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HPV Vaccine: Integrative Review of National and International Guidelines

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Abstract

HPV (Human Papillomavirus) is an adenovirus of the *Papillomaviridae* family with approximately 200 subtypes (subdivided into low and high oncogenic risk groups), responsible for almost 99% of cervical cancers. Worldwide, there are more than 570,000 new cases and more than 311,000 women die each year from cervical cancer; for Brazil, the estimate is of more than 16,000 new cases per year. It is known that cervical cancer is one of the most easily preventable forms of cancer, as there is a highly effective vaccine against HPV. However, the morbidity and mortality rates correlated with human papillomavirus are still concerning, especially in less developed countries. In 2020, the WHO (World Health Organization) presented three goals to achieve by 2030 the worldwide extermination of cervical cancer; among these goals is vaccination. Is the world preparing for this battle? The present work is an integrative review, comparing national and international guidelines for HPV vaccination published in the last five years in the consulted databases, using the descriptors "cervical cancer", "prevention" and "guideline" and the boolean operator "and", from which nine articles were selected. The study made it possible to compare international and national guidelines for vaccination against HPV, showing that developed countries implemented the HPV vaccine longer ago and follow the WHO recommendations more rigorously and effectively than underdeveloped or developing countries. Adopting a single dose as a strategy, as suggested by the WHO in April 2022, could be an important step towards increasing coverage and providing protection for a greater number of girls who do not have access to HPV immunization.

Keywords

Immunization, Prevention, Guidelines, HPV, Cervical Cancer

1. Introduction

HPV is an adenovirus of the *Papillomaviridae* family with approximately 200 subtypes divided into groups of low and high oncogenic risk [1]. HPV-16 and HPV-18 are the most common cancerous types, responsible for almost 70% of cervical cancers, as well as many cases of penile cancer, anal cancer, oroaryngeal carcinoma, and head and neck cancers. HPV-31, 33, 45, 52 and 58 subtypes are also oncogenic and together represent 15% of cervical cancers. HPV-6 and HPV-11 are the two primary types of "low risk" (non-carcinogenic), which cause anogenital warts. Women infected with one type can also be infected with others at the same time [2].

Cervical cancer is a slow and silent developmental disease, which can occur asymptomatically in the early stages, or with precursor lesions, and evolve after years, to intermittent vaginal bleeding (after intercourse), abnormal vaginal secretion to abdominal pain associated with urinary and/or intestinal complaints in advanced cases [3]. Cervical cancer is the fourth most frequent type of cancer among women worldwide, among these cases, 90% occur in women living in middle- and low-income countries [4].

It is known that cervical cancer is one of the most easily preventable and treatable forms of cancer, with primary prevention measures (vaccine and condom), secondary prevention (screening tests for detection of infection and premalignant lesions) and tertiary prevention (early treatment of initial lesions). However, cervical cancer still has high incidence and mortality rates, especially in Africa, Asia and South America [5].

The HPV vaccine, created in 2006 in Australia, may be bivalent to cover the subtypes that most commonly cause cervical cancer: HPV-16 and HPV-18; quadrivalent to also cover the subtypes that are the most responsible for genital warts: HPV-6 and HPV-11 or nonavalent, created in 2010, covering other oncogenic subtypes: HPV-31, 33, 45, 52 and 58 [4].

The need to vaccinate the children and adolescents against HPV occurs because it is a primary prevention method, since the effect of the vaccine is to prevent infection [6]. HPV vaccines are highly effective and promote a significant reduction in infections, consequently also, of neoplastic lesions of the cervix [7]. The HPV vaccine when performed before the age of 17 indicated a nearly 90% reduction in the chances of developing uterine cancer. Serological response after vaccination is better than the response after natural infection [7].

It was found, then, that the immunization strategy within schools is one of the main guarantors of vaccine success, to the detriment of exclusive vaccination in the UBS (Basic Health Units) [8]. In addition, some triggering factors of low coverage are: logistical barriers to access and the lack of continuous education of the population [9]. In addition, the misinformation about the safety and efficacy of the vaccine and the false impression of the stimulus to early sexual initiation [8].

