Rapid communications

EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL ISSUES GUIDANCE FOR THE INTRODUCTION OF HUMAN PAPILLOMAVIRUS (HPV) VACCINES IN EUROPEAN UNION COUNTRIES

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Two prophylactic human papillomavirus (HPV) vaccines have been licensed in Europe: the quadrivalent vaccine, Gardasil® (Sanofi Pasteur MSD) and the bivalent vaccine, Cervarix® (GlaxoSmithKline Biologicals) [1,2]. Both vaccines are made from virus-like particles and are non-infectious [3]. Both vaccines protect against the high-risk HPV types 16 and 18, which cause an estimated 73% of cervical cancer cases in Europe. Gardasil also protects against HPV 6 and 11, which cause most cases of genital warts. Both vaccines have a good safety profile. They have been shown to prevent more than 90% of precancerous lesions associated with types 16 or 18 among HPV naïve women in clinical trials [4].

Cervical cancer is the second most common cancer after breast cancer among women aged 15-44 years in the European Union (EU). Each year, there are around 33,000 cases of cervical cancer in the EU, and 15,000 deaths [5]. Persistent infection of the genital tract by a high-risk HPV type is a necessary, although not sufficient cause of cervical cancer [6]. Genital HPV infections are very common and are usually acquired soon after onset of sexual activity [7]. Most of these infections are clinically asymptomatic and spontaneously cleared. However, persistent HPV infections with a high-risk HPV type can cause cellular changes of the cervix that can progress to cervical cancer. High-risk HPV types are also associated with other ano-genital cancers, and some head and neck cancers in both men and women. Some other HPV types (referred to as low-risk) cause genital warts in both men and women.

The European Centre for Disease Prevention and Control (ECDC) has issued “Guidance for the Introduction of HPV Vaccines in EU countries” on 22 January 2008, at the request of the European Commission and several of the EU Member States [8]. Coordinated by ECDC, a scientific panel of independent experts* was set up to analyse scientific evidence for the introduction of HPV vaccines and list the policy options available to the Member States. The guidance document highlights the issues to be considered and lays down a scientific basis to support policy decisions across the EU.

HPV vaccines are becoming introduced in an increasing number of countries and EU policymakers are urged to consider HPV vaccination [9]. This guidance note should help facilitate this process. The target audiences for the guidance are national immunisation programme managers, policymakers at EU and national level, and experts involved in the decision making process on introduction of HPV vaccines.

To date, there is only about five-year follow-up data from the HPV vaccine studies and many questions remain to be answered in addition to duration of protection. This guidance note, made on the basis of current knowledge will probably need to be reviewed in 6 to 12 months.

HPV vaccines and cervical cancer screening
Well organised cervical cancer screening programmes are proven to reduce cervical cancer incidence by as much as 80-90% in women attending for screening [10]. HPV vaccine offers a complementary tool to improve the control of cervical cancer but does not eliminate the need for cervical cancer screening. Women need to be informed and motivated to attend screening programmes, even if they are vaccinated against HPV 16 and 18. One of the most important challenges will be to achieve integrated vaccination and screening strategies in a cost-effective way with the maximum benefit for women.

Who should be vaccinated?
The primary target group for routine vaccination is young adolescent girls before they become sexually active. Targeting older girls and young women with catch-up vaccination could increase vaccination benefits in the short term. Country-specific factors are important to determine the exact age for routine vaccination, and the ages for any catch-up vaccination.

Strategy options for HPV vaccine delivery in EU countries
School-based immunisation is likely to be the lowest cost option for delivery of HPV vaccines to pre-adolescent girls. However, local issues, such as whether there are school-based health services, funding arrangements for vaccine purchase and administration, and obtaining parental consent may affect the feasibility of this approach. Clinic or practice-based immunisation is a universally available additional or alternative option for HPV vaccine delivery. Sexual and reproductive health and other medical clinics provided specifically for women may be important sites for immunisation.

Modelling costs and outcomes of HPV vaccination
HPV vaccination should be evaluated not only for its effectiveness, but also from an economic point of view. Studies undertaken in a number of countries seem to indicate that HPV vaccination of pre-adolescent girls has a favourable cost-effectiveness profile. Economic evaluations are, however, not entirely exportable, due to the variability of costs and healthcare systems in different
countries. Therefore, efforts should be made by each country to perform economic evaluation, taking into account existing cervical cancer prevention programmes, before taking a decision on the best strategy to prevent cervical cancer.

Monitoring and evaluating the impact of HPV vaccination

Post-licensure evaluation of the HPV vaccines will need to determine vaccination uptake and compliance, long-term efficacy and effectiveness of the vaccines, vaccine safety and herd immunity. Coordination between vaccine monitoring and cancer control programmes will be critical to assess the impact of the vaccine and its benefits compared with other existing prevention interventions such as screening. The minimum set of information to monitor HPV vaccination should include data on vaccine coverage, monitoring of adverse events following immunisation and surveillance of impact on pre-cancer lesions.

*The scientific panel was coordinated by Françoise Hamers and Pierluigi Lopalco from the Scientific Advice Unit at ECDC. It was chaired by Patricia Clayes (University of Ghent, Belgium) and included five other members: Kari Anttila (Finnish Cancer Registry, Finland), Paolo Bonati (University of Florence, Italy), Adam Finn (Institute of Child Life and Health, UK), Daniel Lévy-Bruhl (Institut de veille sanitaire, France), and Kate Soldan (Health Protection Agency, UK).

References


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