



FACT SHEET ON HUMAN PAPILLOMAVIRUS (HPV) VACCINE FOR HEALTH CARE PROFESSIONALS

Human papillomavirus

Human papillomavirus (HPV) is a group of viruses consisting of more than 100 types. Among them, around 40 types infect the human genital tract. They are transmitted through direct contact or sexual intercourse.

'Low risk HPV' types (e.g. HPV 6 and 11) are not associated with cervical cancer. They can cause genital warts and, rarely, warts in digestive and respiratory tracts. HPV 6 and 11 account for more than 90% of genital warts.

Some types of HPV (e.g. HPV 16, 18, 52 and 58) are called 'high risk HPV' as they are associated with cervical cancer. HPV 16 and 18 account for about 70% of all cervical cancer and around 60% of precancerous lesion (high grade Cervical Intraepithelial Neoplasia or CIN) worldwide. High risk HPV can be found in around 50% of atypical squamous cells of undetermined significance (ASCUS), 82-85% of low grade squamous intraepithelial lesion (LSIL) and almost 100% of cervical cancer.

In Hong Kong, surveys showed that the prevalence of HPV infection is 7% - 11% among the women population. The most commonly identified HPV types among cervical cancer specimens are HPV 16 and 18, which account for around 70% of cervical cancer cases. HPV 52 and 58 are found in 12.5% and 8.3% of local cervical cancer cases respectively.

Natural history of HPV infection

Studies have shown that up to 70% of all sexually active women are infected with HPV at some point in their lives.

Approximately 90% of women infected with HPV will spontaneously regress within two years and 10% will develop persistent infection. Women with persistent high-risk types of HPV infection are at risk of developing CIN and cervical cancer.

Currently, there is no antiviral treatment for HPV infection. However, the conditions caused by HPV can be treated, for example, cervical precancerous lesions by local surgery or cryosurgery and genital warts by topical therapy or

cryotherapy.

HPV vaccine

Currently, two recombinant prophylactic HPV vaccines have been developed: a quadrivalent vaccine (against HPV 6,11,16 and 18) and a bivalent vaccine (against HPV 16 and 18). The quadrivalent vaccine contains HPV L1 proteins of the respective HPV types, aluminium - containing adjuvant, sodium chloride, L-histidine, polysorbate, sodium borate and water for injection.

Target population

The vaccine should ideally be given to females before the onset of sexual activity. The vaccine can be given to girls as young as age 9 and girls / women up to age 26, preferably at age 11 - 12. The safety and efficacy of the vaccine have not been evaluated in children younger than 9 years or women older than 26 years.

HPV DNA or serological test is not necessary before vaccination. Females who have not been exposed to the HPV infection will receive full benefits. If girls or women have been infected with the types of HPV contained in the vaccine, the vaccine will not treat the infection.

There is lack of evidence for benefits in vaccinating males. Studies are on-going and any recommendations may have to wait until these results are published.

Route of administration

The vaccine is given in a series of three intramuscular injections over a six-month period for full immunization. The second dose should be given 1 month (for bivalent vaccine) or 2 months (for quadrivalent vaccine) and the third dose should be given at six month (for both vaccines) after the first dose. The vaccine must not be injected intravenously. As there are still no data about subcutaneous and intradermal administrations, these routes of administrations are not recommended.

Vaccine efficacy

The efficacy of HPV vaccine has mainly been studied on young women who had not been exposed to any of the HPV types in the vaccine. Current data showed that both vaccines prevent 100% of HPV 16 and 18 related CIN II/III with a follow-up period of 4.5 years. HPV 16 and HPV 18 infections account for 70% of cervical cancer. The quadrivalent vaccine protects against 90% of HPV 6 and 11 related genital warts. Post-vaccination testing for antibody response is not required. The protection that the women will get after receiving only one or two doses of the vaccine is not yet known. For this reason, it is important to advise women to receive all three doses of the vaccine.

Drug interactions

Results from clinical studies indicated that the HPV vaccine may be administered concomitantly (at a separate site) with hepatitis B vaccine. The efficacy, immunogenicity and safety of the vaccine are not impacted by the use of analgesics, anti-inflammatory drugs, antibiotics and vitamin preparations. Individuals receiving therapy with immunosuppressive agents (such as systemic steroids, antimetabolites, alkylating agents and cytotoxic agents) may not respond optimally to active immunization.

Vaccine safety

Studies so far have shown that the HPV vaccine is safe and causes no serious side effects. Common side effects include pyrexia, erythema, pain and swelling at the injection site. Bronchospasm has been reported as a very rare serious adverse reaction. More data on vaccine safety should be collected from post-vaccination surveillance.

Precautions about the vaccine

The quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast or any component of HPV vaccine. For individuals with thrombocytopaenia or any coagulation disorder, the vaccine should be given with caution. Preliminary research data suggested that the vaccine has no definite adverse effects on pregnancy or the baby. However, pregnant women are recommended to wait until they have completed their

pregnancy. Vaccination of people with moderate or severe illness should be deferred until the illness has improved.

Uncertainty about the vaccine

The duration of vaccine protection is unclear. Current studies indicated that the vaccine is effective for at least 5 years. On-going studies are investigating the long term efficacy of the vaccine and determining whether booster doses are needed.

Cervical screening

The clinical consultation for vaccination provides a good opportunity to offer cytological screening for women who have had sexual activities but not undergone cervical smear testing in accordance with the recommended screening protocol. The cervical screening protocol as recommended by the Cervical Screening Task Force is screening at 3-yearly interval after 2 consecutive normal annual smears for women aged 25-64.

Health care providers should advise vaccinated women that they should continue to receive regular cervical screening as appropriate. This is because the vaccine does not provide protection against all types of HPV, so they will still be at risk of getting cervical cancer that is caused by HPV types not included in the vaccine. Also, women who have already been infected by the types of HPV contained in the vaccine before they are vaccinated may not get the full benefits of the vaccine.

Other ways to prevent cervical cancer

Other measures to reduce the risk of cervical cancer include practising safer sex (such as using condom and avoiding multiple sexual partners), quitting smoking and adopting a healthy lifestyle (such as having diets rich in vegetables or fruits).

Further information

For more information about cervical cancer, Cervical Screening Programme of the Department of Health and HPV, please visit the Cervical Screening Programme website www.cervicalscreening.gov.hk