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Federação Brasileira das Associações de Ginecologia e Obstetrícia

FEBRASGO POSITION STATEMENT

Human papillomavirus vaccination for adult women

Special Edition - 2025

The National Specialty Commission for Vaccines of the Brazilian Federation of Gynecology and Obstetrics Associations (FEBRASGO) endorses to this document. The content production is based on scientific studies on a thematic proposal and the findings presented contribute to clinical practice.

Key points:

- Update obstetrician–gynecologists about human papillomavirus (HPV) vaccination for adult women with Febrasgo position about this matter.
- Emphasize there is a generation of women who reached adulthood without HPV vaccination opportunity and highlight benefits provided by vaccine immunization.
- Address epidemiological and immunological aspects of HPV infection and available vaccines.
- Assess the susceptibility of unvaccinated adult women to oncogenic types of HPV and to lesions caused by HPV.
- Assess the difference in susceptibility to recurrence and reinfections after treatment of HPV-associated lesions among vaccinated adult women compared to unvaccinated adult women.
- Provide knowledge of best evidence for HPV vaccination among adult women and collaborate for an updated clinical practice.

Recommendations:

- Consider vaccination even in adult women with previous HPV infection history, as the natural infection does not seem to offer sufficient immunity to prevent new infections occurrence by the same viral type, unlike the immunogenicity induced by HPV vaccines.
- Consider most adult women have negative serological and molecular tests for the viral types included in vaccines.
- Consider second HPV infection peak in the woman's fifth decade of life.
- Consider adult women without vaccination coverage as still at risk for acquisition of HPV and for developing HPV lesions throughout their lives.
- Consider evidence of recurrences and / or reinfections risk reduction after vaccination of patients with previous lesions caused by HPV and who have already been treated.
- Consider adult women can benefit from individual protection even they are not eligible for vaccination in official programs based on population studies.
- Therefore, we endorse that adult women without HPV vaccination in adolescence, with or without a history of previous infection, may have protection benefits if immunized. In young women (up to 30 years old), these benefits are significant and were demonstrated in several publications. Therefore, this should be part of the medical prescription. However, there is also individual protection for women aged up to 45 years or more who may still be at risk of new infections. This information must be shared by their gynecologists.
- Vaccination schedule according to the National Specialized Commission (CNE) on Vaccines: for those not previously vaccinated against HPV: 9-20 years: two doses of the HPV9 vaccine, six months apart (0-6 months). For those aged 21-45 years: three doses of the HPV9 vaccine (0-2-6 months). The HPV9 vaccine is available in private clinics. Note that the HPV4 vaccine is currently available in the public health system in a single-dose for boys and girls aged 9-19 years, in addition to the priority groups described throughout this text.

Background

Diseases attributed to human papillomavirus (HPV) infection have a high global burden and are considered a major public health problem. Human papillomavirus is associated with 5% of all cancers worldwide occurring in various body sites such as the cervix, anus, penis, vagina, vulva, and oropharynx, accounting for more than 700,000 cases and 400,000 deaths each year. Persistent HPV infection with an oncogenic type and the role of viral oncogenes are the main causes of HPV-related cancers.[1]

In Brazil, according to estimates from the José Alencar Gomes da Silva National Cancer Institute (INCA), cervical cancer ranked third among the ten most common cancers in 2023 by sex, excluding non-melanoma skin cancer with 17,010 new cases, trailing only breast cancer (73,610) and colorectal cancer (23,660).[2]

Although cervical cancer screening programs are effective when organized, the disease continues to affect many women worldwide, especially in developing countries like Brazil. Knowledge of the genetic structure of different HPV types and technological advancements have led to the development of vaccines to prevent infection by oncogenic types of this virus.

What is the prevalence of HPV infection?

