The Outcome of Self-Sampling HPV Test for Primary Cervical Cancer Screening Program in Phitsanulok (HPVPLK2024)†

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Abstract

Objective: To determine the prevalence, genotype distribution, and associated histopathologic outcomes of high-risk human papillomavirus (HR-HPV) infection among women undergoing primary cervical cancer screening using self-sampling in Phitsanulok Province.

Materials and Methods: A cross-sectional study was conducted among women aged 15-60 years who participated in a self-sampling HPV screening program between October 2023 and September 2024. Women positive for HPV16/18 or non-16/18 HR-HPV (OHR-HPV) types with abnormal cytology (ASC-US or worse) were referred for colposcopy and further evaluation. Histopathologic findings were classified according to the CIN system.

Results: Of 8,701 eligible participants, 874 tested positive for HR-HPV, yielding a prevalence of 10.1%. The highest prevalence occurred in the 15 to 29-year age group (35.4%). Non-16/18 HR-HPV genotypes were the most common (82.5%), followed by HPV16 (9.0%), HPV18 (2.4%), and multiple infections (6.1%). Histopathologic examination revealed benign lesions in 79.5%, CIN1 in 10.0%, and CIN2+ in 10.5% of HR-HPV-positive women. HPV16 and OHR-HPV combined demonstrated the highest absolute risk for CIN2+, while OHR-HPV also showed significant associations with high-grade lesions.

Conclusion: The prevalence of HR-HPV infection in Phitsanulok was 10.1%, with non-16/18 genotypes predominating. HR-HPV infection was significantly associated with CIN2+ lesions. These provide important epidemiological data to support public health planning, resource allocation, and underscore the value of self-sampling HPV testing as an effective tool for increasing screening coverage and supporting cervical cancer elimination strategies.

Keywords: High-risk HPV; Self-sampling HPV test; Cervical cancer screening; Cervical histopathology

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Cervical carcinoma is a significant health problem worldwide, especially in low- and middle-income countries. It ranks fourth among female cancers, with an incidence of approximately 13.3 per 100,000 women per year[1]. The disease has a long period of pathogenesis. The initiation and persistent infection of human papillomavirus (HPV) result in cervical dysplasia and may finally progress to cervical cancer. There are certain factors that increase the potential for exposure and acquisition of HPV infection[2,3].

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The World Health Organization (WHO) declared a global goal to eliminate this disease by the year 2030, consisting of three main process indicators: 90% of girls fully vaccinated against HPV by 15 years of age, 70% of women having access to high-performance screening tests, and 90% of those with cervical lesions receiving appropriate treatment[4].

Nowadays, HPV DNA testing is the cornerstone of cervical cancer screening programs, providing highly efficacious results[5,6]. However, there are some limitations. The procedure requires healthcare personnel to collect specimens, creating a heavy workload. Moreover, some women feel embarrassed or reluctant to undergo the test, leading to undercoverage

What is already known about this topic?

While the WHO reported a global HPV prevalence of 11.7% in 2024, this rate varies considerably across different regions. The previous study for HPV DNA screening in Phitsanulok was performed from 2020 to 2022; HPV infection was only 1.7%, and the most common HPV genotype was HPV16 at 43.1%.

What does this study add?

The prevalence of HR-HPV infection among women aged 15-60 years in Phitsanulok Province was 10.1%, with non-16/18 genotypes being the most common.

in the target population. To address these issues, self-sampling HPV testing was introduced, offering greater convenience and privacy. Previous studies have demonstrated that the outcomes are comparable to conventional HPV DNA testing[7].

