Recommendation on the Use of Human Papillomavirus (HPV) Vaccine

Background

The HPV, stands for Human Papillomavirus, is known to cause cervical cancer and anogenital warts. There are more than 200 types of papillomavirus and about 40 of which infect human mucosal areas. Among these, HPV-16 and HPV-18 are the most commonly identified high-risk HPV (HR-HPV) associated with cervical cancer whereas HPV-6, HPV-11 are the commonest low-risk (LR-HPV) which cause anogenital warts.

2. Transmission of genital HPV infection is mainly through sexual contact (both vaginal and anal sex) with an infected person. Epidemiologic studies suggest that up to 75% of all sexually active people will eventually be infected with HPV at some point during their lifetime and most infections are subclinical. Many would have acquired the infection soon after sexual debut.

3. In Hong Kong, the HPV prevalence is between 7-11% in those attending cervical screening services and the rate was higher in those visiting social hygiene or colposcopic clinics. Among those with cervical abnormalities, HPV-16 is most commonly identified type and has been found in 33% to 70% of the subjects. Other commonly identified HPV types were 11 and 18. Infection with HPV-58, unlike western countries where the infection is uncommon, is also commonly detected in 3.8% to 31.5% of subjects, depending on the severity of the lesions.
4. Prevention of HPV transmission is through abstinence of sexual activities, practice of safer sex especially use of condom, as well as reducing the number of sex partners. There has not been any study to support transmission of genital HPV through toilet seats, kissing on the mouth, hugging, or holding hands, poor personal hygiene, sharing food or utensils, or swimming in pools or hot tubs.

5. Persistent infection of HR-HPV is a prerequisite for the development of cervical intraepithelial neoplasia (CIN) III lesions and invasive cervical cancers. Other risk factors of cervical cancer include sexual activity at an early age, having multiple sex partners, and smoking.

6. In Hong Kong, cervical cancer is the 5th leading female cancer in year 2004 with 400 to 450 new cases every year. The annual deaths related to cervical cancer ranged from 100 to 150.

7. Cervical cancer may be treated with radiotherapy, surgery, adjuvant chemotherapy or in combination according to the stage at diagnosis. When diagnosed at precancerous stage, the lesion can be effectively managed by less invasive method. Evidence has shown that cervical screening can effectively prevent cervical cancer.

8. A territory-wide Cervical Screening Programme has been launched in Hong Kong since 2004 with the key objective of reducing cervical cancer burden in Hong Kong. Any women aged 25 to 64 with prior sexual experience is recommended to have regular cervical screening once every 3 years, after two consecutive annual smears found to be normal.

**HPV Vaccines**

9. To date, two prophylactic vaccines against HPV infection have become available. GardasilTM is a quadrivalent HPV vaccine, targeting at HPV types 6, 11, 16 and 18, developed by Merck and Co., Inc. It is approved for use in females aged 9-26 years and 3 doses are to be administered at 0, 2, 6 months. CervarixTM, developed by GSK, is a bi-valent vaccine targeting at HPV types 16 and 18. It is approved for use in females aged 10 to 25 years and is to be administered at 0, 1, 6 months. Interchange of the two vaccines is not recommended because there is currently no data on the relevant safety or efficacy.

10. A review of the available safety and efficacy studies showed that protection among the HPV naïve women against lesions that caused by the types of HPV covered by the vaccine was more than 90% in various endpoints, and reached almost 100% against cervical cancer during the study period. The duration of protection is still not yet defined as the longest duration of clinical studies is 4.5 years.
11. The common side effects of these vaccines include mild local reaction, such as erythema, pain and swelling, and systematic adverse effects such as fever, headache and nausea. Adverse event monitoring in the US suggested caution when administered with other vaccines. The vaccine is contraindicated in persons with a history of immediate hypersensitivity to yeast or any vaccine components. Because of limited data, vaccination during pregnancy is not recommended.

Recommendations

12. Based on the currently available evidence, we consider the HPV vaccine is effective and safe. It can be used for protecting individuals against infection of the specific HPV types targeted by the vaccine. The desirable age of vaccination is before commencement of sexual activity.

13. Regular cervical screening according to the recommended screening programme will still be required to prevent cervical cancer among those who have been vaccinated. The vaccine may not provide the same protection against infection of HPV types not included in the vaccine and hence cannot completely eliminate the risk of cervical cancer.

14. Current findings suggested that the vaccine offers at least 4.5 years of protection. There are ongoing studies on whether booster doses will be required in the long run.

15. Taking into consideration the current understanding about the vaccine, healthcare providers are advised to provide adequate explanations to their clients and parents, especially when they are considering for HPV vaccination, about the protection and limitations of the vaccine and other available options, such that informed decisions for individual client can be made.

16. Healthcare providers are also advised to keep good records of their vaccines and vaccinees for the potential need for booster doses, as well as to provide or arrange for cervical screening in accordance with the latest recommendations.

17. While the HPV vaccine has been added to the public health vaccination programme in some countries, its applicability in Hong Kong should be further examined, taking into consideration a number of key issues relevant to the local context. These include programme logistics, acceptability, cervical screening strategies, sex education, and other preventive measures against HPV infection. More research questions on local epidemiological variables in relation to HPV infections, such as the age of sex debut, HPV prevalence, distribution of HPV types in the population at large need to be
answered more precisely. Modelling studies and cost-benefit analysis are also required to evaluate the impacts of the vaccine as well as any potential modifications to the territory-wide cervical cancer prevention strategies in the local setting.

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