The COVID-19 pandemic was enacted in early 2020, in which emergency

measures were determined to protect the population with SARS-CoV-2 infection. One of the ways to contain the spread of the virus was the restriction of person-to-person contact, aiming that there was no collapse of health institutions, as they might not have the necessary support for the situation. Thus, HPV vaccination, together with other immunizations, recorded vaccine rates far below the desired one, which demonstrates the need for strategic planning for extreme situations [10].

Warning that cervical cancer is a preventable disease, but still has a high incidence and mortality, the WHO (World Health Organization) launched, in August 2020, a campaign for the eradication of cervical cancer in the world by the year 2030 and FEBRASGO (Brazilian Federation of Gynecology and Obstetrics Associations) joined the initiative [11]. WHO's proposed strategy to accelerate the elimination of cervical cancer is based on three goals: 1) to ensure that 90% of girls receive the HPV vaccine by the age of 15; 2) ensure that 70% of women perform a screening test with effective test up to 35 years and another up to 45 years of age and 3) to certify that 90% of women identified with precursor lesions or invasive cancer receive treatment [12].

In line with the WHO proposal, several international guidelines have adopted the vaccination recommendation for girls up to 15 years of age. However, some of them have grown boys and/or increased the ages of the target audience in order to ensure immunization against the most prevalent forms of HPV. However, the recommendations may present specific divergences, in which the conditions of applicability of immunization programs are considered [13].

In April 2022, the WHO SAGE (Immunization Strategies Advisory Group) compared evidence of the efficacy of the single dose of HPV vaccines with evidence of the efficacy of two or three doses in the recommended regimens, and it was concluded that a single-dose may offer significant and non-negligible protection against HPV, in some situations, it may be equivalent to the two doses that are currently recommended for adolescents [13]. These observations would also allow the two-dose regimen to be expanded to ages over 14 years. Therefore, adopting the single dose as a strategy may be an important step to increase coverage and provide protection for a greater number of girls who do not have access to HPV immunization [4].

SAGE's current recommendations for the HPV vaccine are:

- Single dose or two doses for girls from 9 to 14 years of age;
- Single dose or two doses for girls 15 to 20 years of age;
- Two doses six months apart for women over 21 years of age.

Also, in relation to these recommendations, immunocompromised patients, including those living with HIV/AIDS, should continue to receive the three-dose regimen or, when this is not possible, at least two doses. There is no scientific evidence regarding the efficacy of the single dose in this population to date [14].

The single dose is more cost-effective and easier to administer and facilitates the implementation of catch-up campaigns at all ages [15]. Although to date, the

efficacy of the two-dose regimen of HPV vaccine in adolescents for the various outcomes of the infection, for the single-dose regimen, there is still a lack of more consistent evidence, which can be obtained in the coming years with the results of ongoing studies [4].

Given the relevance of immunization against a common cancer, it is interesting to address the guidelines established for HPV vaccination, at national and international level, knowing its peculiarities.

2. Methods

The present work is characterized as an integrative review aiming to explain comparatively the guidelines established for HPV vaccination, both nationally and internationally published in the last five years in the PubMed, MEDLINE and SciELO databases. A search for scientific articles was performed during the second quarter of 2022, in which the descriptors "Cervical cancer", "Prevention" and "Guideline" were used, in addition to the boolean operator "and" among the three descriptors. Exclusion criteria were: articles with research not correlated to human beings, duplicate articles, made available only in the form of abstract, articles that did not directly address the proposal studied or did not meet the other inclusion criteria.

Initially, the search resulted in a total of 815 articles, and then the use of the filters articles launched in the last five years, resulting in 195 articles; publications in either English or Portuguese, with 188 resulting papers; it was also considered access to the full text free of charge, leaving 112 articles; finally, only works carried out in the human species were considered, leaving 98 publications. After being selected, titles and abstracts were read, of which only 15 publications were adapted to the objective of the present study, and 83 articles were excluded due to inadequacy of the content. Finally, after the complete reading of the articles and analysis of the methodology, 9 publications were framed in the objective of the current systematic review (**Figure 1**).

3. Results

After all the methodological stages described were performed, 9 articles were considered appropriate to the proposed one (**Table 1**). These works are identified as below:

1) Title: Vacina HPV quadrivalente é ampliada para homens de até 45 anos com imunossupressão, **Authors:** Brazil—Department of Health; **Year of publication:** 2022.