In Thailand, the Ministry of Public Health has implemented the screening program nationwide using high-risk HPV (HR-HPV) test and liquid-based cytology since 2020[8] and the self-sampling HPV test 3 years later[9]. Moreover, the national HPV vaccination program was initiated for young girls in 2017. Consequently, the prevalence and distribution of HR-HPV infection may have shifted. The up-to-date epidemiological data in different regions are essential for planning healthcare resources and developing public health policy. Currently, comprehensive data on HR-HPV genotypes in Thai women remains limited. Therefore, the primary aim of this study was to determine the prevalence, genotypic distribution, and risk factors of HR-HPV infection, and the secondary aim was to identify the histopathology of cervical lesions according to HPV genotypes among women who underwent primary screening, using self-sampling in Phitsanulok Province.

Materials and Methods

Study Design and Participants

This cross-sectional study was conducted among asymptomatic women who participated in a self-sampling HPV screening program in Phitsanulok Province between October 2023 and September 2024. The inclusion criteria were: 1) Women aged 30-60 years who voluntarily participated, and women aged 15-29 years considered at high risk for HPV infection (sexual debut ≤15 years, multiple sexual partners, previous STD, or immunocompromised conditions). 2) Last HPV screening performed more than 5 years prior. Exclusion criteria included a history of abnormal cervical screening (CIN1 or higher), prior cervical procedures for malignancy, hysterectomy, pregnancy, or postpartum less than 6 weeks.

Women who tested positive for HPV 16 or 18, or non-16/18 HR-HPV (OHR-HPV), accompanied by cytology of atypical squamous cells of undetermined significance (ASC-US) or worse, were referred for colposcopy and management according to the algorithm (Figure 1). Sociodemographic, lifestyle, and reproductive data were collected. The study was approved by the Buddhachinaraj Phitsanulok Hospital Institutional Review Board (HREC No.150/2567) and was registered with the Thai Clinical Trials Registry (TCTR20260328004).

Cervical Specimen Collection

After providing written informed consent, participants received verbal, pictorial, and video instructions from healthcare providers on how to self-collect vaginal specimens. The Aptima Multitest Collection Kit (Hologic, USA) was used for specimen collection. Briefly, participants were instructed to wash their hands, gently insert the cotton-tipped swab into the vagina to approximately half of its length, rotate the swab five to six times, then withdraw and place it into the collection tube containing phosphate buffered saline (PBS). The specimens were stored in a cool box and transported to the Phitsanulok Regional Medical Sciences Center for laboratory processing.

HR-HPV Detection and Genotyping

Specimens were processed using the Cobas 4800/6800 HPV Test (Roche Molecular Diagnostics), a real-time polymerase chain reaction (PCR) system that separately detects HPV16 and HPV18, as well as a pooled group of other HR-HPV types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). Results were categorized as HPV16, HPV18, and OHR-HPV.

Cytology Examination

The specimens for cytology were prepared by using the liquid-based technique (Thin-Prep system, Hologic, Marlborough, MA, USA). The slides were examined by an experienced cytologist, and any abnormal findings were reviewed by a pathologist. The cytology was reported according to the Bethesda system 2001. Abnormal cytology was defined as ASC-US or a higher grade of cellular abnormality.

Colposcopy

A gynecologic oncologist performed colposcopy on women who were HPV16/18 positive or OHR-HPV positive with abnormal cytology. Colposcopic findings were graded using the Reid colposcopic index (RCI). Biopsies were obtained when indicated. Endocervical curettage (ECC) was performed for unsatisfactory colposcopy.

Histological Examination

Biopsy specimens were stained with H&E and classified according to the CIN system (normal, CIN1-3, adenocarcinoma in situ, adenocarcinoma, squamous cell carcinoma). The pathologist was blinded to HPV, cytology, and colposcopy results.

