

PRESS RELEASE

Focus on reaching all girls says ECDC updated HPV vaccination Guidance

Stockholm, 5 September 2012

ECDC publishes today an update to its 2008 guidance on human papillomavirus (HPV) vaccines in Europe in light of the introduction of vaccination programmes in 19 European countries¹ and new evidence from research studies in the past four years. Randomised trials and observations from the field have demonstrated good safety profiles and efficacy against cervical cancer precursors. In spite of this, and that most of these countries are providing the vaccine for free, vaccination rates are lower than expected. Vaccinating girls is shown to be more cost-effective than vaccinating boys. ECDC's guidance is that public health initiatives should continue to focus on vaccinating girls.

Among the deterring factors for the slow uptake are the cost of the vaccine and the regime of three doses in six months. Routine vaccination targets girls between ages 10 to 14 years as the vaccines are clinically proven to be most effective when administered before the onset of sexual activity. These girls require parental permission to be vaccinated therefore the role of parents and healthcare workers is of utmost importance.

Nineteen countries out of the 29 EU/EEA countries have introduced HPV vaccination programmes following the authorisation of the vaccines but vaccination rates in EU countries range from only 17 to 84%. In 2010, only Portugal and the United Kingdom had full vaccination coverage rates above 80% for the target groups out of the seven countries reporting this data.

ECDC Director Marc Sprenger said: "We, public health authorities, frontline healthcare workers and parents alike, have a shared responsibility to protect thousands of women from cervical cancer. We need to work together to ensure that all girls between 10 and 14 years of age are vaccinated. European countries may need to examine why HPV vaccination coverage rates in their countries are not higher and strengthen their vaccination campaigns accordingly."

Since its introduction by some European countries in 2006 the inclusion of boys in HPV vaccination programmes has been an open question. Only the quadrivalent HPV vaccine has been evaluated for men but current data shows that it gives the same, if not better, levels of efficacy for boys as girls of the same age groups. But the personal benefit of the vaccine for men in terms of cancer prevention is very low, most likely resulting in few boys being vaccinated and low vaccination coverage rates.

Marc Sprenger said "ECDC's conclusion is that including boys in the current HPV vaccination programmes is unlikely to be cost-effective. A better investment of public resources is to focus on immunising all girls. This issue can be re-assessed when vaccination costs are significantly reduced."

¹ The nineteen countries that have introduced HPV vaccination programmes are: Austria, Belgium, Denmark, France, Germany, Greece, Iceland, Ireland, Italy, Latvia, Luxembourg, the Netherlands, Norway, Portugal, Romania, Slovenia, Spain, Sweden, the United Kingdom.

Malta is in the process of implementing its decision to vaccinate all 12 year old girls in the coming months.

The [2008 ECDC Guidance](#) recommends that HPV vaccines should be given in three doses within six months. This update does not alter that recommendation. However, a clinical trial showed no significant difference in vaccine efficacy whether two doses or one dose were administered, compared to the three dose protocol. These findings need further research and if confirmed, will have a great impact on costs and strategies for HPV vaccination programmes.

MORE INFORMATION:

HPV vaccine and the 2008 Guidance

Following the authorisation of two HPV vaccines by the European Commission in 2006-7, ECDC published "Guidance for the Introduction of HPV Vaccines in EU countries" in January 2008. 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.

Cervical Cancer and HPV vaccines

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 anogenital cancers, and head and neck cancers in both men and women. Some low-risk HPV types cause genital warts in both men and women.

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 have a good safety profile and new evidence on the efficacy and safety of the vaccines continue to indicate this. See section 2 and appendix 1 of the updated Guidance. 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. The vaccines are given in three doses over a 6-month period. They do not cure existing infections so the evidence for administering to older girls and women is unclear.

Importance of cervical cancer screening

As concluded in the 2008 Guidance, 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% among screened women. 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.

HPV vaccination and boys/men

The rationale for vaccinating boys with the HPV vaccine boys would be effective in the prevention of HPV-related conditions in men, such as condylomata, penile cancer, anal cancer and oro-pharyngeal cancer. Furthermore, universal vaccination for men would prevent cervical cancer in women via herd immunity. Only the quadrivalent HPV vaccine has been evaluated for efficacy in men and is approved for use in males. The bivalent vaccine has not been assessed. The vaccines are also well tolerated and safe. Despite the short follow-up time of the clinical trials, the effectiveness of the quadrivalent vaccine in preventing persistent infections and HPV-related morbidities in boys seems to be high.

In spite of the benefits of the vaccination, current economic models show that including boys in the current HPV vaccination programmes is unlikely to be cost-effective. In all scenarios economic analyses render a much higher cost-effectiveness ratio for campaigns aimed at improving vaccination coverage rates in females. The cost-effectiveness of including boys in HPV vaccination programmes can be re-assessed when more solid data are available for baseline assumptions, and especially if vaccination costs are significantly reduced in the future.

ADDITIONAL LINKS

- [Update to ECDC 2008 Guidance on HPV Vaccination](#)
- [ECDC 2008 Guidance on HPV Vaccination](#)
- [HPV health topic pages on ECDC website](#)
- [European Medicines Agency, responsible for the scientific evaluation of medicines developed by the pharmaceutical industry](#)
- [2nd Edition of the European Guidelines on Quality Assurance in Cervical Cancer Screening](#)

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The European Centre for Disease Prevention and Control (ECDC) is an EU agency tasked with identifying assessing and communicating threats to human health posed by infectious diseases. It supports the work of public health authorities in the EU and EEA/EFTA Member States.