- **Referenced:** Brazil.
- The Department of Health made available, until mid-2022, the quadrivalent HPV vaccine for girls aged 9 to 14 years, boys aged 11 to 14 years and immunosuppressed people (living with HIV/AIDS, undergoing cancer treatment, hematopoietic stem cell transplants or solid organs) from 9 to 45 years for women and 9 to 26 years for men. In July 2020, the National Immunization

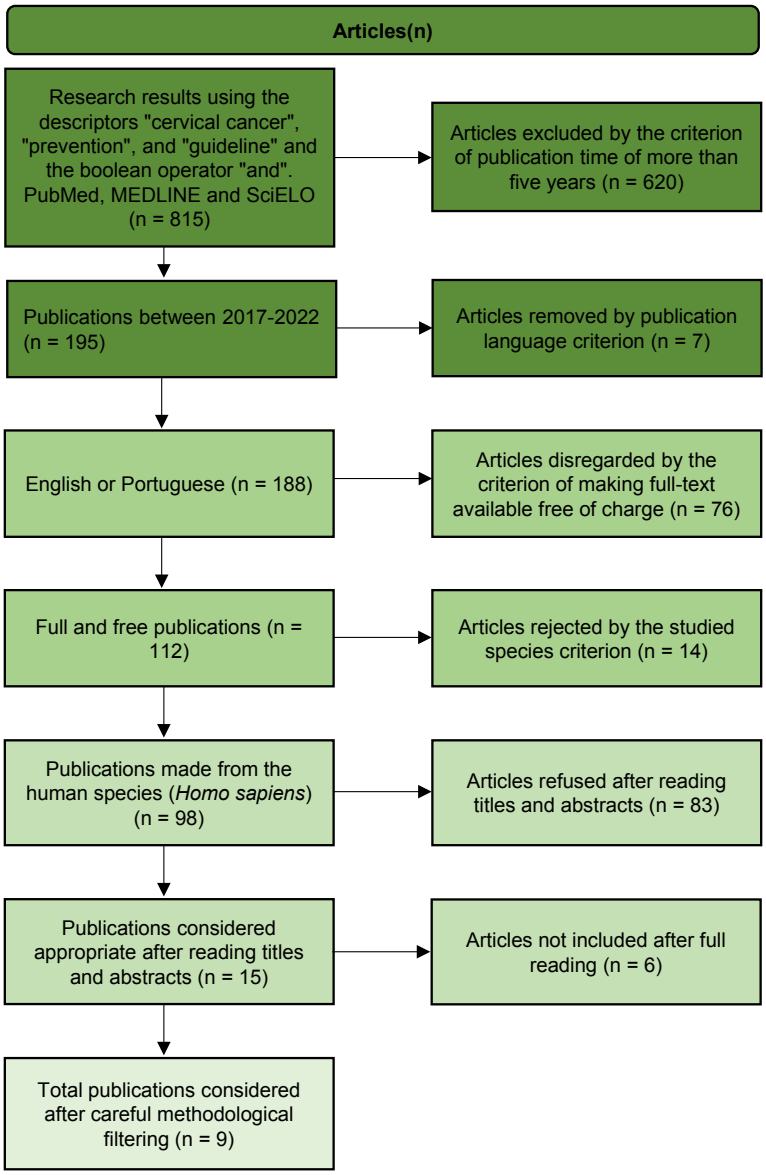

Figure 1. Flowchart representing the methodology used in the study.

Table 1. Identification of countries and their HPV vaccine guidelines.

Country/ Institution	Start of vaccination (year)	Target audience and dosage	Vaccine offered
WHO	2007 (recommendation)	♀: 9 to 14 years (single dose or 2 doses); ♀: 15 to 20 years of age (single dose or 2 doses); ♀: >21 years (2 doses); 6-month interval between doses.	2-Valent 4-Valent 9-Valent
South Africa	2014	9 to 14 years (2 doses); Vaccination site: schools.	2-Valent
Argentina	2011	♀ ♂: >10 years (1 dose or 2 doses, 6-month interval between doses);	Not informed
Australia	2007	♀ ♂: <15 years (2 doses, 6-month interval between doses); ♀ ♂: ≥15 years (3 doses, 2- and 6-month interval between doses).	9-Valent

