PRESS INFORMATION

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ECDC Factsheet on HPV Vaccines

Introduction

Following the authorisation of two Human Papillomavirus (HPV) vaccines by the European Commission in 2006-7, ECDC is today publishing *"Guidance for the Introduction of HPV Vaccines in EU countries"*. 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 lays down a scientific basis to support policy decisions across the European Union (EU).

The target audiences for the Guidance are national immunisation programme managers, policy makers at EU-level and at national level, and experts involved in the decision making process on introduction of HPV vaccines.

Cervical Cancer and HPV Infections in the EU

Cervical cancer is the second most common cancer after breast cancer affecting women aged 15-44 years in the EU. Each year, there are around 33 000 cases of cervical cancer in the EU, and 15 000 deaths. The primary cause of cervical cancer is persistent infection of the genital tract by a high-risk HPV type.

Genital HPV infections are very common and acquired soon after onset of sexual activity. Most of these infections are spontaneously cleared. However, persistent HPV infections with a high-risk HPV type can cause cellular changes of the cervix that can result in cervical cancer. High-risk HPV types are also associated with other ano-genital cancers, and head and neck cancers in both men and women. Some low-risk HPV types cause genital warts in both men and women.

The HPV Vaccine

Two prophylactic HPV vaccines have been licensed in Europe: the quadrivalent vaccine, Gardasil® (Sanofi Pasteur MSD) and the bivalent vaccine, Cervarix® GlaxoSmithKline Biologicals). Both vaccines are made from virus-like particles and are non-infectious. Both vaccines have a good safety profile. Both vaccines protect against the high-risk HPV types 16 and 18, responsible for an estimated 73% of cervical cancer cases in Europe. Gardasil also protects against HPV 6 and 11, which cause most cases of genital warts. In large phase III trials both vaccines have shown to prevent more than 90% of precancerous lesions associated with types 16 or 18 among HPV naïve women. The vaccines are given in three doses over a 6-month period.

HPV vaccines and cervical cancer screening

Well organised cervical cancer screening programmes that achieve high coverage and include effective follow-up and treatment of women with abnormal cytology have been proven to reduce cervical cancer incidence by over 80%. Organised screening

programmes are more successful than opportunistic screening in reaching the women most at risk, in establishing mechanisms for quality control, and in monitoring standardised measures of activity and impact. The HPV vaccine offers a new, complementary tool to improve the control of cervical cancer. However, it does not eliminate the need for cervical cancer screening even for women vaccinated against HPV types 16 and 18 who will still be at risk from other high-risk types.

Who should be vaccinated?

To optimise the impact of the new vaccines on HPV-associated disease, the primary target group to consider for routine vaccination is girls at the age just before sexual activity (and therefore HPV infections) begin to become common in that group. Lowering the age of vaccination below this age would not prevent many infections and should be avoided until there is evidence that the vaccine has a long duration of protection (more than 15-20 years). Targeting slightly older girls and young women with catch-up vaccination at the start of a routine vaccination programme is likely to accelerate the impact of the vaccination programme and increase vaccination benefits in the short term. Country-specific factors will be important to determine the exact year of 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 efficacy, but also from an economic point of view. Economic evaluation aims to determine whether the cost incurred by the society to save a year of life adjusted by its quality (quality adjusted life year or QALY) due to HPV vaccination is similar to that of other commonly accepted interventions in the medical care sector.

Monitoring and evaluating the impact of HPV vaccination

Post-licensure evaluation of the HPV vaccines will need to determine the vaccine uptake and compliance, long-term efficacy and effectiveness of the vaccines, integration of vaccination with other strategies such as organised cervical cancer screening, and vaccine safety. 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 intervention 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.

Final remarks
To date, only 5-year follow-up data on the HPV vaccines is available and many questions remain to be answered. The Guidance therefore will need to be re-evaluated in 6-12 months.

Information on the Scientific Panel

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