Human Papillomavirus (HPV) infection is the sexually transmitted virus with higher incidence worldwide. It is estimated that about 600 million people are infected with HPV globally and that 80% of the sexually active population becomes HPV infected during a lifetime. The first peak of incidence occurs during the second decade of life and the second peak during the fifth and sixth decade of life. While the first peak is related to onset of sexual activity, the second can be explained by new exposure or immunity loss. The immunity against HPV infections in adult women is much lower than the immunity against HPV in adolescents. [4-6]

The relevance of HPV infection was consolidated when its association with cervical cancer was proven. It has been considered as the cause of all cases. The presence of HPV oncogenic DNA was found in 99.7% of cases of cervical cancer. It is the largest cause and effect relationship between an agent and cancer in humans. Several studies have shown that persistent HPV infection is the main risk factor for cervical intraepithelial neoplasia (CIN) and cervical cancer in young and adult females. [4-7]

There is increasing estimate of cervical cancer incidence in countries where there is no organized screening despite the availability of vaccines.[3-7]

In 2020, the World Health Organization (WHO) launched a global strategy to eliminate cervical cancer, a public health problem, aiming to achieve a target of 4 cases per 100,000 woman-years. The 90-70-90 targets must be met by 2030: 90% of girls vaccinated with the HPV vaccine by age 15; 70% of women screened with a high-performance test at age 35 and again at age 45; 90% of women identified with cervical disease receiving treatment (90% of women with premalignant lesions treated and 90% of women with cancer managed).[8]

It is important to note that women remain at HPV infection risk throughout their lives, even though the highest contamination rates are in the young population group. Contamination rates are up to 25% over five years in women aged between 30 and 44 years. In addition, persistent HPV infection is the main risk factor for CIN and cervical cancer for every age group. [5-9]

Does immunity develop after natural HPV infection?

In the 27-45 years age group, most individuals have been previously exposed to HPV, and many of them are able to clear the infection. The development of immunity capable of protecting against reinfection after a natural infection has been the subject of much discussion. A pioneer study carried out in Costa Rica analyzed 10,049 women. It was observed that the incidence of HPV infection in seropositive women for a certain virus type was similar to seronegative women. This indicates inefficiency of the naturally acquired immunity in protecting against new infection or recurrence. This study evidenced that humoral immunity after natural infection may not prevent new infections, because antibodies levels produced are, generally, low and fall rapidly. They may even become negative, keeping individuals susceptible to new infections. [10] For this reason, adult women previously infected in previous years may not be protected against new infections, including the same viral type.

Is there a risk of new exposure to the virus throughout life?

The risk of new exposure to the virus tends to decrease with advancing age, although it remains at significant levels.[5,11-13] Certain individuals continue to be at risk of HPV infection, especially as a result of establishing new sexual partnerships. As already mentioned, prior infection with viral clearance does not confer robust and lasting immunity, keeping these individuals susceptible to new infections.[10,13,14]

Acquisition of new viral types at older ages reduces the likelihood of effective viral clearance. The persistence of oncogenic HPV types is recognized as the main risk factor for the development of lesions.[15] In light of the evidence presented, the Brazilian Federation of Gynecology and Obstetrics Associations (Febrasgo), through its CNE on Vaccines, declared itself in favor of vaccinating adult women in 2022.[16] This position was reaffirmed in 2024 with the publication of the Febrasgo Position Statement entitled "Immunization in Women's Lives: Present and Future"[17] and it remains in this FPS.

Is the vaccination schedule for adult women different?

Since 2007, HPV vaccines have been administered to adolescents in Immunization Programs worldwide, promoting the prevention of cervical neoplasms and clinical lesions induced by the virus. In this target audience, primarily those aged 9-15 years, there is no question about the effectiveness and safety of vaccination.[18,19]