Sample Size

Based on a previously reported HR-HPV

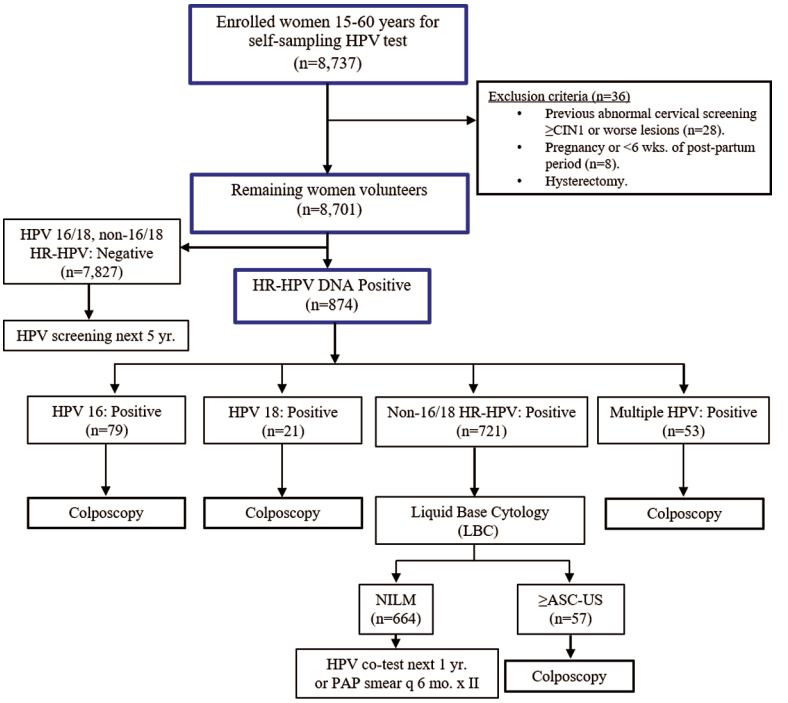

Figure 1. Algorithm of primary self-sampling HPV screening.

HPV: human papillomavirus, HR-HPV: high-risk HPV, NILM: negative for intraepithelial lesions or malignancy, ASC-US: atypical squamous cell of undetermined significance

Note: Multiple HR-HPV 53 cases

- 2 genotypes: 50 cases: HPV16+OHR-HPV 32 cases, HPV18+OHR-HPV 18 cases
- 3 genotypes: 3 cases

prevalence of 1.7%[10], the sample size was calculated with a two-sided alpha error of 0.05 and 80% statistical power, including an additional 20% to account for potential dropout. The required sample size was 8,916 participants.

Statistical Analysis

The statistical analysis was performed using the R Statistical Software. The descriptive statistics for the continuous variables were assigned as means with standard deviations. The categorical data were presented as frequency distributions. The odds ratio determined the association between HPV genotype and cervical histopathology. The absolute risk of HR-HPV infection with respect to 95% confidence intervals (CIs) was determined for CIN2 or worse cervical lesions. HR-HPV genotypes were analyzed as individual and combined results. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 8,737 women enrolled for primary HPV screening. Thirty-six were excluded due to 28 having previous abnormal cervical screening, and 8 were pregnant. The remaining 8,701 were satisfied for study. HR-HPV DNA was detected in 874 women (type 16, 18, and OHR-HPV) as demonstrated in Figure 1. Baseline characteristics of women who had a positive HPV test are shown in Table 1.

The overall prevalence of HR-HPV infection was 10.1%. Nevertheless, in women aged 30-60 years, the prevalence was 9.8%, and in the younger age group (15-29 years), the prevalence was higher (35.4%) as detailed in Table 2. The most common type was OHR-HPV 721 cases (82.5%). HPV16 was 79 cases (9.0%), HPV 18 was 21 cases (2.4%), and two or more types were 53 cases (6.1%) as described in Figure 2.

The HR-HPV infections were more common in younger age women and declined with age. The age at first intercourse of less than 20 years was found more frequently than over 20 years. The participants mostly had one sexual partner and used hormonal contraception (Table 3).

