

HPV vaccine safety profile

Point of view of Public Health Authorities (Europe & Australia)

HPV vaccination in Europe, strengths and weaknesses

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Two vaccines against Human Papillomavirus (HPV) are available in the EU for cervical cancer prevention. Marketing authorization has been granted by the European commission to Gardasil in 2006 and to Cervarix in 2007. The European Medicine Agency (EMA) is responsible for the scientific evaluation of vaccines, as well as other human and veterinary drugs, including safety monitoring. The EMA is also responsible for maintaining EudraVigilance, a reporting system for side-effect reports. Through Eudravigilance, EMA manages signal-identification activities, rapid-alert, and responses to new safety signals in the EU. Safety records of both vaccines are very good, considering the evidence collected through both clinical trials and post-marketing surveillance. A recent study (a meta-analysis conducted selecting 7 different clinical trials, including about 44,000 women) showed that risk of serious adverse events was equal between vaccinated and not vaccinated women [1].

Introduction of HPV vaccination in the EU has been extremely quick, as compared to other newly licensed vaccines like pneumococcal, varicella or rotavirus. A total of 22 out of 31 EU/EEA countries have implemented a routine HPV vaccination programme [2]. Ten EU countries have also implemented catch-up programmes for a wider range of age groups (with the highest upper-limit of 40 years in Austria). In most cases the HPV vaccination programme is covered by the national health insurance system; in few cases vaccination is fully (Austria) or partially (Belgium and France) covered by the recipient.

However, reported vaccination coverage has been suboptimal in most of the EU countries. Only in UK and Portugal reported coverage in targeted age groups above 80%. The same applied to coverage for catch-up campaigns that ranged from 29% to 73% of the targeted population [2].

Lack of effective communication strategies might be the reason for the limited vaccine uptake in many EU countries. In fact, rumours of alleged serious adverse events after HPV vaccination has been strongly detrimental for the success of the vaccination programme in several EU countries. The EMA has been called several times during the last years to reply to rumours on HPV vaccine safety. Every time, EMA's conclusion after careful assessment of the evidence, has been reassuring about the absence of correlation between HPV vaccination and alleged adverse events.

Events like sudden death, convulsions, autoimmune diseases (rheumatoid arthritis, multiple sclerosis, etc.) can happen to be coincidental with HPV vaccination, being those vaccines administered to adolescent or young women. Robust evidence has been collected so far to confirm the absence of causal link between HPV vaccination and such unfortunate events.

References

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Experience with human papillomavirus vaccination (HPV) in Australia: the girls and women of France can be reassured that the vaccine is safe and the benefits are real

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Australia was the first country in the world to introduce a government funded national HPV vaccination program in April 2007, using a course of three doses of the quadrivalent HPV vaccine ('Gardasil'). The program offered vaccination to all females aged 12 to 26 years until the end of 2009 and is now an ongoing program for both girls and boys, which is delivered in the first year of high school at age 12- 13 years.

The program has delivered over 5.6 million doses of the vaccine to Australians so far, with a national vaccine register in place to monitor the uptake of the vaccine. Over 70% of school girls in Australia receive all three doses of the vaccine (1). The safety of the vaccine has been monitored in Australia throughout the program, with Australian reports confirming that the most common side effects of vaccination are local reactions at the site of injection and symptoms relating to the process of being vaccinated, such as headache and nausea. Fainting has also been reported in Australia and rare cases of allergic reactions (anaphylaxis) – both of these conditions can occur with any vaccine and can be managed appropriately and safely by experienced vaccination teams/practitioners. Of direct relevance to the situation in France, cases of suspected multiple sclerosis that occurred among women who had been vaccinated were also investigated in Australia. Reassuringly an in-depth investigation found that there was no increase in the development of multiple sclerosis/ demyelination disorders after HPV vaccination (2). In Australia, as in other countries, young women are in the age group at which serious illnesses such as multiple sclerosis can first develop. This means that reports such as these need to be thoroughly investigated but that if there is no increase in the rate at which the disease occurs among vaccinated women compared to those who are not vaccinated, then it does not support the vaccine causing the disease.

The Australian experience now forms part of the international experience with HPV vaccines which have been given to many millions of women and are demonstrably very safe and effective. Their safety has been confirmed in very large clinical trials prior to licensure, in surveillance data from multiple countries and in large scale studies which directly compare the health of vaccinated and unvaccinated women over time (3)(4). Parents and girls should feel reassured that these vaccines have been incredibly well studied and that all findings to date have shown that the vaccines are safe (5).

Australian data have shown that the HPV vaccine is already benefiting our population. We have recorded large falls in rates of infection with the HPV types the vaccine protects against (6), in genital warts (7) and in precancerous lesions of the cervix (8)(9).

It is truly a remarkable age in which to live, when we can protect our children against being infected with a cancer causing virus. We hope that the people of France will choose to support science over fear, knowing that the HPV vaccines have been well studied, indeed scrutinized, and found to be safe.



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