

INPLASY2023120029

doi: 10.37766/inplasy2023.12.0029

Received: 07 December 2023

Published: 07 December 2023

Jomah, A<sup>1</sup>; Albokhary, A<sup>2</sup>.**Corresponding author:**

Arwa Jomah

arwajo.aleem@hotmail.com

**Author Affiliation:**

Umm Alqura university.

**ADMINISTRATIVE INFORMATION****Support** - NA.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2023120029**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 December 2023 and was last updated on 07 December 2023.**INTRODUCTION**

**Review question / Objective** Given a lack of research regarding HPV vaccines administration, this study aimed to review the effectiveness of Human Papillomavirus vaccine and to synthesis the influence of this vaccine on the quality of women's life. The research hypotheses of this study determined that Human Papillomavirus vaccine could improve women's health. The problem to be addressed through this study is to determine the relationship between the human papillomavirus vaccine and women's health. This study is directed to answer the clinical question: In women (P), the use of Human Papillomavirus vaccine (I) compared to not received the Human Papillomavirus vaccine (C) influence the women's health(O).

**Rationale** HPV has a negative impact on women's health and well-being by profoundly influencing their sexual, emotional, affective, physical, and daily lives (Pereira-Caldeira et al., 2020). The

preventive vaccines are highly effective in preventing cervical infection among women before they are exposed to the virus. In addition, they help to protect against another types of cancers, including vulvar and vaginal cancer, genital warts, anal tumors, as well as mouth, throat, head, and neck cancers (Bruni et al., 2019). Moreover, nurses play a crucial role in combatting HPV. They work as HPV vaccine advocates and can potentially reach an increased percentage of patients because they represent the vast majority of the employees in most healthcare institutions (Lin et al., 2022). The present study is significant, as it will be the first research to examine a major public concern regarding the impact of HPV vaccines on women's health. This study will help to promote women's quality of life by shedding light on how vaccinations affect the incidence of cervical cancer (CC) and another types of diseases. By analyzing the moderating factors that might influence the association between HPV vaccinations and women's health, it will add to the existing HPV literature. In addition, it will clarify the potential

benefits and drawbacks of vaccinations for women and contribute to the creation of evidence-based guidelines that support women's health. This research will help prevent the spread of HPV.

**Condition being studied** The World Health Organization declared that the human papilloma virus (HPV) is the most widespread infection that affects women's reproductive tract. HPV is a serious concern to women's health, as it has a negative impact on women's quality of life (WHO, 2022). In addition, HPV is a pathogen with high prevalence among women in their reproductive age and is responsible for different types of cancers. For instance, it has a 90% association with cervical cancer—the fourth deadliest malignancy in women (Kombe et al., 2021). In Saudi Arabia, approximately 358 new cases of cervical cancer are detected every year among women aged 15 to 44 (Bruni et al., 2023). HPV is a minuscule, double-stranded DNA virus that causes the majority of sexually transmitted infections (STIs) worldwide (WHO, 2023). It affects epithelial cells and causes numerous severe issues for women.

HPV is generally categorized as two groups: low-risk HPVs (LR-HPVs) and high-risk HPVs (HR-HPVs). Cutaneous and anogenital warts are caused by LR-HPVs, while HR-HPVs are responsible for oropharyngeal, cervical, anal, vulvar, vaginal, penile, as well as anogenital cancers. Moreover, with greater incidence than other types, HR-HPV types 16 and 18 have been linked to invasive cervical cancer (Cheng, et al 2020). According to Bruni, (2023), approximately 70% of all occurrences of cervical cancer globally are caused by HPV strains 16 and 18. Certain health consequences caused by HPV can be avoided using HPV vaccinations. In addition, the prevalence of cervical and other anogenital malignancies may be decreased by HPV vaccines that protect against HPV 16 and 18 infections. The use of HPV vaccines plays a significant role in protecting women against the infections in addition to the best preventative immunizations and have made several significant advances in human vaccination (Markowitz & Schiller, 2021).

