

HPV Vaccination

A Public Health Priority for India

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Cervical cancer is a leading cause of cancer deaths in India

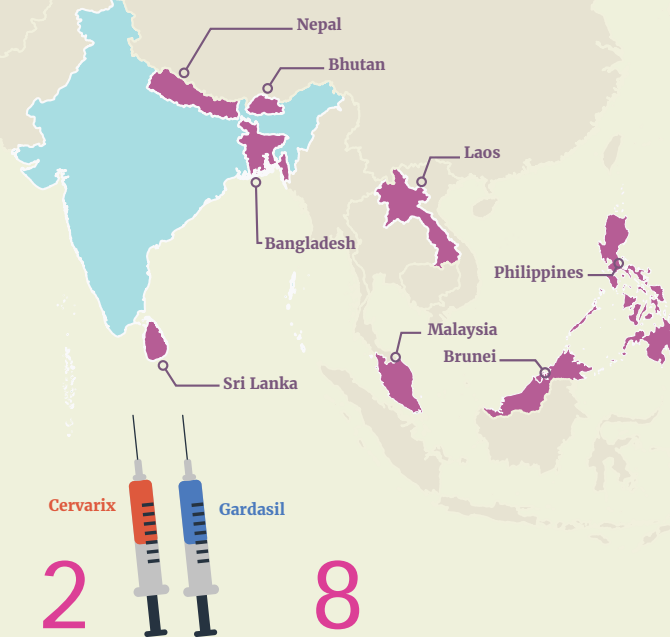
67,477
DEATHS
reported annually¹ from
CERVICAL CANCER
in India alone.

Cervical cancer is a leading cause of cancer deaths in India with approximately 67,477 deaths reported annually¹.

Human papillomavirus (HPV) has been found to be the primary cause of cervical cancer, associated with nearly all cervical malignancies.² Of more than 100 HPV types, about 15 are found to be high-risk with the potential to cause cancer. HPV is a common sexually transmitted infection. Though the majority of HPV infections are asymptomatic and resolve spontaneously, persistent infection with high-risk HPV types, in the presence of co-factors, can lead to the development of pre-cancerous cervical lesions, cervical cancer, and other cancers including vaginal and vulvar cancers in women; penile cancer in men; and anal and oropharyngeal cancers in both men and women.²⁻⁴

Two HPV types, 16 and 18, account for about 70% of cases worldwide.² HPV types 16 and 18 are responsible for 82% of all cervical cancers in India. Although the infection will clear in a majority of women through their natural immunity, there is no reliable method to predict and identify those who will go on to develop cancer. That is why universal primary prevention with the HPV vaccine is essential.

The HPV vaccine is for the primary prevention of cervical cancer



HPV vaccines are available in India.

Asian countries have introduced the HPV vaccine in their National Immunization Program or have adopted policy to do so soon

The two HPV vaccines currently available in India – bivalent (Cervarix®, GlaxoSmithKline) and quadrivalent (Gardasil®, Merck & Co. Inc.) – have demonstrated high efficacy in clinical trials. The efficacy of the vaccines is almost 100% against persistent cervical infection and pre-cancerous cervical lesions associated with HPV types 16 and 18 in girls/women who are free from HPV infection at baseline.⁵ Proof of the efficacy of the HPV vaccine has been obtained from national vaccination programs in countries like Australia, the United Kingdom, Sweden, Denmark and the United States.⁶⁻⁹ These countries were fore-runners in introducing the HPV vaccine in their public health programs.

In light of strong evidence, Asian countries such as Bhutan, Malaysia, Philippines, Brunei, Laos, Nepal (demonstration project in Chitwan and Kaski districts) and Bangladesh (demonstration project in Gazipur district) and Sri Lanka have introduced the HPV vaccine in their national immunization programs or have adopted policy to do so by 2017.¹⁰⁻¹⁷

A recently published study in India observed high immunogenicity and protection against persistent HPV infection among Indian girls in the age group of 10-18 years.¹⁸ The study found that the protection offered by 2 doses (separated by 6 months or more) of the HPV vaccine was similar to the 3-dose regimen.¹⁸

High-quality recommendation from a healthcare provider is the most important factor in parents choosing to vaccinate their child



Endorsed



Age-appropriate



Consistent



Timely



A high-quality recommendation from a health care provider is a key factor in HPV vaccine uptake.¹⁹⁻²³

A high-quality recommendation is one that is age-appropriate (World Health Organization recommends the vaccine for all girls between 9 and 13 years), endorsed (supported and promoted by providers as a cancer vaccine), consistent (recommended to all adolescent girls in the same way as other vaccines) and timely (recommended to adolescent girls whose immune response is better and who are typically not yet exposed to the virus).