According to the study, histopathologic findings are benign lesions (acute-chronic cervicitis, squamous metaplasia (79.5%), CIN1 (10.0%), CIN2 (4.7%),

Table 1. Baseline characteristics of self-sampling HPV test positive women

Characteristics	n=874
Age (years); mean [SD]	43.8 [9.1]
BMI (kg/m^2); mean [SD]	26.7 [5.2]
Age of sexual debut (years); mean [SD]	19.1 [3.3]
Partner; median (min-max)	2 (1-10)
Menopause; n (%)	219 (25.1)
Hormonal used; n (%)	311 (35.6)
Smoking; n (%)	62 (7.1)
Underlying diseases; n (%)	207 (23.7)
HIV infection	16 (1.8)
HT	101 (11.6)
DM	65 (7.4)
DLP	99 (11.3)
Hypo/hyperthyroidism	16 (1.8)
Other	43 (4.9)

SD=standard deviation; BMI=body mass index; HT=hypertension; DM=diabetes mellitus; DLP=dyslipidemia

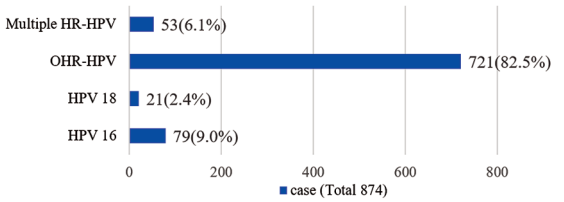

Figure 2. Distribution of high-risk HPV genotypes among HR-HPV positive women.

HPV: human papillomavirus, HR-HPV: high-risk HPV, OHR-HPV: non-16/18 HR-HPV

Note: Multiple HR-HPV 53 cases

- 2 genotypes: 50 cases: HPV16+OHR-HPV 32 cases, HPV18+OHR-HPV 18 cases
- 3 genotypes: 3 cases

Table 2. Age distribution of population who positive HPV-self screening tests

Age (years)	Positive HPV (people)	Population (people)	Prevalence (%)
15-29	29	82	35.4
30-39	276	2,866	9.6
40-49	312	3,472	9.0
50-60	257	2,281	11.3
Total	874	8,701	10.1

HPV=human papillomavirus

Table 3. Characteristics of the population who had self-HPV test positive

	Positive HR-HPV (n=874) n (%)	p-value
Age (years)		<0.001*
15-29	29 (3.3)	
30-39	276 (31.6)	
40-49	312 (35.7)	
50-60	257 (29.4)	
Age at first SI (years)		<0.001*
<20	564 (64.5)	
≥20	310 (35.5)	
Partner		<0.001*
>1	677 (77.5)	
≤1	197 (22.5)	
Hormonal use		<0.001*
Yes	335 (38.3)	
No	539 (61.7)	
Smoking		<0.001*
Yes	62 (7.1)	
No	812 (92.9)	

HR-HPV=high-risk human papillomavirus; SI=sexual intercourse

* Statistically significant at p<0.05 determined by chi-square

CIN3 (4.9%), adenocarcinoma in situ (0.1%), and squamous cell carcinoma (0.8%) (Table 4). HR-HPV infections were significantly associated with high-grade cervical lesions (CIN2+) (Table 4). In the young age group, however, there was no meaningful association between HR-HPV infection and CIN2+ lesions, and no invasive cancer was found (Table 5).

The absolute risk and odds ratios of CIN2+ associated with individual HPV genotypes are presented in Table 6. Notably, HPV16, HPV18, and multiple HR-HPV infections demonstrated a significant risk for CIN2 or greater lesions when compared to OHR-HPV.