Continued

Brazil	2014	♀ ♂ : 9 to 14 years (2 doses); Vaccination site: basic health units.	4-Valent
Canada	2006	♀: 9 to 45 years (2 or 3 doses, 3 to 6 months interval between doses); ♂ : 9 to 26 years (2 or 3 doses, 3 to 6 months interval between doses); Vaccination site: schools.	2-Valent 4-Valent 9-Valent
South Korea	2011	♀: 9 to 45 years (3 doses); ♂ : 9 to 25 years[1] and 26 years[2] (3 doses).	2-Valent[1] 4-Valent[2] 9-Valent[2]
United States	2011	♀ ♂ : 9 to 14 years (2 doses, 6 to 12 months interval between doses); ♀ ♂ : 15 to 26 years (3 doses, 2- and 6-month interval between doses);	9-Valent
Malaysia	Not informed	13 to 14 years;	Not informed
European Union	2006-2018	♀ ♂ : 9 to 14 years (2 doses, 6 to 12 months interval between doses); ♀ ♂ : >15 years (3 doses); Vaccination site: schools.	2-Valent 4-Valent 9-Valent

Program/PNI recommended expanding the HPV vaccine for men aged 9 to 45 with immunosuppression, harmonizing recommendations and availability for immunosuppressed men and women. Even more recently, in September 2022, the PNI expanded the age range for boys to 9 and 14 years old, equally for girls [16].

2) Title: A Vaccine Against Cervical Cancer: Context for the Global Public Health Pratitioner; **Authors:** Mary Carol Jannings & Anagha Loharikar [14]; **Year of publication:** 2018.

- **Referenced:** WHO.
- WHO recommends that all countries include HPV vaccination in the national immunization calendar. The organization indicates that 2 doses are performed for girls between 9 and 14 years of age, with a minimum interval of 6 months, and 3 doses for girls ≥ 15 years of age (**Table 1**). The WHO launched a call in 2020 with the aim of eradicating cervical cancer by 2030, where there are three main points that must be followed: 1) ensure that 90% of girls receive the HPV vaccine by the age of 15; 2) that 70% of women perform a screening test with HPV test up to 35 years of age and another up to 45 years of age; and 3) that 90% of women identified with precursor lesions or invasive cancer receive treatment [5] [14].

3) Title: Adolescent providers' knowledge of human papillomavirus vaccination age guidelines in five countries; **Authors:** Hillary M. Topazian, A. Mitch Dizon, Vito L. Di Bona, Lauren Levitz, Silvina Ramos, Karen Morgan, Chan Joo Kim, Karin Richter, Silvia De Sanjose & Jennifer S. Smith; **Year of publication:** 2019.

- **Countries referenced:** South Africa, Argentina, Malaysia, South Korea and Spain.
- A total of 151 adolescent providers in Argentina, Malaysia, South Africa, South Korea and Spain were interviewed between October 2013 and April

2014 about the recommended age groups for HPV vaccination that are in their country's national guidelines. A substantial proportion of providers incorrectly reported their countries' age guidelines for HPV vaccination, particularly the age limit. As the provider's recommendation is among the strongest predictors of vaccination success among adolescents, better education of national guidelines for providers would be essential.

- The South African immunization program implemented in 2014 recommends the vaccination schedule between 9 and 14 years of age, with 2 doses in the school-based, which favors the success of the desired vaccination coverage [15]. In Argentina, South Korea and Spain the national guideline recommends the vaccination schedule between 11 - 14 and in Malaysia the guideline recommends the vaccination schedule between 13 - 14. Some authors suggest that the success of the school program stems from the fact that teachers become a reference for preventive education, making it easier for parents to accept. There is also awareness of the population in cases where the importance of immunization is often reiterated in the school [17].

4) Title: Cervical Cancer Screening Programs in Europe: The Transition Towards HPV Vaccination and Population-Based HPV Testing; **Authors:** Andreas C. Chrysostomou, Dora C. Stylianou, Anastasia Constantinidou & Leondios G. Kostrikis; **Year of publication:** 2018.

5) Title: Human papillomavirus vaccination: The ESGO-EFC position paper of the European society of Gynecologic Oncology and the European Federation for colposcopy; **Authors:** Elmar A. Joura, Maria Kyrgiou, Francisco X. Bosch, Vesna Kesic, Pekka Niemenen, Charles WE. Redman & Murat Gultekin; **Year of publication:** 2019.

