

KENYA CONFERENCE OF CATHOLIC BISHOPS

CATHOLIC HEALTH COMMISSION OF KENYA



Our Ref:

Your Ref:

KENYA CATHOLIC SECRETARIAT

Waumini House, Westlands

P.O. Box 13475 - 00800, Nairobi

Tel: +254 020 4443133/4/5, / 4443906,4443917

Fax: +254 020 4442910,4441758

Email: health@catholicchurch.or.ke /

secgeneral@catholicchurch.or.ke

Website: www.kccb.or.ke

5TH July 2019

HUMAN PAPILLOMA VIRUS VACCINE SAFETY PROFILE

Human papillomavirus (HPV) is a viral infection that's passed between people through skin-to-skin contact. There are over 100 varieties of HPV, and more than 40 of which are passed through sexual contact and can affect your genitals, mouth or throat.

HPV is the most common sexually transmitted infection. It's so common that most sexually active people will get some variety of it at some point, even if they have few sexual partners.

Because HPV is a skin-to-skin infection, intercourse isn't required for transmission to occur.

In rare cases, a mother who has HPV can transmit the virus to her to her baby during delivery. When this happens, the child may develop a condition called recurrent respiratory papillomatosis where they develop HPV-related warts inside their throat or airways

Because some are likely to cause more complications than others, the types are categorized as low-risk and high-risk HPV.

Low-risk types can't cause cervical cancer and are treatable. High-risk types can cause abnormal cells to form on the cervix, which can develop into cancer if they're left untreated.

Therefore, some cases of genital HPV infection may not cause any health problems. However, some types of HPV can lead to the development of genital warts and even cancers of the cervix, anus, and throat and now the virus has been isolated in breast cancers as well.

As such If you've contracted HPV, identifying the type you have helps your doctor determine next steps. Some types of HPV clear up without intervention. Other types may lead to cancer. Your doctor will monitor your condition so that if cancer cells do develop, they can be detected early.

HPV and related Disease Burden

- The worldwide prevalence of infection with human papillomavirus (HPV) in women without cervical abnormalities is 11-12% with higher rates in sub-Saharan Africa (24%), Eastern Europe (21%) and Latin America (16%).
- In USA, 80 million have HPV right now, and 14 million new diagnoses are expected each year. This means almost anyone who is sexually active will get at least one type of HPV during their lifetime.
- The greatest share of infection-associated cancers in Africa is due to the human papilloma viruses (12.1% of all cancers in Africa and 15.4% in sub Saharan Africa); of these, cervical cancer is by far the most common
- HPV infection has been identified as a definite human carcinogen for six types of cancer: cervix, penis, vulva, vagina, anus and oropharynx (including the base of the tongue and tonsils).
- About 99% of all cervical cancers are related to HPV
- HPV is responsible of 4.5% (630,000) of all new cancer cases globally
- HPV16 is consistently the most frequent genotype in all HPV-related cancer sites
- Cervical cancer is the fourth most frequent cancer among women and the fourth leading cause of cancer deaths worldwide.
- Increasing trends in HPV -related anal and head and neck and breast cancers have been observed in the last decade
- Universal HPV vaccination could prevent between 70% and 90% HPV -related disease

Types of HPV and effects

- HPV 6 and HPV 11 are low-risk types of HPV. They are linked to approximately about 90% of genital warts. HPV 11 can also cause changes to the cervix.
- Genital warts look like cauliflower-shaped bumps on the genitalia. They usually show up a few weeks or months after exposure from a sexual partner who has HPV.

- HPV 16 is the most common high-risk type of HPV and usually doesn't result in any noticeable symptoms, even though it can bring about cervical changes. It possibly contributes about 50% of cervical cancers worldwide.
- HPV 18 is another high-risk type of HPV. Like HPV 16, it doesn't typically cause symptoms, but it can lead to cervical cancer.
- HPV 16 and HPV 18 are together responsible for approximately 70% of all cervical cancers worldwide.
- Many people have HPV and don't even know it, which means you can still contract it even if your partner doesn't have any symptoms. It's also possible to have multiple types of HPV.

