



Critically Appraised Article

Impact of low prevalence of vaccine serotypes in North American women, on the use of human papillomavirus vaccine (HPV)

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Structured abstract:

Objective: to determine the prevalence of HPV (PHPV) in women of the United States.

Design: a representative sample is obtained by using a complex, stratified, multistage probability sample design with unequal probabilities of selection to obtain a nationally representative simple of the civil population of the United States from the National Health and Nutrition Examination Survey (NHANES) All females aged 14 to 59 years selected for NHANES 2003-2004 were eligible for participation in this study.

Location: the United States at a national level.

Study population: 2.026 women of the 2.482 who were interviewed with ages ranging from 14 to 59 years, submitted cervicovaginal swab specimens.

Risk factor evaluation: a questionnaire for demographic data and sexual behavior was done by home interview: females aged 14 to 59 years were asked to self-collect a cervicovaginal sample in the mobile examination center. The analysis of the viral DNA was made by PCR and type specific hybridization. Informed consent was obtained for all the participants and for those aged less than 18 years paternal consent was asked for. Serotypes 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 52, 56, 58, 59, 66, 68, 69, 70, 73, 80, 85 y ISR39 were considered of high risk.

Main outcome measures: the global PHPV was 26,8 % (95% confidence interval [CI]: 23,3%-30,9%). By age groups, PHPV was 24,5% (95% CI: 19,6%-30,5%) between 14 y 19 years, 44,8% (95% CI: 36,3%-55,3%) between 20 y 24 years, 27,4% (95% CI: 21,9%-34,2%) between 25 y 29 years, 27,5% (95% CI: 20,8%-36,4%) between 30 y 39 years, 25,2% (95% CI: 19,7%-32,2%) between 40 y 49 years, y 19,6% (95% CI: 14,3%-26,8%) between 50 y 59 years. This study shows a yearly statistically significant increase of PHPV ($p < 0,001$) from 14 to 24 years of age, followed by a not statistically significant gradual descent until 59 years ($p = 0,06$). The viral types 6 and 11 (low risk) and 16 and 18 (high risk), included in the tetravalent vaccine were detected in 3,4 % of the women, appearing at least in 6,2 % (95% CI: 3.8%-10.3 %) in the group aged from 14 to 19 years. Age, marital status, and number of sexual partners were independent risk factors for the detection of HPV, and significant sociodemographic differences between the respondents and the non respondents were

detected. Viral DNA was detected in 5,2% of women that declared not having sexual relations (88% in the group of 14 to 19 years of age), associated in some cases with other sexually transmitted diseases, making doubtful the veracity of the sexual history.

Author conclusion: the PHPV in women in the United States is greater than previous estimates, with a maximum between 20 and 24 years of age. However, the PHPV of types included in the vaccine is relatively low.

Competing interests: none declared.

Financial source: Division of STD Prevention, Centers for Disease Control and Prevention.

Commentary:

Justification: HPV infection is the most frequent sexually transmitted disease in the United States and a necessary condition for the development of uterine cervix cancer (UCC) and possibly other genital cancers¹. There are 100 viral types described, and 15 are considered as high risk for cancer. Low risk types are associated with condilomas, respiratory recurrent papillomatosis, and low grade changes in the cells of the cervix. The tetravalent vaccine against HPV, approved by the FDA in June 2006 and with an efficacy of 100% has made the Advisory Committee on Immunization Practices (ACIP) of the CDC recommend the routine administration in girls of ages 11 to 12 years². Knowledge of the pre vaccination PHPV can help to evaluate the impact that the vaccine will have in the reduction of infection, principally of the types 6, 11, 16, and 18.

Validity: in this study sociodemographic differences were detected between Women that answered ($n = 1.921$) and those that did not answer, or whose vaginal swab collection was not sent or inadequate ($n = 466$ or 23%), which could cause an estimation bias of the PHPV. On the other hand, the system of sampling is not described and the self-collection of the cervicovaginal swab has a sensibility of 74%³. Due to the fact that many infections cure spontaneously, the study can only take into account the presence of HPV, not allowing the estimate of the incidence cumulative to be estimated, or persistent infection after repeated exposure.

Clinical relevance: this study documents the prevalence

of HPV in the United States and the low prevalence of the viral types of the vaccine. On the other hand, it shows the feasibility of the method for self-collection of a cervicovaginal swab by the women for the detection of viral DNA.

Applicability in clinical practice: the efficacy of the vaccine for the prevention of premalignant disease in women is high⁴. The women in the United States have a low prevalence of the HPV serotypes included in the vaccine.; it is important to know these data of baseline population prevalence for Spain. In relation to UCC, Spain has the lowest adjusted incidence rate of all Europe (7.6/100,000 women) with a mortality of 3.1/100.000 women⁵. In our country, screening for UCC has a very variable rate of cover, with great variability in the inclusion criteria (age of initiation and periodicity). The identification of HPV and this vaccine will probably force a restructuring of the screening methods for UCC⁶.

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