- **Organization referenced:** European Union.
- The recommendation of the European societies includes the three available vaccines (bivalent—16 and 18; tetravalent—6, 11, 16 and 18; nonavalent—6, 11, 16, 18, 31, 33, 45, 52 and 58), in a 2-dose schedule for those who are up to 14 years of age and 3 doses for those who start immunization from the age of 15 [18]. Until then, of the 32 member or associated countries of the European Union, only 5 had no vaccination programmes in progress until the year 2018. There is a heterogeneity regarding the year of implementation in immunization campaigns, being between 2007 (France, Germany and Spain) and 2018 (Estonia), being the country that took the longest to start vaccination [18].

6) Title: Clinical guidelines for 9-valent HPV vaccine: Korean Society of Gynecologic Oncology Guideline; **Authors:** Kyung-Jin Min, Sang-Hoon Kwon, Kidong Kim, Sunghoon Kim, Hyun Jung Kim, Seok Ju Seong, Yong Jung Song, Keun Ho Lee, Shin-Wha Lee, Jeong-Won Lee, Suk-Joon Chang, Woong Ju, Young-Tak Kim & Jae-Kwan Lee; **Year of publication:** 2019.

- **Referenced country:** South Korea.
- The KSGO (Korean Society of Oncologic Gynecology) recommends in its 2019 guideline the variable therapeutic regimen, depending on the type of

vaccine used:

- Bivalent: schedule with 3 doses (9 to 45 years of age for female; 9 to 25 years for male).
- Tetravalent and Nonavalent: scheme with 3 doses (9 to 45 years of age for female; 9 to 26 years for male).

- The institution also indicates the vaccination of previously infected women, because there will be protection against future infections by subtypes other than the first infection [19] [20].

7) Title: Human papillomavirus in 2019: An update on cervical cancer prevention and screening guidelines; **Authors:** Salina Zhang & Pelin Batur; **Year of publication:** 2019.

- **Referenced country:** United States.
- The Advisory Committee on Immunization Practices (ACIP) recommends that the U.S. vaccination schedule be gender and age-adaptive. For female between 9 and 14 years of age, 2 doses with an interval of 6 to 12 months between applications are indicated. For those between 15 and 26 years old, the regimen with 3 doses (0, 1 or 2 months for the second application, and 6 months to complete immunization) is offered. The ACIP does not recommend immunization of male audiences between the ages of 21 and 26, however, considers that it should be something agreed between the parties. In this wake of availability without routine recommendation, the female audience between 27 and 45 years old also enters the female audience. The nonavalent vaccine is the only one available in the United States until the time of publication of this study, because the bivalent was discontinued in 2016, and the tetravalent had its use finalized in 2017 [13].

8) Title: Scientific evidence supporting recommendations on the use of 9-valent HPV vaccine in a 2-dose vaccine schedule in Australia; **Authors:** Peter Wnukowski-Mtonga, Sanjay Jayasinghe, Clayton Chiu, Kristine Macartney, Julia Brotherton, Basil Donovan, Madeline Hall, David W Smith, Karen Peterson, Sue Campbell-Lloyd, Christine Selvey, Michelle Giles, John Kaldor & Helen Marshall; **Year of publication:** 2020.

- **Referenced country:** Australia.
- Australia, through the NIP (National Immunization Program), began vaccination in 2007 with the tetravalent vaccine, for the female public aged between 12 and 26 years, expanding in 2013 for male adolescents. The current recommendation of the Australian Technical Advisory Group on Immunization (ATAGI) guideline is a vaccine schedule for boys and girls with 2 doses, before the age of 15, preferably between 12 and 13 years of age, with an interval between applications ranging from 6 to 12 months. Those who started vaccination after 15 years should receive 3 doses, with an interval of 2 and 6 months after the first application, respectively. In 2018, the country replaced the 4-valent vaccine with the 9-valent vaccine, including being used to finalize the scheme if it had been started with the tetravalent [21].

9) Title: Screening for the prevention and early detection of cervical câncer: protocol for systematic reviews to inform Canadian recommendations; **Authors:** Allison Gates, Jennifer Pillay, Donna Reynolds, Rob Stirling, Gregory Traversy, Christina Korownyk, Ainsley Moore, Guylène Thériault, Brett D. Thombs, Julian Little, Catherine Popadiuk, Dirk van Niekerk, Diana Keto-Lambert, Ben Vandermeer & Lisa Hartling; **Year of publication:** 2021.

