

A PHARMACOVIGILANCE STUDY ON THE SAFETY PROFILE OF HPV VACCINES IN THE MALE POPULATION: DATA FROM US VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

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Background: Human Papilloma Virus is one of the most common sexually transmitted infection, responsible of cervical cancer, anal cancer, cervical intraepithelial neoplasias and genital warts. It affects both men and women. To date three HPV vaccines are available: Gardasil®, Gardasil9® and Cervarix®. Our aim was to contribute to the analysis of the safety profiles of HPV vaccines in the male population.

Methods: We reviewed all the reports of Adverse Events Following Immunization (AEFI) reported in the US Vaccine Adverse Event Reporting System (VAERS) from January 2006 to September 2018. We focused on males aged 6-29 years. The analysis was performed using the Reporting Odds Ratio with 95% confidence interval and p value $\leq 0,05$, as statistical parameter to evaluate vaccine – event pairs distribution.

Results: A total of 5,493 reports of AEFI were retrieved in the database. Of these, 354 were serious. The main AEFIs experienced by males were: syncope (N=701, ROR= 2,85, CI 1,414- 5,757), loss of consciousness (N=425, ROR=2,79 CI 1,358- 5,718), fall (N=272, ROR= 3,54 CI 2,003- 6,265), immediate post- injection reaction (N=208, ROR=3,40 CI 1,877- 6,158), presyncope (N=122, ROR= 4,13 CI 2,513- 6,779), dyskinesia (N=104, ROR= 2,90 CI 1,447- 5,817), others AEFIs described were nausea, vomiting, fatigue and hyperhidrosis. ADRs reported in males and females are similar. All ADRs are listed and reported in the Summary of Product Characteristics of the corresponding vaccine.

Conclusions: The HPV vaccine was generally well tolerated in men. Despite government recommendations, HPV vaccination coverage is still low. It's necessary to spread a positive approach to immunization. The extension of HPV vaccines to males will probably help to prevent more HPV-related cancers in both females and males.