Management of HPV

Diagnosis

- HPV testing can be performed for women with a Pap test (commonly known as a Pap smear), which is a screening test for cervical cancer. HPV testing is only available for women, and it can determine if HPV is present. If present, the test can determine whether the HPV is a low- or a high-risk type.
- The HPV test isn't recommended as routine screening for women under the age of 30. This is because many women will have some strain of HPV by that age. Most of these will clear spontaneously without intervention.
- However, if a person's Pap test showed abnormal cells, the HPV test would be done to assess their risk of more serious conditions, including cervical cancer.
- If your test shows you have HPV, it doesn't mean you'll develop cervical cancer. It does mean that you *could* develop cervical cancer in the future, especially if you have a high-risk type of HPV. Your doctor will review your results with you and discuss treatment or surveillance options.

Vaccination

The types of HPV the different vaccines protect against vary:

- The HPV bivalent vaccine (Cervarix) will only protect against HPV 16 and 18.
- The HPV quadrivalent vaccine (Gardasil) will protect against HPV types 6, 11, 16, and 18.
- The HPV 9-valent vaccine, recombinant (Gardasil 9) can prevent HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.

Since Gardasil 9 protects against a much wider spectrum of HPV strains without a noted increase in side effects or adverse reactions, this choice offers more protection against HPV.

Common side effects of the Gardasil 9 vaccine is irritation at the injection site, including pain, swelling, or redness. Some people may have a headache following the injection.

Getting the HPV vaccine may help prevent HPV 6. The vaccine also offers some protection from HPV 11.

For the HPV vaccine Gardasil 9, clinical trials showed up to 89 to 99 percent effectiveness in protecting against HPV types 6 and 11. This significant reduction against contracting these types was noted in 9- to 26-year-olds.

The HPV vaccine Gardasil 9 can protect against a number of types of HPV, including HPV 16 and HPV 18.

HPV vaccines, Gardasil, Cervarix, and Gardasil 9 are used in the primary prevention of HPV related cancers.

Gardasil and Gardasil 9 are available for use in both females and males ages 9 to 26, while Cervarix is available for females ages 9 to 25. Gardasil 9 was approved by the FDA for prevention against additional HPV types

At present, all three vaccines are effective in reducing cervical disease and anogenital dysplasia in industry sponsored clinical trials and in limited study of clinical effectiveness

Models predict elimination of HPV infection with global vaccination rates of 80% and benefits in reducing malignancy at 20% global coverage.

HPV vaccines provide a promising primary approach to preventing malignancy and barriers to vaccine access must be addressed to meet vaccination goals.

The recommendation is to receive the vaccines prior to becoming sexually active, since the vaccine can't protect against a strain of HPV that a person has already been exposed to.

Treatment

If you do contract HPV 6 or HPV 11, your doctor can prescribe medications such as imiquimod (Aldara, Zyclara) or podofilox (Condylox). These are topical medications that destroy genital wart tissue.

This local destruction of the wart tissue helps enhance your immune system's ability to fight the STI virus. You can apply these medications directly to your genital warts.

Other Modes of Prevention that have been adopted

- Avoid multiple sexual partners
- Avoid sexual contact with a partner if genital warts are present.
- Use of latex condoms every time during sexual intercourse. But keep in mind that HPV is spread through skin-to-skin contact — not through exchange of bodily fluids. This means that while condoms may not always prevent the spread of HPV, they could reduce your risk.
- If you're a woman, make an appointment with your gynecologist for a cervical cancer screening. You should start screening at age 21 and continue until you're 65.

Safety profile of HPV vaccine (Cervarix®) and qHPV (Gardasil®)

- Initial approval of HPV vaccine by the US Food and Drug Administration (FDA) was granted after extensive trials involving over 20,000 participants, with strict criteria for assessing efficacy and safety (FDA).
- Over 244 million doses of Gardasil® have been distributed worldwide by December 2017, and by May 2018, 81 countries (42% of UN Member

States) had introduced HPV into the national routine immunization schedule (**WHO 2018**).