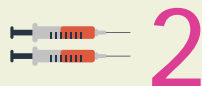
Parents usually learn about the vaccines from a healthcare provider. Several studies from India have underscored that there is limited knowledge about the HPV vaccine among the general population.²⁴⁻²⁷ However, there is willingness to accept the vaccine if it is made available and recommended by physicians.^{24,26,27}

03

The HPV vaccine is best given to adolescent girls

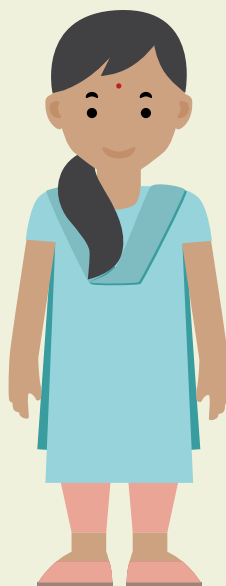


Below 15 years



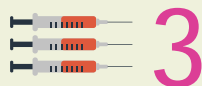
Doses

at 6–12 months interval



Above 15 years

including immuno-compromised individuals



Doses

at 6–12 months interval

The best protective effect is seen when the vaccine is given to adolescent girls.^{28,29}

The World Health Organization (WHO) recommends that adolescent girls 9–13 years of age be vaccinated because the vaccine is highly immunogenic at this age and girls are typically not yet exposed to the virus.^{3,30}

Only two doses of the vaccine administered at a 6 to 12 month interval are enough to protect girls under 15 years of age. Girls/women 15 years of age and older, as well as those who are immuno-compromised, e.g., living with HIV, require 3 doses. International organizations like WHO, the UNICEF, the United Nations Populations Fund and Indian professional organizations like the Federation of Obstetric and Gynecological Societies of India and the Indian Academy of Pediatrics have all strongly recommended the use of the HPV vaccine to protect against cervical cancer.

The HPV vaccine is safe and does not cause serious side effects



Over
200

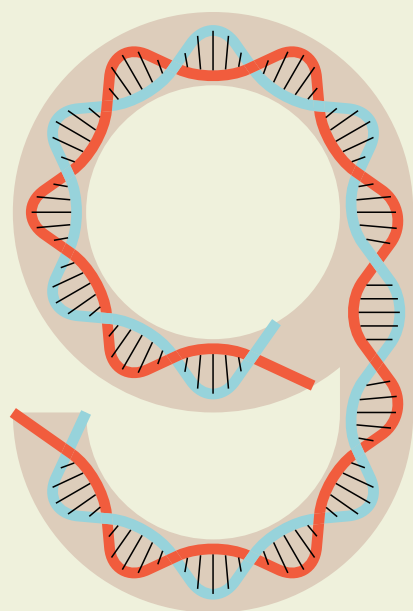
million doses have
been administered
globally

HPV vaccines are not new and have been available since 2006. Over 200 million doses of the vaccine have been administered globally with close monitoring to study any adverse reactions. Careful consideration of safety and cost-benefit data have led to licensing the vaccine in over 100 countries across the globe, with 80 countries having introduced the vaccine in their national immunization programs.^{31,32} As with all vaccines, international and national monitoring agencies continuously report, monitor and evaluate any serious and non-serious adverse events. No increase in the incidence of auto-immune diseases, neurological disorders or other significant new onset chronic diseases has been documented in vaccinated populations.³³⁻³⁷

The recently published results of a study from India that administered approximately 35,000 doses in girls 10-18 years of age with a 4-year follow-up reported no serious adverse events attributable to the HPV vaccine.¹⁸

In 2016, the WHO Global Advisory Committee on Vaccine Safety conducted a careful analysis of all reported adverse event cases from across the globe and found no safety issues that would alter its recommendations for use of the vaccine.³³

