RESEARCH ARTICLE

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Performance of HPV Self-Sample Collected by a Novel Kit in Comparison with Clinician Collected Sample for Cervical Cancer Screening

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Abstract

Background and Objectives: We are reporting the performance of HPV self-sample collected by a novel kit in comparison with clinician collected cervical sample for HPV testing for cervical cancer screening. **Methods:** Consenting, eligible women aged 25 to 60, with a positive cervical cancer screening test report in the past one year but without any prior treatment for cervical abnormalities were enrolled in the study. Each woman provided 2 samples for the HPV test (vaginal self-sample collected with the CERVICHECK™, an indigenous kit from India and cervical sample collected by the clinician). These samples were analysed using cobas HPV test on 4800 platform and for liquid-based cytology. **Results:** We enrolled 156 eligible, consenting participants at 2 study sites. The agreement for the sample collected by CERVICHECK™ and clinician collected sample for any high-risk HPV was 95.1% (k= 0.90, SE 0.036, 95% CI 0.83-0.97). The agreement for HPV 16 or 18 only was 95.1%, (k=0.88, SE 0.045, 95% CI 0.79-0.97). The overall acceptability of the kit was good, participants expressed that self-sampling was easy and > 90% women were willing to recommend it to their friends. **Interpretation and Conclusions:** There was almost perfect or perfect agreement between the HPV self-sample collected by CERVICHECK™ and clinician collected cervical sample. Self-sampling was highly acceptable to the participating women.

Keywords: HPV- cervical cancer screening- self-sample- cervical cancer

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Introduction

Cervical cancer is the fourth most common cancer among women worldwide. In 2022, there were an estimated 660,000 new cases and 350,000 deaths due to this preventable cancer [1] of which 60% contribution of new cases is from Asia [1]. This high burden in the Asian countries is due to lack of availability as well as capacity of screening and treatment services, lack of knowledge, lack of awareness and lack of separate funding for the programme sustainability [2].

The World Health Organization's (WHO) global cervical cancer elimination strategy rests on 3 major milestones to be achieved by 2030. Cervical cancer screening of 70% of women using a high-performance test at least twice in the life time of a woman, once at 35 and again at 45, is one among its key strategies to prevent deaths due to cervical cancer among adult women [3]. Although HPV vaccination of adolescent girls will help in reducing cervical cancer incidence in low- and middle-income countries (LMICs) by more than 85% over the next century [4], adult women who do not benefit by the preventive HPV vaccines need immediate intervention of cervical cancer screening and appropriate management of pre-cancers to prevent cervical cancers. Several randomized controlled trials and cross-sectional studies including a meta-analysis have shown that human papillomavirus (HPV) detection is the most superior primary screening test for detection of cervical intraepithelial neoplasia (CIN) [5] and is also recommended by the WHO in the 2021 guidelines [3].

One of the essentials of secondary prevention of cervical cancer is the screening coverage and the WHO's elimination strategy recommends screening of at least 70% of the women of eligible age. There are several HPV assays available in the market that are validated and thus suitable for primary screening [6]. Screening with the HPV test offers a unique opportunity for HPV-self sampling [7]. Polymerase chain reaction (PCR) based HPV assays to detect high-risk HPVs are as accurate on

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HPV self-samples as the clinician collected samples [8]. The acceptability of HPV self-sampling has been shown to be very good among participating women, the sample can be collected in their own private environment without having to visit the clinic or hospital, and self-sampling can also help women in overcoming multiple barriers [9-11]. HPV self-sampling increases the screening participation rates [12] and thus increases the screening coverage [13]. There are a couple of validated assays [6], and there are several types of brushes or Dacron swabs, in the global market, for HPV self-sample collection [14, 15]. However, the self-sampling devices are not readily available in the low- and middle-income countries including India and are currently expensive.

