Human papillomavirus vaccine trials and tribulations

Vaccine efficacy

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Learning objectives
After completing this learning activity, participants should be able to identify the timeframe for efficacy of the human papilloma virus vaccines currently available; list the human papilloma virus vaccines recommended for various patient populations; and discuss study data comparing the cost effectiveness of human papilloma virus vaccinations in the United States.

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As of December 2014, there were 3 approved vaccines for human papillomavirus (HPV): bivalent Cervarix (GlaxoSmithKline, New York, NY), quadrivalent Gardasil (Merck and Co, Kenilworth, NJ), and 9-valent Gardasil-9 (Merck and Co). The average cost per dose is $120, with a recommended 3-dose course. The quadrivalent vaccine is the most widely administered worldwide. As with the bivalent and 9-valent vaccines, the vaccine is considered safe, although concerns have been raised. In addition to immunization against the targeted HPV types, there is evidence that there is cross protection against other types of HPV. This continuing medical education review evaluates the differences in vaccines that are currently on the market; part II focuses on the cost-effectiveness of vaccination, the HPV vaccination programs currently instituted around the globe, efficacy, and safety. (J Am Acad Dermatol 2015;73:759-67.)

Key words: anal cancer; Cervarix; cervical cancer; condylomas; Gardasil; human papillomavirus; vaccine.

INTRODUCTION

Key points

- **The quadrivalent human papillomavirus vaccine is recommended for both boys and girls**
- **The bivalent human papillomavirus vaccine is recommended for girls only**
- **The 9-valent human papillomavirus vaccine is recommended for both boys and girls**

The current recommendation by the Advisory Committee on Immunization Practices (ACIP) for human papillomavirus (HPV) vaccine dosing is for females to receive either the bivalent HPV or quadrivalent HPV vaccine at 11 or 12 years of age; males are approved only to receive the quadrivalent HPV vaccine at 11 or 12 years of age.[1] The 9-valent vaccine has been approved by the US Food and Drug Administration (FDA) for

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Abbreviations used:

ACA:	Affordable Care Act
ACIP:	Advisory Committee on Immunization Practices
AIN:	anal intraepithelial neoplasia
CDC:	Centers for Disease Control and Prevention
CHMP:	European Committee for Medicinal Products for Human Use
CIN:	cervical intraepithelial neoplasia
FDA:	US Food and Drug Administration
HPV:	human papillomavirus
ICER:	incremental cost-effectiveness ratio
MSM:	men who have sex with men
MSW:	men who have sex with women
OPSCC:	oropharyngeal squamous cell carcinoma
QALY:	quality-adjusted life year
VLP:	virus-like particle

females 9 to 26 years of age, but the vaccine has not yet been added to the ACIP dosing schedule (Table I). Females are also recommended to receive the vaccine between 13 and 26 years of age and males between 13 and 21 years of age if they have not been vaccinated previously. The ACIP also recommends vaccination of men who have sex with men (MSM) and those who are immunocompromised up to 26 years of age even if they have not been vaccinated previously.[1] With a per-dose cost of $120, health care payers must decide whether expenditures for HPV vaccination are cost-effective. Diagnoses of HPV-associated cancers averaged 26,900 per year between the years 2004 and 2008 in the United States—of which approximately 4100 women die of cervical cancer.[3-5] Although screening frequency for cervical cancer is similar, the highest risk for cervical cancer is among nonEnglish speakers, Hispanics, and black women, primarily due to poor follow-up.[6] Studies following recipients of the HPV vaccine have shown that vaccination rates are lowest among urban black and Hispanic women as well as all people of low socioeconomic status.

Vaccine differences

There are currently 3 licensed HPV vaccines in the United States. All are composed of type-specific HPV L1 protein. The bivalent HPV vaccine has 2 noninfectious virus-like particles (VLPs); the quadrivalent HPV vaccine has 4 VLPs and the 9-valent HPV vaccine has 9 VLPs. The Centers for Disease Control and Prevention (CDC) has made recommendations for use of the bivalent, quadrivalent, and 9-valent vaccines[7] (Table I). The 9-valent vaccine has shown equal efficacy in women 16 to 26 years of age when compared to the quadrivalent vaccine.[8] In addition, it has shown efficacy against the additional 5 HPV types at a rate of 97.1%.[9]

VACCINATION COST-EFFECTIVENESS

Key points

- **In the United States, $6.8 billion is spent annually on cervical dysplasia screening**
- **If female human papillomavirus vaccination rates rise above 75%, it is not cost effective to vaccinate males**
- **The cost per quality-adjusted life year could be reduced if women were vaccinated and human papillomavirus cytology screening was reduced from every 3 to 5 years**
- **The incremental cost ratio of providing men who have sex with men the quadrivalent human papillomavirus vaccine before 27 years of age is $87,240 per quality-adjusted life year**

As a result of the novelty of the vaccine being so new, the rate of reduction of HPV-related cancers is unknown.[10] The cost to vaccinate an individual with a 3-shot course of either the bivalent or quadrivalent vaccine is between $350 and $500.[11] Roughly 55 million cervical Papanicolaou (Pap) smears are performed annually in the United States, at an average cost of $103 per screening, totaling $5.67 billion.[12-14] The cost for follow-up of Pap smears—including false positives and cervical intraepithelial neoplasia (CIN)—is $1.2 billion annually.[15] More than $1 billion is spent annually on the treatment of genital warts, cervical cancer, and oropharyngeal cancers combined[16] (Table II). Via mathematical models, the most cost-effective immunization technique to prevent cervical cancer is to vaccinate all females, and not males, because females are at the highest prevalence of HPV complications from infection.[17] Although HPV infections and cervical cancer are higher among unmarried, low-income black women, with low education, cost-effectiveness studies have not been performed on immunizing individuals based on income, education, or race.[18] Because of the lower incidence of anal, penile, and oropharyngeal cancer in males—compared to the incidence of HPV-induced cancers in women—the cost-effectiveness of vaccinating males is diminished.[19]

Disease burden, which encompasses both quantity and quality of life lived, is measured by quality-adjusted life year (QALY), where a perfect health year is valued at 1.0 and death is valued at 0.0. Measurement in QALYs is used to determine the value for money of intervention, with a lower cost to QALY gained, known as incremental cost effectiveness ratio (ICER), preferred. If the female vaccination rate remains low (ie, <30% by 12 years of age) and

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