Evidence suggests that three forms of prophylactic vaccines have been widely used and are effectively successful in lowering the incidence of HPV infection and HPV-related diseases: the quadrivalent HPV vaccine, the bivalent HPV vaccine, and the nonvalent HPV vaccine. In addition, this success is due to the fact that they specifically target and elicit immunity against the LR- and HR-HPVs, which are responsible for 70 and 90% of genital and cutaneous warts and malignancies, respectively (Wang et al., 2019).

However, the Center of Disease Control and Prevention (CDC) reported that the prevalence of cervical cancer has declined by 40% among women who have taken a vaccine. This vaccine is used as antigens to prevent HPV infections and the onset of associated diseases (CDC, 2019).

## METHODS

**Search strategy** The population, intervention, comparison, and outcome (PICO) approach was used to develop the search strategy. P represents the population, which was women in this research; I is the HPV vaccine; C is no vaccine or a placebo; and O represents the influence on women's health. The final search terms were generated for the six electronic databases.

For the P, I, C, and O terms, the Boolean operator "OR" acts as an expander to find all specified synonyms, both singular and plural. This increases the probability that any phrase in the search terms will have applicable hits for it, particularly keywords. The Boolean operator "AND" narrows a search by only retrieving articles that have all the search words and expressions.

To further refine the results, all the search phrases included in the search string will be returned. For instance, in each database, the publication years were restricted to January 2019 until August 2023. An asterisk (\*) was used at the end of words as a truncation symbol to retrieve all words that include the root of the word. In addition, language limitations were imposed. Many journals were found in different languages, but the English language was best suited for this systematic research.

### Selection of studies for inclusion

In a systematic review, a thorough search is needed to identify articles connected to the PICO topic. Following sections describe the search terms used in each chosen database.

First, the EBSCO databases offers three journals including Medline, ERIC, and Academic Search Ultimate, which were searched for the following terms: (women OR woman OR female\* OR adult\* OR young) AND (HPV OR human papillomavirus OR vax OR vaccin\* OR immunisation OR immunization) AND (women's health OR female\* OR wellness). Moreover, the subject thesaurus was used to specify women's health and HPV vaccines in this research, so a filter was applied. Finally, full text was automatically applied from the website to retrieve the full text of the articles.

The second database searched was PubMed; the following search string was used: (women OR woman OR young OR adult\* OR female\*) AND (HPV OR human papillomavirus OR vaccin\* OR vax OR immunization OR immunisation) AND (women's

health OR female\* OR wellness). The filters applied to free full text, clinical trial, RCT, human, English language, female, and three age groups (adult: 19–44 years, middle age: 45–64 years, and aged 65+ years).

The third database searched was the ProQuest database, and the following search string was used: (women OR woman OR young OR adult\* OR female\*) AND (HPV OR human papillomavirus OR vaccin\* OR vax OR immunization OR immunisation) AND (women’s health OR female\* OR wellness) AND (women’s health OR female\* OR wellness). Restrictions were also placed on language and publication date, which was within 5 years. A filter was applied to the subject thesaurus to focus on women’s health, vaccines, and human papillomavirus.

The fourth database searched was ScienceDirect. The terms used were as follows: (women OR woman OR young OR female) AND (HPV OR human papillomavirus OR vaccine OR immunization OR immunisation) AND (women’s health). The filters applied to these subjects were research articles and vaccine.

The fifth database searched was the Cochrane Database. The search was as follows: #1 (women OR woman OR young OR female), #2 (HPV OR human papillomavirus vaccine), and #3 (women’s health or female\*). Finally, the Google Scholar database was searched. The terms utilized in the search included the following: (women) AND (vaccines OR HPV “human papillomavirus”).