- **Referenced country:** Canada.
- The recommendation of the Canadian guideline is a 2-dose vaccination schedule, with the nonavalent vaccine, available to females aged 9 to 45 years and 9 to 26 years for the male. Immunization is available in schools throughout the country, which provides good vaccination coverage, except for populations in social vulnerability, that is young people who do not have access to schools. This format has been used in several other countries and demonstrates good results. However, the access factor to vaccination sites is an important logistical and social barrier, especially in underdeveloped or developing countries [22].

4. Discussion

It was identified in this study that developed countries implemented HPV vaccination earlier than underdeveloped or developing countries; in 2006, Canada; in 2007, France, Germany, Spain and Australia; in 2011, United States and South Korea; in 2014, South Africa and Brazil and in 2018, Estonia.

Less developed countries also face more difficulties in vaccine success. In the first year of implementation of the HPV vaccine in Brazil, the PNI established that vaccination occurred in schools, which brought good initial results, with more than 5 million doses applied. However, the second dose ended up reaching just over 3 million young people. Barriers such as access to vaccination sites, misinformation regarding vaccine safety, or taboo about incitement to early sexual initiation are points that need attention to adequate coverage, it is even suggested that vaccination is returned to schools [23].

The knowledge of providers (parents or guardians) about the guidelines for HPV vaccination was evidenced in a study that a substantial proportion where providers incorrectly reported the target ages of their countries for HPV vaccination [15]. As the providers' recommendation is among the strongest predictors of successful vaccination among adolescents, better education and clarification of national guidelines for providers administering HPV vaccination are essential to optimize infection prevention and associated diseases [15]. Not only do providers have low knowledge about HPV, but it has been verified in a before-and-after clinical trial in order to assess the prior knowledge of medical students about HPV; the percentage of correct answers was 45.6% showing limited knowledge on the subject [24].

In October 2017, PAHO (Pan American Health Organization) held a seminar in Antigua City, Guatemala, with the participation of 24 countries, aiming to

share experiences gained with the introduction of the HPV vaccine. It was concluded that countries had difficulties to reach the target population to vaccinate, that vaccination in schools is the easiest strategy to capture the population and that it has been a challenge to constantly inform HPV vaccination coverage. Also in the conclusions of the analysis of this seminar PAHO identified that some countries do not report the doses applied, only coverage or do not inform the target population or considered as target population, to receive the first dose, only girls captured for vaccination; other countries consider the target population, for the reception of the second dose, the girls captured who had received the first dose and some countries do not consider cohort data, and cite more girls vaccinated with the second dose than the first [25].

In contrast, countries that have achieved high vaccination coverage among adolescents such as England and Australia have a decrease in the incidence of cervical cancer. In England, there has been an 87% reduction in cases in the last 5 years, especially in women, who was vaccinated in adolescence [2].

In 2022, WHO modified the recommendations for HPV vaccine cited in the article captured by this study and published in 2018, because the WHO SAGE compared evidence of the efficacy of the single dose of HPV vaccines with evidence of the efficacy of two or three doses in the recommended regimens and concluded that a single-dose of the vaccines available worldwide may offer significant and non-negligible protection against HPV, in some situations, may be equivalent to the two doses that are currently recommended for adolescents; these are the current recommendations: single dose or two doses for girls from 9 to 14 years of age; single dose or two doses for girls 15 to 20 years of age; two doses six months apart for women over 21 years of age [12].

However, the CNE (National Specialized Commission) in FEBRASGO vaccines suggests, at this time, to maintain the recommendation of the regimen of two doses of the HPV vaccine (with an interval of 6 to 12 months between doses), waiting for more evidence to support a change in the schedule; another reason not to adopt the single dose would be that, in Brazil, currently, there is no shortage of HPV vaccines [4].

5. Conclusion

In summary, the countries included in this research have very similar guidelines for HPV vaccination (based on WHO guidelines). The discordant points reflect attempts to circumvent the difficulties faced by cultural and socioeconomic disparities that wind up reflecting not only in the lower vaccination coverage for HPV, but also in the higher incidence of cases of cervical cancer in less developed countries. A worldwide effort is made in the applicability of effective guidelines consistent with local realities, especially the most deprived populations.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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