

# INTRODUCTION OF HUMAN PAPILLOMAVIRUS (HPV) VACCINATION IN SWEDEN

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The Swedish National Board of Health and Welfare (NBH) decided that a vaccine that protects against cervical cancer caused by human papillomavirus (HPV) should be included in the childhood vaccination directive as a nationwide-programme targeting 12-year-old girls from 2010 as a part of the school-health programme. Currently, vaccination of girls 13-18 years of age is covered by the public insurance. In this paper we describe the decision-making process behind the introduction of HPV vaccination in Sweden.

Sweden, as many other countries, has a fairly complicated system for decision-making on introduction and financing of new vaccines in the national vaccination-programme. The programme is currently regulated by directives and recommendations from the National Board of Health and Welfare (NBH). The programme is implemented and financed by the counties through child health clinics (for children aged up to five years) and by the communities through the school-health system (for children from the age of six years).

In response to the number of candidate vaccines that have become available on the market in recent years, the NBH has established a ten-point list of factors to be evaluated for new vaccines [1]. The NBH then appoints an expert-group for a vaccine that is considered a possible candidate for introduction, to collect the knowledge about the vaccine following this general outline. This is further analysed by the NBH in a dialogue with responsible stakeholders in the field before a final decision on the inclusion of the vaccine in the directive on childhood vaccinations can be taken.

For the vaccination against human papillomavirus (HPV), this work started in 2007. The expert group concluded that HPV infection was established as a cause of cervical cancer, condylomas, vulvar cancer, vaginal cancer, anal cancer and tonsillar cancer and that HPV16/18 infection annually contributed to about 500 cases of cancer and about 200 cancer deaths per year in Sweden [2]. Approximately 38,000 annual cases of condyloma were estimated to be caused by HPV6/11 [2]. Modelling of the infection based on Swedish serosurveys and sexual behaviour data indicated that the largest health gains would be seen by vaccination of girls aged 12-18 years [2,3].

Based on the report from the expert-group, the NBH decided that a vaccine that protects against cervical cancer caused by

HPV should be included in the childhood vaccination directive as a nationwide-programme targeting 12-year-old girls from 2010 as a part of the school-health programme. The directive specifies for which diseases vaccines should be offered but not what vaccines should be used. The NBH also decided that an introduction could only be recommended if an extensive follow-up programme was implemented. This is in line with the World Health Organization (WHO) recommendations of follow-up for coverage, safety and population effectiveness and its aim is also to ensure that the screening programme continues to be at least as effective as today [4].

In the meantime, both available vaccines have already been included in the national pharmaceutical products insurance programme, meaning that all girls 13-18 years of age can get the vaccine covered by the public insurance, which ensures that any family will not pay more than 180 euros for medicines prescribed by a physician for their children during a year. This coverage starts at the age of 13 years not to interfere with the vaccination programme but rather to complement it.

The follow-up programme is currently being developed as a project by NBH. The vaccination-coverage needs to be followed and the current system can be used for the vaccinations given in schools. To follow the effect on an individual level, an HPV vaccination registry was launched concomitantly with the first licensure of HPV vaccines in Sweden in 2007. The registry has used the legal basis for research projects (informed consent and international review board (IRB) approval) with informed consent brochures enclosed with the vaccine dose packages. Consent includes permission to follow with registry linkages and to do HPV testing of biospecimens that may later be taken during routine healthcare.

An early effectiveness at population level is obtained by laboratory-based surveillance of incidence of specific virus types. To do this, laboratory capacity and quality needs to be in place. For the quality assurance the WHO HPV LabNet Global Reference Laboratory which is located in Sweden plays an important role. It performs international collaborative studies and proficiency panels for quality assurance and international standardisation of HPV DNA typing and HPV serology [5,6]. The collection of viral samples in

Sweden will be further strengthened by a directive for HPV typing of samples from all women with CIN2-3 changes.

Finally and most importantly, coordination between vaccine monitoring and quality assurance of the cervical screening will be vital to assess the overall impact of the cervical cancer preventive strategies. The nationwide registration of all cervical smears is an essential part of a coherent evaluation strategy [7].

### Conclusion

Sweden has pursued implementation of HPV vaccination with high ambitions in providing a solid evidence base for decisions, logistics likely to favour very high population coverage as well as extensive and careful HPV surveillance programmes for monitoring of HPV vaccine programme effectiveness as a part of the cervical cancer prevention programme.

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