CERVICHECK™ is an indigenously developed and patented HPV self-sampling kit developed by Pragmatech Healthcare Solutions Pvt. Ltd., India. The material used for the self-sampling device is medical grade polypropylene and it does not interfere with the PCR test [16] or cause any skin irritation or cytotoxicity. The self-sample collection kit contains an instruction manual for sample collection, disinfected disposable collection device, BD SurePath™ Collection vial, lubricant gel (Cupid Ltd, India) and a resealable biohazard bag for keeping the collected sample. The device has an outer hollow tube and a cytobrush inside with a piston to push the cytobrush out of the tube once the hollow tube is inserted in the vagina as per the instructions. Then with the other hand the knob is rotated clockwise so that it is pushed out of the tube to collect the sample. After rotating the knob for 5 to 10 times, the knob is pulled so that the brush goes inside the tube and then the device is pulled out of the vagina. The brush is the subsequently dropped into the sample collection medium.

We are reporting the findings of a study conducted to evaluate if the self-sample collected by the CERVICHECK™ yields the same HPV test report as that of the clinician collected cervical sample when tested by the cobas® HPV test. We also evaluated the agreement between the liquid based cytology (LBC) report in the self-sample and as that of the clinician collected cervical sample.

Materials and Methods

We conducted a cross-sectional study at 2 sites in India; Prayas, a non-governmental, non-profit organisation in Pune (Site 1) and Baroda Medical college and Sir Sayajirao General Hospital, Baroda (Site 2) between 1st April 2022 and 20th September 2022. The study was approved by the ethics committees of both the institutes. Consenting women aged between 25 and 60, referred for colposcopy with an abnormal cervical cancer screening test report (abnormal cytology or positive visual inspection with 5% acetic acid (VIA) or a positive HPV test report) within the past year were enrolled in the study. Women who were pregnant, who were menstruating, who had received any treatment for precancer in the past, those who had used any vaginal product in the past 1 week or had undergone hysterectomy were excluded from the study.

Study participants were provided with an information leaflet and were shown a video in the local language (https://drive.google.com/file/d/1RuBTdkp1pMnjYqQIGJ4EFKu6GmGhaMOX/view) for the self-sampling procedure. Samples were collected from each study participant by both methods (self-sample and clinician collected sample) in separate vials. The self-sample was collected first using the CERVICHECK™ in the clinic with the study nurse by the side of the participant to assist in case of any help. This was followed by a clinician collected cervical sample using the brush provided along with the BD SurePath™ Collection Vial. These vials were numbered using a identification numbers mentioned in the masking sheet provided by the statistician. The vials were assigned a unique sample tracking number masked to eliminate bias at the testing laboratory. This numbering scheme was generated for each site. This scheme was maintained under safe custody of the statistical centre and incorporated in the database for the final data analysis. All participants completed an acceptability questionnaire before leaving the clinic. The participants were reimbursed for their time for the study participation and the amount was approved by the local Ethics Committees.

The samples were shipped and analysed using cobas 4800 platform for HPV detection and LBC at a central laboratory at Cancer Institute WIA, Chennai, India. The cobas® HPV test for use on the cobas® 4800 System (cobas® HPV Test) is a qualitative in vitro test for the detection of Human papillomavirus in clinician-collected cervical specimens using an endocervical brush/spatula or broom. This test detects high-risk HPV 16 and HPV 18 types separately and other high-risk types (HPV 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68) as aggregate. The samples were also analysed using liquid based cytology (LBC). The LBC slides were prepared using the Huropath-CelltraZone automatic slide preparation method. The slides were stained and reported using the 2014 Bethesda system of reporting cervical cytology by a cytopathologist.

Sample size

A sample size of 150 participants was powered to detect substantial agreement (κ=0.80) between self- and physician-collected specimen with a 5% significance level. Samples collected from each study participant (by both methods) were assigned a unique sample tracking number and masked to eliminate bias. This numbering schema was generated for each site. This schema was maintained under safe custody of the independent statistical centre and was incorporated in the final database for analysis.

Statistical analysis

The analysis was performed for both sites combined. All participants for whom both samples were collected were included in the analysis pertaining to concordance.

