HPV Vaccines

Description

Two vaccines against human papillomavirus (HPV)—a sexually transmitted virus that causes cervical cancer—were approved in 2006 and 2007, respectively, after more than ten years of intensive research and commercial development. Both vaccines—Gardasil®, the quadrivalent vaccine, and Cervarix®, the bivalent vaccine—prevent infection and precancerous cervical lesions caused by HPV types 16 and 18. Gardasil® also prevents infection with types 6 and 11, which cause genital warts and respiratory papillomatosis. HPV types 16 and 18 account for approximately 70 percent of cervical cancer cases worldwide and a similar proportion of anal cancers. The USFDA recently also approved the quadrivalent vaccine for use in boys and men 9 to 26 years of age for prevention of anal precancerous lesions, cancer, and genital warts. The vaccines also offer some degree of cross-protection against a few non-vaccine cancer-causing types. Both vaccines are given in a series of three intramuscular injections over a six-month period.

More than half of all sexually active people will contract an HPV infection at some point in their lives, although only a relatively small percentage of women will progress to cervical cancer. However, this translates to an estimated 530,000 women worldwide developing cervical cancer every year and 275,000 dying from the disease. The vast majority of these women—around 85 percent—live in developing countries, where life-saving services to screen for and treat precancerous lesions are not available (e.g., Pap smears or other screening technologies, followed by treatment). By 2030, cervical cancer is expected to kill more than 474,000 women per year, with more than 95 percent of these deaths in low- and middle-income countries.

Efficacy, target groups for vaccination, and duration of protection

In large, international clinical trials in young adult females, both vaccines were shown to be at least 92 percent efficacious in preventing HPV infections and precancerous lesions caused by vaccine types when administered prior to HPV infection. While efficacy against infection and lesions was not demonstrated in young adolescents (because most were not yet exposed to infection), bridging studies have shown that antibody levels after vaccination are as high or higher in young adolescent females and males as in young adult females. According to the World Health Organization, young adolescent girls aged 10 to 13 years are the primary target group for HPV vaccination because the vaccines are most efficacious in people not yet exposed to the viruses. Some countries have also targeted a secondary group for “catch-up” vaccinations, often women aged 14 to 18 years. There is evidence that duration of protection is at least five years for the quadrivalent and more than eight years for the bivalent vaccine (the length of follow-up studies published to date), and longer-term efficacy is still being evaluated.

Global use

HPV vaccines are available through the private sector in more than 100 countries and have been introduced into public immunization programs in more than 30 countries. While they are not yet widely available in the developing world, several middle-income countries—including Mexico, Panama, Peru, and Malaysia—and some low-income countries—including Bhutan and...
Rwanda—have started national vaccination programs. For information on research into the feasibility, acceptability, and cost of HPV vaccination programs in low-resource settings, visit www.path.org/projects/cervical_cancer_vaccine.php. For publications with practical information on planning for and implementing HPV vaccination programs, see http://www.rho.org/HPV-vaccine-implementation.htm.

Manufacturers

Gardasil® is manufactured by Merck & Co., Inc. (www.merck.com). Cervarix® is manufactured by GlaxoSmithKline (www.gsk.com).

In 2009, the World Health Organization "prequalified" both HPV vaccines for procurement by United Nations agencies such as the United Nations Children’s Fund (UNICEF) and the Pan American Health Organization (PAHO) Revolving Fund for Vaccine Procurement.

Registration status

As of April 2011, Gardasil® was approved in 123 countries and Cervarix® in 114. However, licensed vaccines may not yet be marketed in a given country.

Public-sector price agreements

The GAVI Alliance, an immunization coalition of the world’s top global health agencies, governments, and private partners, offers subsidized vaccines to more than 70 countries in the developing world. In 2012, GAVI began offering HPV vaccines as well. GAVI is continuing price negotiations with the two manufacturers, and the lowest publically documented price per dose is US$5 for the quadrivalent HPV vaccine. Merck & Co., Inc. quoted this price to GAVI in June 2011. Countries requesting GAVI-supported vaccine will be responsible for a co-pay of about US$0.20 to 0.40 per dose for the vaccine itself, and will be responsible for delivery costs. Now that GAVI has begun subsidizing the vaccine, it is likely—based on recent experience with demonstration projects in Africa, Asia, and Latin America—that many low-resource countries will add HPV vaccine to their national programs. GAVI’s support will put HPV vaccine within reach of the world’s poorest nations.

References


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This publication forms part of a series of technical briefs, written by members of the Caucus on New and Underused Reproductive Health Technologies, a thematic group established under the auspices of the Reproductive Health Technologies Coalition. The Caucus’ aim is to broaden the discussion within the Coalition of reproductive health technologies that are not well-integrated into the public or commercial health sectors. Responsibility for the selection and contents of the product briefs rests solely with the Caucus and does not imply endorsement by the Coalition or its wider membership. For additional information, please contact secretariat@rhsupplies.org.

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