**Participant or population** The participants in the selected studies were women aged 18 to 76 years. 1) women with residual/recurrent cervical intraepithelial neoplasia (CIN 1) or high-grade CIN (CIN 2–3), 2) women with low-grade squamous intraepithelial lesions (LSILs) or atypical squamous cells of uncertain significance who tested positive for HPV, 3) patients with histologically verified CIN 2–3 (regardless of their high-risk HPV (HR HPV) status) and without a history of HPV vaccination, or 4) patients undergoing CIN therapy who were scheduled for an LEEP.

**Intervention** The use of Human Papillomavirus vaccine.

**Comparator** Compared to not received the Human Papillomavirus vaccine.

**Study designs to be included** Cross-sectional, or retrospective cohort study, or randomized controlled trial, or prospective study.

**Eligibility criteria** The inclusion criteria were: • Women aged 18–76 years. • Peer – reviewed, •

Published between 2019 to 2023. • Studies that describe the effectiveness of Human Papillomavirus vaccine. • Studies worldwide. • Articles in English. • Quantitative Studies (A cross-sectional, or retrospective cohort study, or randomized controlled trial, or prospective study). • Placebo for control group. The exclusion criteria were: • Male participants. • Females under 18 years of age or greater than 76. • Women with HIV. • A study does not achieve systematic review aim. • A study does not answer research question for systematic review. • Studies before 2019 • None English articles • Studies without peer review • None full text articles. • None original articles.

**Information sources** EBSCO, PubMed, Cochrane, Google Scholar, Science Direct and ProQuest were selected as electronic databases for systematic research.

**Main outcome(s)** The review aimed to appraise the efficacy of the human papillomavirus vaccine and assess its influence on women’s quality of life.

#### **Quality assessment / Risk of bias analysis**

**Quality Assessment** - The included studies were evaluated using the Joanna Briggs Institute (JBI) methodological quality checklist tool. In addition, two reviewers conducted the appraisal process following the JBI guideline in order to critically assess each study’s methodological quality. This assessment helped to evaluate the methodological quality of a study along with the extent to which bias risk has been controlled.

**Critical Appraisal Techniques** - This critical appraisal tool was created by the JBI and collaborators and approved by the JBI Scientific Committee following extensive peer review. This tool encompasses 9–13 questions based on the study design. The questions address the feasibility and appropriateness of the study sample and measure the validity and reliability of the data collection techniques. Through standardized “yes,” “no,” “unclear,” or “not applicable” responses, the researchers sought to identify the strengths and weaknesses, validity, and biases of each study. The goal of this evaluation is to appraise a study’s methodological quality and ascertain how well it has handled the potential for bias in its preparation, conduct, and analysis. Subsequently, the evaluation outcomes may be utilized as guides for the integration and analysis of the research findings (Moola et al., 2020).

**Strategy of data synthesis** Two reviewers extracted the data using according to the following: author(s) name, publication year and study region; type of sample; sample size and

sampling method; data collection method; data analysis; and the study findings.