Analysis was performed using standard statistical software. Agreement rates of perfect matches for HPV detection between the self- and physician collected samples was calculated, as well as agreement rates for HPV-16/-18 and other high-risk HPV. The concordance between paired samples was assessed using the Kappa statistic. 95% CIs were calculated (Cohen's Kappa; κ) and defined as "Poor" ($\kappa \leq 0.20$), "Fair" ($0.21 \leq \kappa \leq 0.40$), "Moderate" ($0.41 \leq \kappa \leq 0.60$), "Good" ($0.61 \leq \kappa \leq 0.80$),

or "Very good" ($\kappa \geq 0.81$). The sensitivity and specificity of HPV self-sampling was calculated using physician sampling as the standard. Data on discordant pairs was tabulated. Liquid-based cytology results concordance was examined by employing the above methods.

Results

A total of 156 eligible, consenting participants were enrolled in the study (125 participants at Site 1 and 31 at Site 2). Four participants withdrew consent hence they are not included in the analysis. The mean age of the consenting women was 41.1 years (SD 6.7, range 25 to 58).

Demographic and other reproductive history details of the enrolled participants is presented in Table 1. Among the 156 enrolled, 91 (58.3%) had completed some schooling, 32 (20.5%) had completed higher education and 33/156 (21.2%) were illiterate. Almost all the women 155/156 had at least one child. Majority of the women were menstruating (119/156, 76.3%) and 37 (23.7%) were menopausal. Only one participant had received an HPV vaccine in the past and was screened as she was eligible for screening. Of the 125 participants enrolled at Site 1, 119 had prior experience of vaginal self-sample for the HPV test when they were screened previously with the Hybrid Capture 2 test using HPV self-samples in different outreach screening camps and since they were HPV positive, they were referred for colposcopy when they were enrolled in this study.

Table 1. Demographic and Reproductive History Details of Study Participants

Demographic characteristic (n= 156)	n	%
Age		
25 to 35	36	23.1
35 to 60	120	76.9
Education Level		
Illiterate	33	21.2
Some schooling	91	58.3
Higher education	32	20.5
Parity		
Nulliparous	1	0.0
One child	45	28.8
2 or more children	110	70.5
Menstruation history		
Less than 12 months	119	76.3
More than 12 months	37	23.7
Received HPV vaccine in the past		
No	155	99.40%
Yes	1	0.60%
Previous experience of any self-sampling device to collect vaginal sample		
No	37	23.70%
Yes	119	76.30%

The performance of HPV detection in the HPV self-sample and cervical sample collected by the clinician is presented in Table 2. The agreement for any high-risk HPV including HPV 16 and 18 was 95.1% (k= 0.90, SE 0.036, 95% CI 0.83-0.97). The sensitivity of the kit for the detection of any high-risk HPV was 96.2% (95% CI 89.2-99.2) and specificity of 93.9% (95% CI 85.2-98.3). The agreement for HPV 16 and or HPV 18 was 95.1% (k=0.88, SE 0.045, 95% CI 0.79-0.97). The sensitivity of the kit for the detection of HPV 16 and or HPV 18 only was 97.1% (95% CI 91.8-99.4) and specificity was 90.0% (95% CI 76.3-97.2).

There were 9 discordant cases between clinician collected and vaginal self-collected sample for HPV detection and they are presented in Table 3. The agreement for the self-sample and clinician collected cervical sample for LBC was 95% (k=0.80, SE 0.072, 95% CI 0.66-0.94) [Data not shown].

The experience of using CERVICHECK™ kit is presented in Table 4. All the participants found that the instructions for using the self-sampling kit were clear (152/152, 100%, 95% CI 97.6-100). Although majority of the participants (99/152, 65.1%, 95% CI 57.0-72.7) felt that it was better to get the sample/ test done by a clinician than a self-sample, 145/152 (95.4%, 95% CI 90.7-98.1) felt that self-sample will be opted by women who are uncomfortable to provide a sample at the clinic. The self-sampling was reported to be easy by the majority of the participants (150/152, 98.7%, (95.3 – 99.8%) and only 43/152 (28.3%, 95% CI 21.3-36.2) women felt that self-sampling was unpleasant. Majority of the women also reported that they would recommend self-sampling to their friends and family (92.8%, 95% CI 87.4-96.3).

