Cervarix HPV Vaccination Series

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In 2011, United Kingdom pharmaceutical company GlaxoSmithKline released Cervarix, a vaccination series protecting girls and women from two strains of Human Papillomavirus, or HPV. HPV, a sexually transmitted infection, can present in men and women without symptoms, or may cause symptoms such as genital warts. There is a link between HPV and cervical, vaginal, anal, head, neck, and face cancers, and Cervarix can reduce genital cancers in girls and women, particularly cervical cancer. Gardasil, a similar vaccination against HPV, approved by the United States Food and Drug Administration, or FDA, and available in the US in June 2006 was on the market five years prior to Cervarix's approval in October 2009. In 2014, because of the heightened cost and lesser coverage, the US market discontinued Cervarix, but as of 2020, it remains popular in Europe, especially in the United Kingdom. Cervarix is the first HPV vaccine administered in China.

Cervarix protects girls and women from contracting HPV strains sixteen and eighteen linked to eighty percent of cervical cancer instances in women. HPV is a sexually transmitted infection and primarily transmitted through genital contact, infecting the surface level epithelial cells that line organs. People with HPV can experience symptoms such as genital warts, or more commonly, they will not experience any symptoms at all. Some HPV strains are associated with increased risks of cancer, as HPV is an oncogenic virus, meaning it can cause cancer.

Women typically get diagnosed with HPV and cervical cancer through Pap smears, a diagnostic tool that collects cells from the cervix. Physicians analyze Pap smear samples of cervical tissue, looking for abnormal cells, and use laboratory techniques to detect HPV DNA in the sample cells. While there is no cure for HPV, doctors can remove genital warts and are able to remove infected cells from a woman's cervix. As of 2020, treatments for cervical cancer are chemotherapy, radiation, surgical excision of the cells, and sometimes, complete surgical removal of the woman's reproductive organs.

The discovery that HPV can cause cervical cancer led to the development of Cervarix. According to a 1966 Journal of the American Medical Association article, "Cervical Cancer Linked to Early Intercourse: Promiscuity," scientists and physicians believed cervical cancer to be a consequence of women behaving promiscuously. At that time, scientists had yet to discover HPV and its connection to cancer. In 1976, after analyzing cervical cancer tumor samples, virologist Harald zur Hauzen theorized that HPV caused cervical cancer. From 1980 to 1984, zur Hauzen discovered four strains of HPV. In 1991, vaccine researchers Ian Frazer and Jian Zhou made a discovery that led to the invention of the HPV vaccines. In 2011, pharmaceutical company GlaxoSmithKline released Cervarix.

Some physicians recommend that women receiving Cervarix should not yet be sexually active. Since Cervarix is a protective measure against HPV commonly transmitted by sexual contact, if a woman is already sexually active, there is a chance she may carry some strains of HPV. This renders the vaccine potentially ineffective against those strains. However, according to the GlaxoSmithKline pamphlet, physicians recommend vaccinating females with Cervarix from the ages of fifteen to twenty-five regardless of the recipient's history of sexual activity. Physicians only administer Cervarix to girls and women, because the two strains that it protects against are the strains most responsible for cervical cancer. Men do not have a cervix and cannot develop cervical cancer.

Prior to Cervarix's release in 2011, GlaxoSmithKline tested Cervarix for safety and efficacy within two controlled, double-blind clinical trials in multiple countries. The first clinical trial studied the effects of the vaccination series on girls and women who tested negative for all strains of HPV. After the trial, staff periodically checked the participants' immunity over six years, the study demonstrated that Cervarix had a ninety-seven percent efficacy rate against HPV strains sixteen and eighteen for women who were free of HPV infection prior to vaccine administration.

A later clinical trial performed assessed women's HPV status prior to administering the vaccine series, but did not take into account the results when randomly assigning the women to the study's population that included women with and without past or present HPV infection, which would yield a more representative population when considering vaccinating sexually active women. Women in that group may have already accumulated precancerous cervical cell changes, which is a warning sign that a woman has contracted HPV and may develop cervical cancer. Approximately twenty-six percent of women vaccinated had evidence of current or prior HPV infection, though less than one percent of women were positive for both HPV strains sixteen and eighteen, which are the two strains against which Cervarix protects. Among the varied women included in the study, Cervarix demonstrated a range of efficacy against further HPV infection by protecting approximately ninety to ninety-five percent of vaccinated women. The clinical trial staff conceded that the lower efficacy rates might be due to strains of HPV that less commonly cause cervical cancer and against which Cervarix does not protect.

Some scientists have conducted studies comparing Cervarix with its HPV vaccine competitor, Gardasil. While Gardasil protects both men and women against more strains of HPV than Cervarix does, studies have shown that Cervarix administered to
women and not men may result in better protection against HPV strains sixteen and eighteen. Some studies, including one published in *Human Vaccinology* in 2009, found that Cervarix results in higher concentration of antibodies in the blood than Gardasil, which may indicate a better protection among recipients against the virus. Another study published in 2013 in the *Journal for Infectious Disease* found Cervarix to be more effective than Gardasil in women who already had compromised immune systems due to autoimmune diseases or Human Immunodeficiency Virus, or HIV.

Ultimately, according to journalist Nick Mulcahy, the US discontinued Cervarix in 2014 due to competition with Gardasil. Mulcahy stated in a 2016 article that a company spokesperson reported there was very low demand for the vaccine in the US, especially after 2015, when Merck introduced Gardasil's new nine-strain HPV vaccination. Mulcahy provided statistics stating that in 2015, Cervarix only accounted for three million US dollars in the US and 107 million US dollars worldwide, compared to Merck's global sales of over 1.9 billion US dollars. In July 2017, Cervarix, the approved vaccine for cervical cancer prevention in mainland China, passed inspections and was supplied to the market. In 2018, because of the high incident of cervical cancer the age limit of Cervarix vaccination expanded from nine to forty-five years of age for the female population in China.

Since the introduction of Cervarix in 2011, a meta-analysis of the vaccine's efficacy revealed that Cervarix is up to ninety-three percent effective when given to females before sexual contact, and over fifty-three percent effective for the general public. Rates of cervical cancer have also decreased according to the American Cancer Society from 2015 to 2017. There are research studies conducted to find less expensive means to administer the vaccine in addition to manufacturing a vaccine in fewer doses. While Cervarix is no longer available in the US, in 2014, it was the first HPV vaccination administered and accepted in China.

Sources

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