**Subgroup analysis** NA.

**Sensitivity analysis** NA.

**Country(ies) involved** Saudi Arabia.

**Other relevant information** Bruni L, Albero G, Serrano B, Mena M, Collado JJ, Gómez D, Muñoz J, Bosch FX & de Sanjosé S (2023). Human Papillomavirus and Related Diseases in Saudi Arabia. ICO/IARC Information Centre on HPV and Cancer (HPV Information Centre). Summary Report 10 March. Retrieved from: <https://hpcvcentre.net/statistics/reports/SAU.pdf> Cheng, W., Xu, F., Gao, L., & Liu, J. (2020). The Correlation between the Determination of Vaginal Micro-Ecological Composition and the Outcome of HPV Infection by High-Throughput Metagenome Sequencing Information Technology on the Illumina Platform. *Journal of Infection and Public Health*, 13(12), 1961–1966. <https://doi.org/10.1016/j.jiph.2020.05.024> Center for Disease Control and Prevention (2019). Reasons to Get Vaccinated. United States: Retrieved from <https://www.cdc.gov/hpv/parents/vaccine/six-reasons.html> Kombe, A. J. K., Li, B., Zahid, A., Mengist, H. M., Bounda, G., Zhou, Y., & Jin, T. (2021). Epidemiology and burden of human papillomavirus and related diseases, molecular pathogenesis, and vaccine evaluation. *Frontiers in Public Health*, 8. <https://doi.org/10.3389/fpubh.2020.552028> Lin, Y., Hu, Z., Alias, H., & Wong, L. P. (2022). The role of nurses as human papillomavirus vaccination advocates in China: perception from nursing students. *Human Vaccines & Immunotherapeutic*, 18 (1). <https://doi.org/10.1080/21645515.2022.2030169> Markowitz, L. E., & Schiller, J. T. (2021). Human papillomavirus vaccines. *The Journal of Infectious Diseases*, 224(Supplement 4), S367–S378. <https://doi.org/10.1093/infdis/jiaa621> Pereira-Caldeira, N. M. V., Góes, F. G. B., Almeida-Cruz, M. C. M. de, Caliari, J. de S., Pereira-Ávila, F. M. V., & Gir, E. (2020). Quality of Life for Women with Human Papillomavirus-induced Lesions. *Revista Brasileira de Ginecologia e Obstetrícia / RBGO Gynecology and Obstetrics*, 42(04), 211–217. doi:10.1055/s-0040-1709192 Wang, R., Pan, W., Jin, L., Huang, W., Li, Y., Wu, D., & Liao, S. (2019). Human papillomavirus vaccine against cervical cancer: opportunity and challenge. *Cancer Letters*. doi:10.1016/j.canlet.2019.11.039 World Health Organization: WHO (2023). Human Papillomavirus (HPV). Retrieved from: [https://www.who.int/teams/health-product-policy-and-](https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/human-papillomavirus)

[standards/standards-and-specifications/vaccine-standardization/human-papillomavirus](https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/human-papillomavirus) World Health Organization: WHO (2022). Cervical Cancer. Retrieved from: <https://www.who.int/news-room/fact-sheets/detail/cervical-cancer> Pereira-Caldeira, N. M. V., Góes, F. G. B., Almeida-Cruz, M. C. M. de, Caliari, J. de S., Pereira-Ávila, F. M. V., & Gir, E. (2020). Quality of Life for Women with Human Papillomavirus-induced Lesions. *Revista Brasileira de Ginecologia e Obstetrícia / RBGO Gynecology and Obstetrics*, 42(04), 211–217. doi:10.1055/s-0040-1709192 Bruni L, Albero G, Serrano B, Mena M, Collado JJ, Gómez D, Muñoz J, Bosch FX & de Sanjosé S (2023). Human Papillomavirus and Related Diseases in Saudi Arabia. ICO/IARC Information Centre on HPV and Cancer (HPV Information Centre). Summary Report 10 March. Retrieved from: <https://hpcvcentre.net/statistics/reports/SAU.pdf> World Health Organization: WHO (2023). Human Papillomavirus (HPV). Retrieved from: <https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/human-papillomavirus> Lin, Y., Hu, Z., Alias, H., & Wong, L. P. (2022). The role of nurses as human papillomavirus vaccination advocates in China: perception from nursing students. *Human Vaccines & Immunotherapeutic*, 18 (1). <https://doi.org/10.1080/21645515.2022.2030169> Kombe, A. J. K., Li, B., Zahid, A., Mengist, H. M., Bounda, G., Zhou, Y., & Jin, T. (2021). Epidemiology and burden of human papillomavirus and related diseases, molecular pathogenesis, and vaccine evaluation. *Frontiers in Public Health*, 8. <https://doi.org/10.3389/fpubh.2020.552028>.

**Keywords** Human Papillomavirus (HPV), sexually transmitted infections (STIs), cervical cancer, women's health, women's quality of life (QoL).

#### Contributions of each author

Author 1 - Arwa Jomah - extracted and review the data, drafted and edited the manuscript.

Email: uni.aj@hotmail.com

Author 2 - Afnan Albokhary - reviewed and edited the manuscript.

Email: aalbukhari@uqu.edu.sa