Discussion

This evaluation of the CERVICHECK™ self-sampling kit for an HPV test for cervical cancer screening has demonstrated that there is almost perfect agreement between the HPV test performed using cobas® 4800 platform on the provider collected cervical sample and the vaginal self-sample collected by the women in the clinic (k=95.1, for both; HPV 16 and HPV 18 genotypes and other high-risk HPV). We also observed very good

Table 2. Performance of HPV Detection in Self-Collected and Clinician Collected Samples

	Agreement rate (%)	Kappa, SE (95% CI)	Sensitivity (95% CI)	Specificity (95% CI)
Any high-risk HPV (including HPV 16/18)	95.10%	0.90, 0.036 (0.83 - 0.97)	96.20% (89.2 – 99.2%)	93.90% (85.2 – 98.3%)
HPV 16 / 18 only	95.10%	0.88, 0.045 (0.79, 0.97)	97.10% (91.8 – 99.4%)	90.00% (76.3 – 97.2%)

Table 3. Discordant Cases (N=9) between Self-Collection and Clinician Collection Samples

Screening Number	Age (Years)	HPV Genotype Clinician Collection	HPV Genotype Self-Collection
1	33	Other high-risk HPV	Negative
2	31	Other high-risk HPV	HPV 16 +Other high-risk
3	48	Other high-risk HPV	Negative
4	43	Other high-risk HPV	Negative
5	44	HPV 16 +Other high-risk	HPV 16
6	32	Negative	Other high-risk HPV
7	49	Negative	HPV 16
8	49	Negative	Other high-risk HPV
9	36	Negative	Other high-risk HPV

Table 4. Experience of Using Self-Collection Kit

			Number (N = 152)	%	95% CI
1	Did you find the instructions for cervical sampling with the CERVICHECKTM Kit clear?	Yes	152	100.00%	(97.6 – 100%)
		No	0	0.00%	(0 – 0.02%)
		No opinion	0	0.00%	(0 – 0.02%)
2	I feel that a sample taken by a doctor is better than a self-sample.	Yes	99	65.10%	(57.0 – 72.7%)
		No	50	32.90%	(25.5 – 41.0%)
		No opinion	3	2.00%	(0.4 – 5.7%)
3	I think the majority of women will choose a self-sample instead of going to a doctor.	Yes	132	86.80%	(80.4 – 91.8%)
		No	16	10.50%	(6.1-16.5%)
		No opinion	4	2.60%	(0.7 – 6.7%)
4	Self-sampling is good for women who are uncomfortable to give a sample at the clinic	Yes	145	95.40%	(90.7 – 98.1%)
		No	4	2.60%	(0.7 – 6.7%)
		No opinion	3	2.00%	(0.4 – 5.7%)
5	The self-sampling was easy.	Agree	150	98.70%	(95.3 – 99.8%)
		No opinion	0	0.00%	(0.0 – 2.4%)
		Don't agree	2	1.30%	(0.1 – 4.7%)
6	I found the self-sampling unpleasant.	Agree	43	28.30%	(21.3 – 36.2%)
		No opinion	1	0.70%	(0.02 – 3.6%)
		Don't agree	108	71.10%	(63.2 – 78.1%)
7	I would recommend self-sampling to my friends/family.	Agree	141	92.80%	(87.4 – 96.3%)
		No Opinion	2	1.30%	(0.1 – 4.7%)
		Don't Agree	9	5.90%	(2.7 – 10.9%)

agreement between the self-sample and clinician collected cervical sample for LBC (k=0.80). The self-sampling device received good acceptability by the participating women.