The effectiveness of the HPV vaccine does not decrease over time



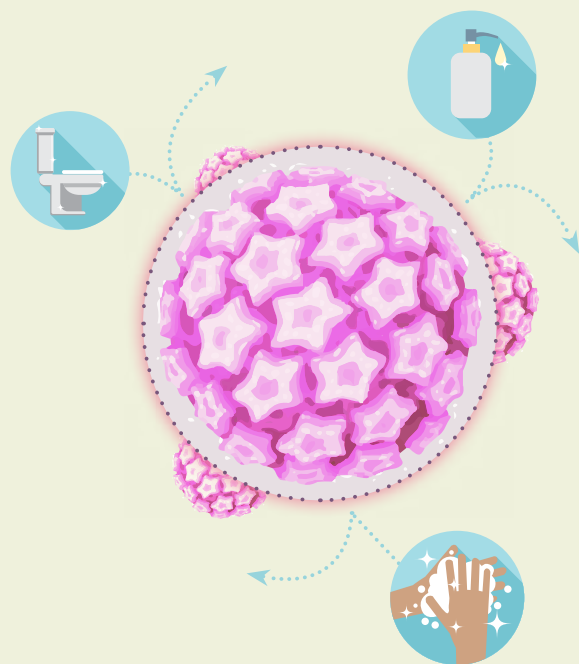
years

Australia was the first country to introduce the HPV vaccine in its national immunization program in 2007, closely followed by the US, the United Kingdom and other European countries.

Even after nearly 10 years of use there is no evidence of waning vaccine effectiveness and no breakthrough cases (pre-cancerous cervical lesions caused by vaccine type HPV in vaccinated women) have been reported.

This observation is consistent with vaccine trials that have demonstrated that the protective effect of the vaccine remains unchanged up to at least 9 years after vaccination.⁴⁰ Research is continuing to monitor the duration of protection and need for a booster dose.

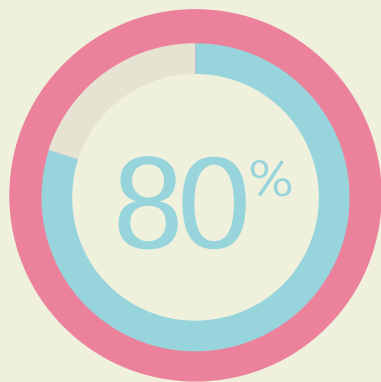
Sanitation and hygiene are not linked to cervical cancer



There is no consistent evidence indicating that improving sanitation and hygiene (or menstrual hygiene) will reduce cervical cancer incidence.⁴¹

Even in countries such as the US, the United Kingdom and Australia, where the population has access to ideal sanitation and hygienic conditions, cervical cancer is controlled through HPV vaccination and regular screening. While access to safe water, along with adequate sanitation and hygiene certainly has an impact on health and well-being, there is overwhelming evidence supporting the need to invest in comprehensive cervical cancer prevention through vaccination, screening and treatment as the best way to address the burden of cervical cancer.

Combining HPV vaccine with screening will have the greatest impact on reducing the future burden of cervical cancer



of cervical cancers can be prevented by HPV vaccination

HPV vaccination can prevent up to 80% of cervical cancers² and is an important part of a comprehensive cervical cancer prevention strategy.

Regardless of HPV vaccination status, cancer screening by Pap test, visual inspection with acetic acid (VIA) and/or HPV testing are also recommended as the vaccine does not protect against all high risk HPV types.

Even though there are 13 other high-risk HPV types associated with cervical cancer, the vaccines target HPV 16 and 18 since they are responsible for the large majority (70–80%) of cervical cancers. Protection against these two types will have a huge impact in a country like India where cervical cancer screening is non-existent or sporadic and HPV types 16/18 contribute to 82% of cervical cancers.² Moreover, the total protection offered by the vaccine is actually higher due to the cross-protective effects on other non-vaccine HPV types.

The HPV vaccine does not adversely affect fertility



Claims of HPV vaccine-induced infertility are anecdotal and not substantiated by research or clinical trials.³⁸ It is possible that the treatment of cervical cancer could leave a woman unable to have children, and treatment for cervical pre-cancers could also put a woman at risk for cervical incompetence, leading to preterm delivery and neonatal loss.

The HPV vaccine can actually help protect fertility by preventing gynecological problems related to the treatment of cervical cancer and pre-cancerous lesions.^{38,42}

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