Discussion

The identification of HR-HPV infection and genotype distribution remains an essential strategy for cervical cancer elimination. In this study, the prevalence of HR-HPV infection among women in Phitsanulok Province was 10.1%, which is higher than the rates reported from nearby regions[11], such as Nakhon Sawan (7.69%). Studies from other regions of Thailand have also shown variable prevalence. Swangvaree et al. reported a prevalence of 8.2% in hospital-based populations in Bangkok[12], and Sukvirach et al. identified prevalence rates of 8% in northern Thailand and 3.8% in the southern region[13]. Internationally, the highest rates have been reported in sub-Saharan Africa (24%), Eastern Europe (21%), and Latin America (16%), while the global average is approximately 11% to 12%[6,14]. These variations may be attributed to differences in study populations, PCR

Table 4. Cytology and histopathologic findings related to the genotypes of HPV infection

Cytology-histopathology	n (%)					p-value
	HPV16 (n=79)	HPV18 (n=21)	OHR-HPV (n=721)	Multiple HPV infections (n=53)	Total (n=874)	
Benign lesion	8 (10.1)	6 (28.6)	664 (92.1)	17 (32.1)	695 (79.5)	-
CIN1	31 (39.2)	6 (28.6)	26 (3.6)	24 (45.3)	87 (10.0)	<0.001*
CIN2	14 (17.7)	3 (14.3)	17 (2.3)	7 (13.2)	41 (4.7)	<0.001*
CIN3	21 (26.6)	5 (23.8)	12 (1.7)	5 (9.4)	43 (4.9)	<0.001*
Adenocarcinoma in situ	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.1)	0.201F
Squamous cell carcinoma (SCC)	4 (5.1)	1 (4.7)	2 (0.3)	0 (0.0)	7 (0.8)	<0.001*

HPV=human papillomavirus; OHR-HPV=non-16/18 high-risk HPV

* Statistically significant at p<0.05 determined by chi-square, F Fisher's exact test

Note: No adenocarcinoma was found.

Table 5. Cytology and histopathologic findings of women age 15-29 years

Cytology-histopathology	HR-HPV infection (n=29) n (%)	Odd ratio (95% CI)
Benign lesion	23 (79.3)	-
CIN1	4 (13.8)	4.61 (0.79 to 26.96)
CIN2+	2 (7.9)	1.15 (0.20 to 6.74)

HR-HPV=high-risk human papillomavirus; CI=confidence interval

Note: No adenocarcinoma in situ, adenocarcinoma, and squamous cell carcinoma was detected.

Table 6. The absolute risk of histopathologic findings CIN2 or worse corelated to genotype of HPV infection

HPV infection	Number of cases	CIN2+ n (%)	Absolute risk (%)	Odd ratio	95% CI
HPV16	79	40 (50.6)	4.58	14.65	8.69 to 24.72
HPV18	21	9 (42.9)	1.03	6.96	2.85 to 17.0
OHR-HPV	721	31 (4.3)	3.51	5.67	3.65 to 8.80
Multiple HR-HPV	53	12 (22.6)	1.37	2.71	1.37 to 5.37

HPV=human papillomavirus; HR-HPV=high-risk human papillomavirus; OHR-HPV=non-16/18 HR-HPV; CI=confidence interval

sensitivity, geographic distribution of HPV genotypes, and regional immune responses.

The considerably higher prevalence in our study compared with earlier local data (1.7% by clinician-collected sampling) likely reflects improved accessibility and acceptability of self-sampling[10]. Barriers such as embarrassment, anticipated pain, financial constraints, and lack of transportation to the screening unit often decrease participation in clinician-based screening programs. Self-collection provides greater convenience, privacy, and autonomy, thus potentially increasing coverage and improving the detection rate.

OHR-HPV genotypes constituted the majority of infections (82.5%). HPV16 was the second most common genotype, followed by multiple infections. This trend suggests a possible shift in genotype distribution after the nationwide HPV vaccination program, which targets HPV16 and HPV18. The observed predominance of non-16/18 types highlights the need to consider vaccines with broader genotype coverage in future immunization strategies.