In the developed countries where screening programmes are in place, most cervical cancers are seen in women who have never been screened [17]. Cervical cancer screening coverage has remained consistently low particularly in the LMICs where cervical cancer burden is the highest. Worldwide two out of three women have ever been screened in their lifetime [18]. Thus improving the screening coverage is an important priority of any screening programme. HPV testing has been shown be cost-effective in spite of its initial higher cost when compared to cytology or visual inspection of the cervix with 5% acetic acid (VIA) [19], it is still expensive and not adapted in most of the low- and middle-income countries. An affordable HPV test is urgently needed [20] and so are the HPV self-sampling kits which can help in bringing down the cost further. HPV self-sampling can help in reaching the never screened or hard to reach population and it is also convenient to the health care facility by reducing the logistics and additional costs associated with cervical sample collection. Thus the clinical evaluation and approval of the CERVICHECK™ self-sampling kit by the Drugs Controller General of India (DCGI) is an important milestone.

Although cervical cytology has been tried earlier on self-samples in some previous studies and self-HPV sampling compared favourably with physician-sampling as well as cytology [21, 22], cytology on self-samples has not performed favourably [23]. HPV self-sampling

method is not recommended for collection of cervical cells for cytology since the necessary scraping of the squamocolumnar junction / transformation zone as well as the endocervical canal cannot be ensured with a blind procedure. However in this pilot study we tried to compare the performance of LBC on samples collected by the self-sampling device with that of cervical sample and this provided us an assurance that the length of the device was adequate to reach the cervix in the vagina and if the same sample can be used for reflex cytology for triaging HPV positive samples in the future.

Almost all the participants appreciated the experience of using the CERVICHECK™ self-sampling kit for the HPV test and reported that the instructions for using the kit were easy to follow and more than 90% were willing to recommend the kit to the family and friends. The overall acceptability of vaginally administered products has been reported to be very good among Indian women previously [24] however we are not sure if the mailing of HPV self-sample kits will work in India due to the illiteracy and lack of awareness of this cervical cancer screening approach which has worked well in the developed countries [25]. HPV self-sampling in the clinic / community setting can ease the logistics associated with a high-volume screening programme.

Our study has some limitations. About 80% of our participants (all from Site 1) had prior experience of vaginal self-sample when they were screened with the Hybrid Capture 2TM assay test in a community programme for cervical cancer screening. HPV positive women were referred to the colposcopy clinic when they were enrolled in the study of CERVICHECK™. It is possible that their prior experience of self-sample might have affected the acceptability of the CERVICHECK™ kit.

To conclude, this pilot study demonstrates very good or perfect agreement between the clinician collected cervical sample and HPV self-sample for the detection of high-risk HPV as well as for cytology assessment. The kit is ready to be evaluated with a novel, low-cost, indigenously developed HPV test following the international guidelines which can further help wider implementation of HPV based screening which is a lifesaving intervention particularly in the low- and middle-income countries.

Author Contribution Statement

SJ was responsible for the study design, study conduct, acquisition of data, statistical analysis, interpretation of the data and manuscript preparation. BKK was responsible for the study design, randomization, monitoring, statistical analysis, interpretation of the data and manuscript preparation. SPP was responsible for study design, interpretation of the data and manuscript preparation. NM, VR, TSS, SR were responsible for acquisition, interpretation of data and manuscript preparation.

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Data sharing

External researchers can make written requests to Pragmatech Healthcare Solutions Pvt. Ltd., Vadodara, Gujarat. A brief analysis plan and data request will be required and will be reviewed by the Ethics Committees of the participating institutes for approval of data sharing. When requests are approved, anonymised data can be shared electronically in password protected files. All data sharing will abide by rules and policies defined by the sponsor and the Ethics Committee regulations. Data sharing mechanisms will ensure that the rights and privacy of individuals participating in research will be always protected.

Conflict of interest

Sayantani Pramanik Palit is a co-founder of Pragmatech Healthcare Solutions Pvt. Ltd. She did not have any involvement in the conduct of the study, data acquisition and data analysis. The remaining authors do not have any conflict of interest.