The National Immunization Program (PNI) introduced the HPV4 vaccine with particles of viruses 6, 11, 16, and 18 for girls aged 11-13 years in 2014.[20] As research progressed, the need to vaccinate boys was recognized, and they were incorporated as a target population in 2017.[21] Another group that also achieved benefits in

vaccination were immunosuppressed individuals (living with HIV/AIDS, solid organ and bone marrow transplant recipients, and cancer patients), initially for girls/women aged 9-26 years in 2015[20] and later, also for boys/men aged 9-26 years in 2017.[22] From 2021 and 2022, there was a further expansion of the age range from 9-45 years for both sexes.[23,24] In 2023, victims of sexual violence were incorporated, and in 2024, those with recurrent respiratory papillomatosis (RRP). In 2024, it was also decided for the catch-up vaccination of girls and boys up to 19 years of age.[24-26] The number of doses for boys and girls was reduced as immunogenicity was demonstrated in order to reduce costs and achieve greater vaccination adherence. A single dose is currently used for girls and boys aged 9-14 years, with catch-up vaccination up to 19 years, 11 months, and 29 days.[25] Immunosuppressed individuals, regardless of age, should always be vaccinated with a three-dose schedule (0-2-6 months). Victims of sexual abuse in the age group of 9-14 years should receive two doses, and in the age group of 15-45 years, three doses. People with RRP aged 2 years and older should receive three doses of the vaccine. HIV Pre-Exposure Prophylaxis (PrEP) users aged 15-45 years should receive three doses. For these groups, the vaccine must be administered with a physician's prescription.[25,26]

The HPV4 vaccine is available in vaccination rooms at Basic Health Units or at Reference Centers for Special Immunobiologicals (CRIEs) for individuals with special needs.

Although young adults (up to 26 years old) who have not been vaccinated are outside the free program, immunization against HPV has clear benefits and vaccination should be recommended.[18,19] The HPV9 vaccine, containing particles from viruses 6, 11, 16, and 18, plus five additional types (31, 33, 45, 52, and 58), is available in private vaccination centers.

The Febrasgo CNE on Vaccines held the first scientific forum on immunization in October 2023 to update the recommendations for vaccines currently in use and new, innovative vaccines about to become available.

Based on the lack of long-term efficacy data for reduced vaccination schedule and the fact that only the impact on cervical lesions with reduced vaccination schedule was evaluated, the forum members recommended the following dosing schedule for HPV vaccines.

For those not previously vaccinated against HPV: 9-20 years old, HPV4 vaccine (available in the public health system) or HPV9 vaccine (through shared decision-making): two-dose schedule, six months apart (0-6 months). For those aged 21-45 years: three doses of the HPV9 vaccine (0-2-6 months).

The adoption of a single-dose HPV vaccine schedule up to age 20 (and not up to age 19, as recommended by the Ministry of Health and the Brazilian Society of Immunizations) was based on a publication by the World Health Organization.[27]

The preferred recommendation is the HPV9 vaccination for all age groups, based on a shared decision between the healthcare professional and the woman/family. Febrasgo recommends the HPV9 vaccine for those previously vaccinated with a complete or incomplete schedule of HPV4 and HPV2 vaccines and who wish to extend protection against other types of HPV, using a schedule tailored to their age group, in a decision shared between the healthcare professional and the woman/family.[17]

Although new studies regarding dose reduction for women over 20 years of age have emerged, we still need further discussion to change our recommendation.

What is the clinical value of HPV vaccination for adult women?

Note that the age groups between 9 and 15 years with catch-up vaccination up to 26 years of age (with some variations in age limits according to each country's guidelines) are considered the populations that will benefit most from the HPV vaccine and have the greatest epidemiological impact on reducing diseases associated with the virus. However, data show a low adolescent number completing the immunization schedule recommended by PNI in Brazil. On the other hand, studies show that vaccines are effective in adult population even after onset of sexual activity. Besides, a considerable proportion of women did not have active infection due to the types of HPV contained in the vaccine after maturity.[6-10, 28, 29]

About 99.6% of sexually active women up to 45 years old would benefit from HPV vaccines. Studies analyzed the viral infection presence of vaccine virus types in groups of women aged 16 to 23 and 24 to 45 years-old or more women. It was found that most women were seronegative or positive for only one of the viral types studied regardless of age.[28-33]

A recent cohort study in Sweden showed that HPV vaccination with quadrivalent vaccine was associated with a significant decrease of invasive cervical cancer risk among girls and women aged 10 to 30 at the population level.[34]

