



the major capsid protein and self-assembles into viruslike particles (VLPs). Species-specific VLP vaccines provide protection against infection and disease. Protection was associated with the development of neutralizing antibodies. Serum from vaccinated animals conferred protection to unvaccinated animals.

The HPV-6, HPV-11, HPV-16, and HPV-18 L1 VLP vaccine is manufactured in *Saccharomyces cerevisiae* (yeast), and yeast-derived vaccines have been given to millions of children and adults. The vaccine includes amorphous aluminum hydroxyphosphate sulfate adjuvant and is given in a 0-, 2-, 6-month dosing scheme. Phase I trials (300 participants) were performed to establish immunogenicity and tolerability of a range of doses of monovalent HPV L1 vaccines. Phase II trials (3,500 participants) were performed to establish the immunogenicity and tolerability of a range of HPV L1 VLP vaccine dose formulations and provide preliminary proof of concept. Phase III trials (20,000 participants) will determine the efficacy of the HPV L1 VLP vaccine by using prevention of type-related CIN I, genital warts, and CIN II/III as the endpoints.

The results of the phase II trial of the HPV-16 VLP vaccine have been recently published (1). The primary endpoint of this trial in 2,392 young women was persistent HPV-16 infection (detection in consecutive visits) and HPV-16-related CIN. In 16- to 23-year-old women who were HPV-16-naïve at baseline, the vaccine was 100% effective; HPV-16 and CIN were detected in 41 unvaccinated (placebo) women and in no vaccinated women. The vaccine was generally well tolerated, and no serious vaccine-related adverse events were seen.

The phase III efficacy trial addressing women 16–23 years is underway. Approximately 25,000 women in 33 countries and 100 sites have been enrolled. The evaluation includes Pap testing and HPV polymerase chain reaction at defined intervals. An adolescent program (for girls 9–15 years of age) is ongoing to demonstrate vaccine immunogenicity and tolerability in boys and girls. In addition, a study with Nordic Cancer Registries is planned for long-term (>10 years) follow-up postlicensure to determine duration of efficacy, long-term safety, and replacement of vaccine types with other HPVs. Phase III programs will definitively evaluate clinical and public health impact of the HPV vaccine in adolescents and adult women.

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Reference

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Impact of HIV on Women Internationally

Women bear about half of the HIV infections worldwide. In sub-Saharan Africa, 58% of those infected are women; in Asia this figure is 30%. While the epidemic occurs in varied geographic regions, all women are biologically and socioculturally vulnerable.

Our common prevention options fail to take into account women's realities: being in, or wanting to be in, a union; wanting to have children; the imbalance of power in male/female relationships; inaccessibility of education; the threat of sexual violence; and the economic vulnerability that leads to engaging in sexual activity for survival. Female-controlled methods, including female condoms and microbicides, are essential and must take into account these realities. The prevention needs of women already infected with HIV must be addressed by supporting disclosure, fighting stigma, and being sensitive to the threat of violence and disinheritance.

The burden of care for those living with HIV/AIDS most often falls to women and girls. Recognition of the value of this work is vital, as is addressing practical issues that can help alleviate this burden of care.

HIV-Positive Women's Perspective, Advocacy, Sexual and Reproductive Rights

Biomedical, social, and human rights factors are compelling reasons for giving particular attention to women and HIV. However, research on women and HIV/AIDS in terms of treatment, adherence, and opportunistic infections is deficient. Women lack access to treatment, and women's representation in treatment advocacy initiatives remains wanting.

In terms of sexual and reproductive health, women face barriers in accessing treatment for sexually transmitted infections and have inadequate access to prophylactic treatments such as Pap smears and sexual health screenings. Female condoms are often unobtainable, and accelerated research on woman-controlled barriers is needed. Many programs for HIV-positive women lack services to support safe conception, frequently consider women only or primarily in terms of reproduction, and can unethically deny HIV-positive women reproductive health services.

Scientific research, programs, and initiatives should focus on HIV-positive women and their interrelation with treatment, adherence, opportunistic infections, female-

controlled prevention methods, and reproductive health. These findings must then be translated into ethical policy and practice.

HIV among Young Women in Developing Countries

Youths (persons 15–24 years of age) are a major part of the HIV epidemic around the world, making up an estimated half of new HIV infections, and young women are typically infected earlier than are men. Young women have both biological and social vulnerabilities. They can be susceptible to “sugar daddy” relationships, they are vulnerable to sex trafficking or coercion, and they have less education, including HIV prevention education, than their male counterparts. Some countries have had success in reducing HIV among young women; however, many program challenges remain: lack of evaluation, limited resources, the unique vulnerabilities of youth ignored, and the lack of influence by young persons.

Fifteen million children 15 years of age and younger have lost one or both parents to AIDS, and this situation also presents challenges, including increased risk of sexual exploitation, the loss of educational opportunities as young people are forced to leave school because they lack school funds or must work to support remaining family members, and the need for HIV prevention education that addresses orphans' special needs.

Some promising youth programs have been initiated, among them curriculum-based programs, peer education, and voluntary counseling and testing; however, more resources and evaluation must be devoted to youth programs, and these programs should view youth as assets, not as problems.

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Hepatitis B in Women: Domestically and Internationally

Globally, hepatitis B virus (HBV) infection is a major cause of infectious disease-related death, causing approximately 620,000 deaths annually. Without hepatitis B vaccination, an estimated 1.4 million HBV-related deaths would occur in the 2000 birth cohort over the lifetime of the cohort. HBV infections acquired in the perinatal and early childhood periods account for 21% and 48%, respectively, of HBV-related deaths worldwide. Thus, routine vaccination of infants and children serves as the basis for a global hepatitis B prevention program.

In 1992, the World Health Organization recommended that hepatitis B vaccine be included in childhood immunization programs in all countries, but because of financial constraints, many countries were unable to initially implement this recommendation. In 1999, a global initiative began to make hepatitis B vaccine available to children living in 69 of the world's poorest countries, and by the end of 2003, routine childhood hepatitis B vaccination was included in national immunization programs in >151 countries. However, many countries, mainly in sub-Saharan Africa, have not yet introduced the vaccine, and coverage with the three-dose vaccination series remains low in many countries that have introduced the vaccine. When all countries have introduced the vaccine and coverage with the three-dose vaccination series reaches 90%, up to 84% of global HBV-related deaths will be prevented.

Hepatitis B in the United States

In the United States, an estimated 5% of the civilian, noninstitutionalized population has serologic evidence of past or present HBV infection, and 0.4%-0.5% have chronic infection and are the primary source of infection for others. From 1990 through 2002, the incidence of reported acute hepatitis B declined 67%. The incidence of acute hepatitis B among men has been consistently higher than among women. In 1990, the incidence among men and women was 9.8 and 6.3 per 100,000, respectively; in 2002, the incidence was 3.7 and 2.2 per 100,000, respectively. Overall, incidence among women has declined more than among men. Trends in acute hepatitis B reflect poor vaccination coverage among persons who engage in high-risk behavior.

Persons at high risk for HBV infection often seek health care in settings in which vaccination services could be provided. During 1996–1998, approximately half of persons with reported acute hepatitis B previously had been treated for a sexually transmitted disease (STD) or incarcerated: 89% of injection drug users, 35% of men who have sex