References

1. Ferlay J, Ervik M, Lam F, Laversanne M, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F. Global Cancer Observatory: Cancer Today (version 1.1). Lyon, France: International Agency for Research on Cancer. Available from: https://gco. iarc. who. int/today, accessed. 2024.
2. Zhao S, Huang L, Basu P, Domingo EJ, Supakarapongkul W, Ling WY, et al. Cervical cancer burden, status of implementation and challenges of cervical cancer screening in Association of Southeast Asian Nations (ASEAN) countries. Cancer Lett. 2022;525:22–32. https://doi.org/10.1016/j.canlet.2021.10.036
3. WHO. [Internet]. [cited 2023 Apr 25]. Cervical Cancer Elimination Initiative. Available from: https://www.who.int/initiatives/cervical-cancer-elimination-initiative.
4. Brisson M, Kim JJ, Canfell K, Drolet M, Gingras G, Burger EA, et al. Impact of HPV vaccination and cervical screening on cervical cancer elimination: a comparative modelling analysis in 78 low-income and lower-middle-income countries. Lancet. 2020;395(10224):575. https://

doi.org/10.1016/S0140-6736(20)30068-4.
5. Arbyn M, Ronco G, Anttila A, Chris CJL, Poljak M, Ogilvie G, et al. Evidence regarding human papillomavirus testing in secondary prevention of cervical cancer. Vaccine. 2012;30(SUPPL.5):F88-99. https://doi.org/10.1016/j.vaccine.2012.06.095.
6. Arbyn M, Simon M, Peeters E, Xu L, Meijer CJLM, Berkhof J, et al. 2020 list of human papillomavirus assays suitable for primary cervical cancer screening. Clin Microbiol Infect. 2021;27(8):1083–95. https://doi.org/10.1016/j.cmi.2021.04.031.
7. Snijders PJF, Verhoef VMJ, Arbyn M, Ogilvie G, Minozzi S, Banzi R, et al. High-risk HPV testing on self-sampled versus clinician-collected specimens: a review on the clinical accuracy and impact on population attendance in cervical cancer screening. Int J Cancer. 2013;132(10):2223–36. https://doi.org/10.1002/ijc.27790.
8. Arbyn M, Smith SB, Temin S, Sultana F, Castle P. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. BMJ. 2018;363:k4823. https://doi.org/10.1136/bmj.k4823.
9. Daponte N, Valasoulis G, Michail G, Magaliou I, Daponte AI, Garas A, et al. HPV-Based Self-Sampling in Cervical Cancer Screening: An Updated Review of the Current Evidence in the Literature. Cancers (Basel). 2.023;15(6):1669. https://doi.org/10.3390/cancers15061669
10. Baussano I, Tshering S, Choden T, Lazzarato F, Tenet V, Plummer M, et al. Cervical cancer screening in rural Bhutan with the care HPV test on self-collected samples: an ongoing cross-sectional, population-based study (REACH-Bhutan). BMJ Open. 2017;7(7): e016309. https://doi.org/10.1136/bmjopen-2017-016309
11. Sowjanya AP, Paul P, Vedantham H, Ramakrishna G, Vidyadhari D, Vijayaraghavan K, et al. Suitability of self-collected vaginal samples for cervical cancer screening in periurban villages in Andhra Pradesh, India. Cancer Epidemiol Biomarkers Prev. 2009;18(5):1373–8. https://doi.org/10.1158/1055-9965.EPI-08-1171.
12. Costa S, Verberckmoes B, Castle PE, Arbyn M. Offering HPV self-sampling kits: an updated meta-analysis of the effectiveness of strategies to increase participation in cervical cancer screening. Br J Cancer. 2023;128(5):805–13. https://doi.org/10.1038/s41416-022-02094-w.
13. World Health Organization. WHO recommendations on self-care interventions: human papillomavirus (HPV) self-sampling as part of cervical cancer screening. World Health Organization; 2020. Available from: https://apps.who.int/iris/handle/10665/332333.