- Eight African countries have introduced HPV vaccination in the National Immunization programs (Botswana, Lesotho, Mauritius, Seychelles, Senegal, Rwanda, Uganda and South Africa) (Human Papillomavirus and Related Diseases Report, 2019)
- Ongoing surveillance and monitoring has shown that the vaccine is safe (HSE, 2019, CDC 2019).
- World Health Organization (WHO) Global Advisory Committee for Vaccine Safety (GACVS) has similarly monitored the safety of HPV vaccines across multiple countries over ten-year period, and no reported safety concerns with HPV vaccines reported (**WHO, 2017**).
- Safety of the next generation 9-valent vaccine (Hu et al 2017; Costa APF, 2017) has been assessed and shown to be comparable to the earlier vaccine generations.

References:

US FDA: Information from FDA and CDC on Safety of Gardasil vaccine.
<https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/gardasil-vaccine-safety>

The World Health organization (WHO): Global Market Study HPV.
https://www.who.int/immunization/programmes_systems/procurement/v3p/platform/module2/WHO HPV market study public summary.pdf

Human Papillomavirus and Related Diseases Report (Accessed July 2019)
<https://hpvcentre.net/statistics/reports/XFX.pdf>

HSE: The Human Safety HPV Vaccine Safety and Effectiveness 2006 - 2019
<https://www.hse.ie/eng/health/immunisation/hcpinfo/othervaccines/hpv/hpvsafety/>

Centers for Disease Control and Prevention (CDC): HPV Safety and effectiveness: <https://www.cdc.gov/hpv/parents/vaccinesafety.html> (Reviewed April 2019)

The World Health Organization (WHO): Safety update of HPV vaccines.
https://www.who.int/vaccine_safety/committee/topics/hpv/June_2017/en/ (June 2017)

Hu WK et al 2019: Final efficacy, immunogenicity, and safety analyses of a nine-valent human papillomavirus vaccine in women aged 16–26 years: a randomised, double-blind trial. *The Lancet* . Volume, 390 (10108): 2143-2159.

November

2017.

<https://www.sciencedirect.com/science/article/pii/S0140673617318214?via%3Dihub>

Costa APF et al. Safety of Human Papillomavirus 9-valent vaccine: A meta-analysis of randomized trials: Journal of Immunology Research Volume 2017. <https://www.hindawi.com/journals/jir/2017/3736201/>

Forman D¹, de Martel C, Lacey CJ, Soerjomataram I, Lortet-Tieulent J, Bruni L, Vignat J, Ferlay J, Bray F, Plummer M, Franceschi S. Global burden of human papillomavirus and related diseases. Vaccine. 2012 Nov 20;30 Suppl 5:F12-23. doi: 10.1016/j.vaccine.2012.07.055.

St Laurent J¹, Luckett R², Feldman S³. HPV vaccination and the effects on rates of HPV-related cancers. Curr Probl Cancer. 2018 Sep;42(5):493-506. doi: 10.1016/j.crrproblcancer.2018.06.004. Epub 2018 Jun 23.

Contributors:

1. Rt. Rev. Joseph Mbatia, Chairman, KCCB – Catholic Health Commission of Kenya
2. Rt. Rev. Joseph Obanyi, Vice Chairman, KCCB – Catholic Health Commission of Kenya
3. Dr. Benhards Ogutu, KCCB Representative to the MOH/KCCB Vaccines Experts Committee
4. Dr. Daniel Ochiel, KCCB Representative to the MOH/KCCB Vaccines Experts Committee
5. Jacinta Mutegi, National Executive Secretary, KCCB – Catholic Health Commission of Kenya

SIGNED: 

Jacinta Kathamu Mutegi, National Executive Secretary, KCCB – Catholic Health Commission of Kenya