

The specified reactions are normally temporary and subside quickly and inconsequentially.

Are vaccination complications possible?

Vaccination complications are very rare effects of a vaccination exceeding the normal degree of a vaccination reaction, which significantly affect the person vaccinated. Allergic reactions of the skin (rash, hives) have been observed following the HPV vaccination. Immediate allergic reactions, including shock, are very rare. Bronchospasm (spasm of the bronchial muscles) as well as complications of the nervous system (e.g. nerve inflammations, temporary paralyses) are likewise described very rarely in temporal connection with the vaccination; no causal link has been proven.

Consultation with the vaccinating practitioner regarding potential side effects

In addition to this information sheet, your practitioner will offer you an information consultation. If symptoms occur following a vaccination, which exceed the aforementioned quickly passing general reactions, the vaccinating practitioner is naturally available to you for consultation.

You can reach the vaccinating practitioner:

Declaration of Consent

for Providing the Vaccination against Human Papillomaviruses

(Forms with a copy are also available in order to be able to provide a copy to persons receiving the vaccination or their parent/guardian in accordance with the Patient Rights Act.)

Name of the person receiving the vaccine _____

Date of birth _____

I have taken note of the content of the information sheet and have been informed of the vaccination in detail during a discussion with my practitioner.

☐ I have no further questions.

☐ I consent to the recommended vaccination against diseases due to human papillomaviruses.

☐ I am refusing the vaccination. I have been informed of potential drawbacks of refusing this vaccination.

Notes: _____

Location, date: _____

_____	_____
Signature of the person receiving the vaccine or of the parent/guardian	Signature of the practitioner

Disclaimer
The original version (06/2018) of the information sheet was translated for the Robert Koch Institute courtesy of Das Deutsche Grüne Kreuz e.V. The German text is authoritative; no liability shall be assumed for any translation errors or for the relevance of the present translation in the case of a future revision of the German-language original.