14. Joshi S, Basu P, Lucas E. Using HPV tests for cervical cancer screening and managing HPV-positive women – a practical online guide: IARC CancerBase No. 18 [Internet]. Lyon, France: International Agency for Research on Cancer; 2023. Available from: https://screening.iarc.fr/atlasHPV.php, accessed on 28 June 2023.
15. Ertik FC, Kampers J, Hülse F, Stolte C, Böhmer G, Hillemanns P, et al. CoCoss-Trial: Concurrent Comparison of Self-Sampling Devices for HPV-Detection. Int J Environ Res Public Health. 2021;18(19):10388. https://doi.org/10.3390/ijerph181910388.
16. Hedman J, Rådström P. Overcoming inhibition in real-time diagnostic PCR. Methods Mol Biol. 2013;943:17–48. https://doi.org/10.1007/978-1-60327-353-4_2.
17. Pierce Campbell CM, Menezes LJ, Paskett ED, Giuliano AR. Prevention of invasive cervical cancer in the United States: past, present, and future. Cancer Epidemiol Biomarkers Prev. 2012 ;21(9):1402–8. https://doi.org/10.1158/1055-9965.EPI-11-1158.
18. Bruni L, Serrano B, Roura E, Alemany L, Cowan M, Herrero R, et al. Cervical cancer screening programmes and age-specific coverage estimates for 202 countries and territories worldwide: a review and synthetic analysis. Lancet Glob Health. 2022;10(8):e1115. https://doi.org/10.1016/S2214-109X(22)00241-8.
19. Mezei AK, Armstrong HL, Pedersen HN, Campos NG, Mitchell SM, Sekikubo M, et al. Cost-effectiveness of cervical cancer screening methods in low- and middle-income countries: A systematic review. Int J Cancer. 2017;141(3):437–46. https://doi.org/10.1002/ijc.30695.
20. Krivacsy S, Bayingana A, Binagwaho A. Affordable human papillomavirus screening needed to eradicate cervical cancer for all. Lancet Glob Health. 2019;7(12):e1605–6. https://doi.org/10.1016/S2214-109X(19)30423-1.
21. Gibert MJ, Sánchez-Contador C, Artigues G. Validity and acceptance of self vs conventional sampling for the analysis of human papillomavirus and Pap smear. Sci Rep. 2023;13(1):2809. https://doi.org/10.1038/s41598-023-29255-y.
22. Bhatla N, Dar L, Patro AR, Kumar P, Kriplani A, Gulati A, et al. Can human papillomavirus DNA testing of self-collected vaginal samples compare with physician-collected cervical samples and cytology for cervical cancer screening in developing countries? Cancer Epidemiol. 2009;33(6):446–50. https://doi.org/10.1016/j.canep.2009.10.013.
23. Arbyn M, Latsuzbaia A, Castle PE, Sahasrabuddhe VV, Broeck D Vanden. HPV testing of self-samples: Influence of collection and sample handling procedures on clinical accuracy to detect cervical precancer. Lancet Reg Health Eur. 2022;14:10332. https://doi.org/10.1016/j.lanepe.2022.100332.
24. Joglekar NS, Joshi SN, Deshpande SS, Parkhe AN, Katti UR, Mehendale SM. Acceptability and adherence: findings from a Phase II study of a candidate vaginal microbicide, "Praneem polyherbal tablet", in Pune, India. Trans R Soc Trop Med Hyg. 2010;104(6):412–5. https://doi.org/10.1016/j.trstmh.2009.12.007.
25. Tranberg M, Bech BH, Blaakær J, Jensen JS, Svanholm H, Andersen B. Preventing cervical cancer using HPV self-sampling: direct mailing of test-kits increases screening participation more than timely opt-in procedures - a randomized controlled trial. BMC Cancer. 2018;18(1):273. https://doi.org/10.1186/s12885-018-4165-4.