HPV vaccination together with cervical screening and management are complementary preventive actions with the potential to reduce the incidence of cervical cancer.[35] According to the literature, vaccinated women aged 25-45 years have reduced, albeit significant, vaccine efficacy of approximately 50% (regardless of HPV status) compared to the efficacy in protocol groups, of around 85%-90%, in which HPV DNA is negative among study participants. Clearly, HPV DNA-positive women showed no evidence of protection against diseases related to the HPV types for which they tested positive at the time of vaccination. Thus, vaccination may offer protection to women without a current infection or disease, regardless of previous viral exposure. Among those currently infected, it may protect against new infections and reinfection with the same HPV type. According to these statements, HPV vaccination should be offered to all women across a broad age range from 9 to 45 years, or even 50 years in some settings, regardless of viral infection status. In addition to vaccination,

women should be screened using a validated HPV test as part of their initial consultation. Women who test positive for HPV will undergo screening, follow-up diagnostic testing and treatment according to recommended guidelines, achieving a success rate of nearly 90% against cervical cancer and over 90% in reducing mortality from this disease.[35]

Is there a benefit in vaccinating women with a history of treatment for high-grade squamous intraepithelial lesions (HSIL) cervical intraepithelial neoplasia 2/3?

The literature also shows that, even in patients with previous HPV-triggered lesions who have already been treated, there is evidence of a reduction in recurrences with vaccination. The rate of persistent or recurrent disease ranges from 4% to 18%, depending on factors such as surgical margin status, HPV status, and surgical technique.[36] With vaccination, these numbers can decrease by 60% to 80%.[30,31]

Although the vaccine is prophylactic and not therapeutic, vaccination of women treated for CIN 2+ (cervical intraepithelial neoplasia) may provide benefits, conferring protection against future infections with HPV types to which the woman has not been previously exposed. Furthermore, HPV vaccination may provide cross-protection with other viral types not covered by the vaccine[37] and may enhance the immune system's response to HPV infection of the same type, thus providing additional protection against reinfection with the same HPV type or its reactivation from latency.[38,39]

Studies have examined the adjuvant prophylaxis of HPV vaccination in reducing the risk of recurrence in women treated for CIN 2+ who were not previously vaccinated. These studies had heterogeneous designs (retrospective, prospective non-randomized, randomized clinical trials, and post hoc pooled analysis of randomized clinical trials). Meta-analysis data show that CIN 2+ after surgical treatment occurred at rates of 1.72% and 4.0% in the vaccinated group compared with 4.76% to 5.9% in the unvaccinated cohort, with an overall reduction in the risk of recurrent CIN 2+ of 57% to 66%.

For the risk of recurrent CIN 2+ associated with HPV 16/18 (the HPV types targeted by the HPV2 and HPV4 vaccines with which the studies were analyzed), a similar result was found, with a risk reduction (59% to 74%) in recurrent CIN 2+.[10,12,14,40-42]

The United Kingdom presented the first cost-effectiveness analysis comparing the outcomes of surgical procedures for local treatment of CIN alone versus prophylactic vaccination with the HPV9 vaccine in conjunction with treatment, suggesting health and economic benefits from the perspective of the National Health Service (NHS). Vaccination combined with post-treatment surveillance was cost-effective, with a favorable cost-effectiveness increase ratio per quality-adjusted life years. The results of the probabilistic sensitivity analysis showed that vaccination of treated patients was cost-effective within the budget limits recommended by the UK Joint Committee on Vaccination and Immunization.[43]

Studies prior to the UK study analyzed the cost-effectiveness of HPV vaccination in patients treated for CIN 2+ and found that in China and the United States, vaccination was cost-effective and led to better health outcomes in women after treatment.[44,45] Zou et al. (2023)[44] concluded that the three-dose HPV4 vaccine strategy was more cost-effective for preventing cervical infections and subsequent genital warts.[44] In the analysis by Chaiken et al. (2023),[45] HPV vaccination over four years was cost-effective, reducing subsequent diagnoses of CIN, Pap smears, colposcopies, and new excisional procedures.[45] Although these studies support the findings from the United Kingdom, limitations existed in all of them.[43-45]

Is the vaccine safe in adult female?