The age-specific prevalence pattern demonstrated the highest HR-HPV burden among young women aged 15-29 years (35.4%), followed by a second moderate peak at age 50-60 years. This resembles the U-shaped distribution reported in several previous studies[6,14]. The second peak was less pronounced in our study, likely due to the upper age limit of 60 years in the screening program, whereas other studies reported the second peak at 75-80 years. The high prevalence in young women may be attributed to transient infections that often regress spontaneously, supporting the recommendation to initiate routine screening at age 30 to reduce unnecessary evaluations and treatments in younger women[15].

Several behavioral and reproductive factors, including early sexual debut, multiple sexual partners, hormonal contraceptive use, and smoking, were associated with HR-HPV infection, consistent with a previous study[6]. Hormonal contraceptive use may modulate cervical susceptibility through hormone-mediated enhancement of HPV oncogene expression, whereas smoking introduces carcinogens that impair local cervical immunity, decreasing the clearance of HPV and increasing the likelihood of persistent infection and progression to CIN2+[6]. These findings emphasize the role of modifiable behavioral and reproductive factors in HR-HPV acquisition and persistence, and reiterate the importance of strengthening targeted public health education and preventive strategies aimed at reducing such risk behaviors.

Regarding disease severity, HR-HPV infection

was associated with normal histology in 79.5% and CIN1 or worse in 20.5%, with CIN2+ detected in 10.5% of infected women. HPV16 carried the highest risk of CIN2+, followed by HPV18, multiple infections, and OHR-HPV. These findings align with large-scale cohort studies, such as ATHENA[15-17], which demonstrated substantially elevated risks of high-grade lesions in HPV16/18-positive individuals. The significant risk associated with OHR-HPV, particularly genotypes 31/33/35/52/58, underscores the importance of appropriate triage strategies. Women with OHR-HPV and abnormal cytology should undergo colposcopy, whereas those with negative cytology should be followed annually. However, emerging evidence suggests that certain OHR-HPV types may warrant direct referral for colposcopy even when cytology is normal[18].

Multiple infections were identified in 6.1% of participants, which is lower than 20% to 45% rate reported in previous studies[19,20]. Differences in detection methods, sample collection techniques, and regional genotype distribution may explain these discrepancies. Multiple infections were significantly associated with CIN2+, likely due to synergistic viral interactions and increased viral load, emphasizing the importance of vigilant follow-up[15].

Overall, the findings confirm the strong correlation between HR-HPV infection and the risk of high-grade cervical lesions, reinforcing the need for strict adherence to screening and triage algorithms.

Conclusion

The prevalence of HR-HPV infection among women aged 15-60 years in Phitsanulok Province was 10.1%, with non-16/18 genotypes being the most common. HR-HPV infection was significantly associated with CIN2+ lesions. These findings provide important epidemiological data to support public health planning, resource allocation, and the development of cervical cancer prevention strategies aligned with national and global goals to eliminate cervical cancer.

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Authors Contributions

RR: Contributed to patient recruitment, data collection, interpreted or analyzed the data, and prepared the manuscript. AN and CC: revised the manuscript for important intellectual content, gave final approval of the version, and agree to be accountable for all aspects of the work.

Clinical Trial Registration

This study was reviewed and approved by the Thai Clinical Trials Registry (TCTR) Committee on 09 April 2026. The TCTR identification number is TCTR20260409004.

Conflicts of Interest

The authors declared no conflicts of interest.

Ethics Approval and Consent to Participate

This study was approved by the Institutional Review Board of the Buddhachinaraj Phitsanulok Hospital (HREC No.150/2567). After providing written informed consent, participants received verbal, pictorial, and video instructions from healthcare providers on how to self-collect vaginal specimens.

Data Availability Statement

The authors confirm that the data supporting the findings of this study are available within the article and its Supplementary material. Raw data that support the findings of this study are available from the corresponding author upon reasonable request.

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This study received no funding.

Use of Artificial Intelligence

The authors used Gemini to perform grammatical checks and refine the English expression within this manuscript. However, the interpretation of the data and the formulation of all conclusions remain the sole responsibility of the authors.

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