

## Executive Summary

The author of this letter is a Chinese American who received formal medical education and training in China from 1951 to 1961, and has practiced laboratory medicine in North America for more than 50 years.

This letter asks for delaying implementation of HPV vaccination of children and young women in China. HPV vaccination is being promoted for cervical cancer prevention by GlaxoSmithKline (GSK), the HPV vaccine manufacturer. The risks-versus-benefits of the proposed HPV vaccination programme should be further discussed before implementation for public interest.

Cervical cancer is a significant cause of death among women in China. About 25,000 women died of cervical cancer in 2012 according to a report published by the National Office for Cancer Prevention and Control, National Central Cancer Registry, National Cancer Institute, Beijing. In the same year, about 183,000 of women died of lung cancer, 93,000 of stomach cancer, 83,000 of liver cancer, 68,000 of colorectal cancer, 62,000 of esophageal cancer, 62,000 of breast cancer, and 33,000 of pancreatic cancer. This shows that the number of female deaths caused by cervical cancer in China ranks No.8 following the above mentioned 7 kinds of cancer.

Although cervical cancer is not a leading death-causing cancer of women, it is the most preventable death-causing cancer by periodic screening followed by treatment of precancerous lesions after detection, as demonstrated by the past experience in the developed countries of the world. Now, cervical cancer is primarily a disease among unscreened or rarely screened women in the developed countries. The proven effective approach to prevent cervical cancer for China is implementation of a general cervical screening programme as part of routine women's health care.

In the 1980's, the discovery that infection by certain high-risk human papillomavirus (HPV) types may become persistent, and persistent HPV infection may lead to certain abnormal, but self-reversible cellular changes in the cervical epithelium. In rare cases, these cellular self-reversible changes, called CIN2 lesions, may progress to precancer or cervical cancer.

Since HPV 16 or HPV 18 was found in about 70% of the cervical cancers of the patients from America and Europe, vaccine manufacturers have developed HPV vaccines against these two HPV genotypes to prevent the infection by HPV 16 and HPV 18. However, the vaccines developed for the American and European populations may not suitable for women living in China. For example, HPV 52 and HPV 58 have been reported to be as prevalent as HPV 16 and HPV 18 in the cervical cancers of a group of Chinese women patients living in Shanghai. It is possible that other HPV genotypes are more commonly associated with cervical cancers of patients living in other provinces.

Since HPV vaccines are genotype-specific, more research on HPV genotype distribution among women living in different regions of China should be conducted before any HPV vaccine is adopted for the population. China is a big country with many ethnic groups in different regions. If an HPV vaccination is considered, perhaps, it needs more than one version of HPV vaccine in China.

The public and health care policy makers in China should be informed that HPV vaccination has not been shown to prevent a single case of cervical cancer in any clinical trials. The claim for the HPV vaccine efficacy is based on analyzing surrogate endpoints, such as the self-reversible histology changes in the cervical epithelium as a result of HPV infection and HPV infections which are also self-reversible. Cervical cancer has not been used as an endpoint for vaccine efficacy evaluation in these clinical trials.

The public and health care policy makers in China should also be informed that HPV vaccination has been associated with a higher rate of serious adverse reactions among the vaccines than other vaccinations against infectious diseases. Many of the vaccinated adolescents have suffered permanent disabling disorders after HPV vaccination, and some poorly understood sudden unexpected deaths have been reported after HPV vaccination.

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