There is no record of serious adverse events related to vaccination in any age group. Several regulatory agencies evaluate its safety globally. The HPV vaccines confirm, in practice, an excellent safety profile consistent with initial HPV vaccines trials. Therefore, there is no contraindication to vaccinate women aged up to 45 years or older (depending on the vaccine), since the vaccines are immunogenic and safe for various age groups. They must be individualized for each patient. [3-5,19, 46-48]

What are the additional benefits of adult female HPV vaccination?

Besides many adolescents did not receive HPV vaccination at the appropriate time, as discussed, most women seen by gynecologists are above the age limit recommended in the immunization schedule. Therefore, not missing the opportunity to indicate vaccination and avoid HPV infection complications is a fundamental point of the gynecologist care. Even for women who had high-grade precursor lesions and were treated, several studies showed that vaccination after treatment can decrease relapses. It is known that women who have developed HPV lesions have cofactors that facilitate viral action. As these cofactors tend to remain, it may result in pathologies elsewhere. Thus, women with precursor lesions are theoretically at greater risk for other related lesions. In that fashion, vaccination would have a more accurate indication. [29-31, 47, 48]

Does the vaccine confer immunogenicity in adult female?

Antibody response, i.e. immunogenicity in women aged between 24 and 45 years was compared to immunological data of women aged 16 to 23 years, and these were comparable for the HPV-16 type and slightly smaller for HPV-6, 11 and 18. Furthermore, in a study, viral types contained in the vaccine were comparable to those observed at month 48 (end of baseline study), indicating no subsequent reduction in titers between four and six years after vaccination. [29-34,46,47,49, 50]

Should vaccination in adult women be systematic?

Studies show that vaccination of women aged 30 to 45 years is less effective when compared to vaccination in adolescents and young women (up to 30 years old), especially when DNA-HPV status is ignored or positive. This does not justify the systematic recommendation or calling protocol for vaccination. The woman must be evaluated individually. [34, 46-51] Anyhow, HPV vaccination together with cervical screening and management are complementary preventive actions with the potential to reduce the incidence of cervical cancer in this population.[35]

Final remarks

The reduction in diseases caused by HPV is causally related to high HPV vaccination coverage among the target groups (children and adolescents). The vaccine is routinely administered before virus exposure. If universal coverage is available, it will be possible to substantially decrease morbidity and mortality of diseases attributed to HPV worldwide. This could provide a breakthrough in global public health. The school-based vaccination program was suspended years ago. Its return may increase adolescent vaccination coverage. Therefore, it will no longer be necessary to discuss adult female vaccination in the future. Stimulating wide vaccination of adolescents is a fundamental point in primary health care that must not be overlooked. However, we must not miss the opportunity to indicate vaccination for adult women who have not benefited from vaccination as teenagers, especially in countries with lower than expected vaccination rates. This can provide clear benefits as shown by studies. It is important to note that the HPV vaccine administration, at any age, does not replace health promotion actions. Cervical cancer screening should be maintained according to the age group. HPV vaccine and cervical cancer screening are complementary methods to protect women from developing genital cancer. Some fundamental points regarding vaccination still need to be better elucidated among gynecologists and health professionals. Among them, the indication of vaccination stands out, regardless of whether there is any suspicion or evidence of active HPV infection. In addition, vaccination can be recommended after the treatment of high-grade cervical lesions. It has benefits in reducing relapses, although these are extremely low. Concluding about HPV vaccination in adult women who have not been previously vaccinated, there is no discussion about vaccinating them routinely up to 30 years old, as the benefits have already been demonstrated, and gynecologists should be aware of vaccine prescription. National programs around the world recommend calling these women up for vaccinations. However, data demonstrate there are also benefits in vaccinating women aged up to 45 years or more. These women must be evaluated individually, and the indication must be shared with them. The benefit of vaccinating with the coming-of-age depends on the risk of exposure to new infections.

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