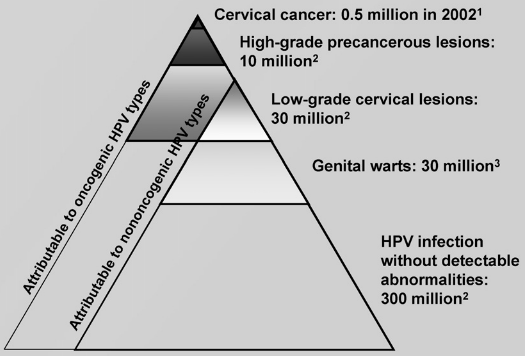
[연수강좌]

예방주사를 이용한 자궁경부암의 예방

김 현 호

한국 엠에스디

Estimated World Burden of HPV-Related Disease and Diagnoses



1. Parkin DM, Bray F, Ferlay J, Pisani P. *CA Cancer J Clin.* 2005;55:74–108. 2. World Health Organization. Geneva, Switzerland: World Health Organization; 1999:1–22. 3. World Health Organization. WHO Office of Information. *WHO Features.* 1990;152:1–6.

Merck Quadrivalent HPV Vaccine

- HPV types 6, 11, 16, 18[1]
- VLPs are produced in *Saccharomyces cerevisiae*[1]
  - Yeast-derived vaccines given to millions of children and adults
- Proprietary aluminum adjuvant 225 μg per dose[1]
- Each intramuscular 0.5 mL injection volume contains HPV types 6/11/16/18 (20/40/40/20 μg L1 protein, respectively)[1]
- 0-, 2-, 6-month dosing regimen[1]

Merck Quadrivalent HPV Vaccine is a trademark of Merck & Co., Inc., Whitehouse Station, NJ, USA.
1. Merck Quadrivalent HPV Vaccine Prescribing Information. Merck & Co., Inc., Whitehouse Station, NJ, USA.

Merck's HPV Vaccine :
Prevention of Major HPV-Related Diseases

- Administration of Merck's HPV vaccine will reduce overall risk of:
  - Cervical cancer
  - Cervical intraepithelial neoplasia (CIN)
  - Vaginal/Vulvar Pre-cancer (VIN/VaIN)
  - Genital warts

  in proportion to the distribution of vaccine types in such lesions

Approved in 70 more countries –
under accelerated review
Actively selling doses in 52 countries

Ph III–P016 Safety/Immunogenicity 9- to 15-year-old boys and girls

Phase III Bridging Study[1]

Study Design

Age Range	Number Enrolled Female	Male
10–15 years of age	506	510
16–23 years of age (bridging)	513	—

- Vaccine administered at day 1, month 2, and month 6
- Primary end point: Immunogenicity
- Safety
  - Follow-up after each injection: 2-day and 14-day clinical (safety); 5-day body temperature and injection-site reactogenicity
  - Serious vaccine-related AEs collected throughout the study

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1. Block SL, Nolan T, Sattler C, et al. Submitted. 2006.

Ph III–P016 Safety/Immunogenicity 9- to 15-year-old boys and girls

Immune Response: Percent Seroconversion at Month 7[1]

Percentage of seroconversion comparable between groups (noninferior; P <0.001)*

Assay	Girls 10–15 Years % (n value)	Boys 10–15 Years % (n value)	Females 16–23 Years % (n value)
Anti-HPV 6	**100** (426)	**100** (431)	**100** (320)
Anti-HPV 11	**100** (426)	**100** (431)	**100** (320)
Anti-HPV 16	**100** (427)	**100** (430)	**100** (306)
Anti-HPV 18	**100** (429)	**99.7** (432)	**99.1** (340)

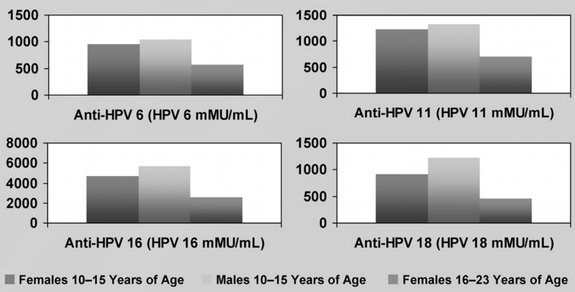
*A P value <0.025 supports a conclusion that the specific type of anti-HPV response in 10- to 15-year-old females or males was noninferior to the response in 16- to 23-year-old females.

1. Block SL, Nolan T, Sattler C, et al. Submitted. 2006.

Ph III–P016 Safety/Immunogenicity 9- to 15-year-old boys and girls

Immune Response: Neutralizing Anti-HPV GMTs at Month 7[1]

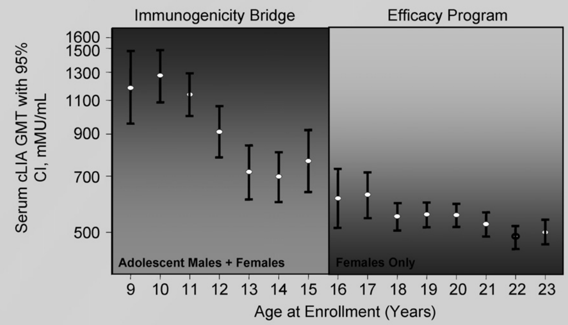
GMTs comparable between population groups (noninferior; P <0.001)*



*A P value <0.025 supports a conclusion that the specific type anti-HPV response in 10- to 15-year-old adolescents was noninferior to the response in 16- to 23-year-old females.
1. Block SL, Nolan T, Sattler C, et al. Submitted. 2006.

Neutralizing Antibodies By Age at Enrollment[1]

PPI population (ages 9–26)
Neutralizing anti-HPV 6 GMTs at month 7



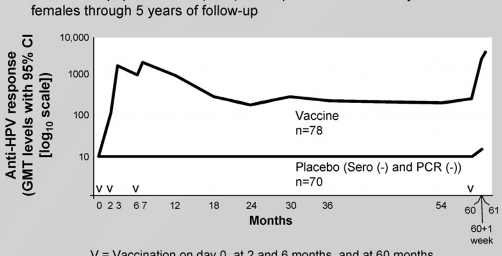
1. Data on file, MSD.

Ph II–P007 Dose-Ranging 16- to 23-year-old women

Antibody Response Is Durable[1]

Long-term Persistence of Anti-HPV 16 cLIA Responses*

Anti-human papillomavirus (HPV) 16 responses in 16- to 23-year-old females through 5 years of follow-up



V = Vaccination on day 0, at 2 and 6 months, and at 60 months