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# Comparison of diagnostic accuracy and acceptability of self-sampling devices for human Papillomavirus detection: A systematic review

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ABSTRACT

*Objective:* Cervical cancer screening coverage remains low in many countries worldwide. Self-sampling approach for cervical cancer screening has a good potential to improve the screening coverage. This study aims to compare different types of HPV self-sampling devices for cervical cancer screening to identify the most accurate and acceptable device(s).

*Methods:* A systematic review was performed on data extracted from all studies specific to HPV self-sampling devices by searching relevant articles in PubMed, Google Scholar, Scopus, Web of Science, ScienceDirect, Cochrane Library, and EBSCO published from 2013 to October 2023. The study was registered in PROSPERO (CRD42022375682).

*Results:* Overall, 70 papers met the eligibility criteria for this systematic review and were included in the analysis: 22 studies reported self-sampling devices diagnostic accuracy, 32 studies reported self-sampling devices acceptability and 16 studies reported both (accuracy and acceptability). The most popular self-sampling devices were Evalyn Brush, FLOQ Swab, Cervex-Brush, and Delphi Screener. Out of overall 38 studies analyzing self-sampling devices' diagnostic accuracy, 94.7% of studies reported that self-collected specimens provided sensitivity and specificity comparable with clinician-collected samples; acceptability of Evalyn Brush, FLOQ Swab, Delphi Screener, and Colli-Pee, varied between 84.2% and 100%.

*Conclusion:* The self-sampling approach has a good potential to increase cervical cancer screening coverage. Evalyn Brush, Cervex-Brush, FLOQ Swab, and Delphi Screener self-sampling devices for HPV detection were the most commonly utilized and found to be the most accurate, and patient-acceptable. HPV detection accuracy using these self-sampling devices had no significant difference compared to the sampling performed by healthcare providers.

## 1. Introduction

Despite profound advancements in the prevention and treatment, cervical cancer continues to be a significant cause of morbidity and mortality in many countries and remains the fourth most common cancer to affect women worldwide (Wakeham and Kavanagh, 2014; Small et al., 2017; Wu et al., 2021). In 2018, out of the 570,000 cervical cancer cases identified, 311,000 resulted in patients' death (Arbyn et al.,

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2020). Cervical cancer is proven to be associated with high-risk HPV types (Zur, 2009). Out of all known HPV types, HPV-16 and HPV-18 are the most common genotypes leading to precancerous cervical lesions and invasive cervical cancer (Kamolratanakul and Pitisuttithum, 2021; Nishimura et al., 2021; Zhong et al., 2021; Akhatova et al., 2022). Despite HPV vaccines availability and its proven effectiveness, there is still low awareness and poor accessibility of the vaccines in low-income and middle-income countries (LMICs), (Kamolratanakul and Pitisuttithum, 2021). In 2019, the global HPV vaccination coverage was determined to be only at 15 % (Gallagher et al., 2018). Therefore, due to the unavailability of HPV vaccination to a large proportion of women worldwide, it is pertinent to investigate efficient screening methods for cervical cancer.

There are a variety of current cervical cancer screening methods available, including cytology via Papanicolaou testing (Pap-test) and HPV genotyping (Rerucha et al., 2018). Since the 1950s when Pap-test was first implemented and used as a cervical cancer screening method, the cervical cancer rate has been substantially reduced (Safaeian et al., 2007). Different countries have implemented various cervical cancer screening programs' modalities. The American College of Obstetricians and Gynecologists (ACOG) recommends the screening to be performed every 3 years for patients between ages 21 and 65 years (ACOG, 2023). However, there is evidence stating that the cytology screening approach is insufficient for the prevention of cervical cancer (Najib et al., 2020). The sensitivity (SN) of cytological screening with Pap-test for the identification of high-grade precancerous lesions or worse is between 51 % and 64 % (Rizzo and Feldman, 2018; Najib et al., 2020). Thus, up to half of the women with high-grade pre-cancerous lesions were falsely diagnosed as negative based on the Pap-test (Rizzo and Feldman, 2018). Taking into account these concerns, along with classical cytology screening HPV DNA testing was encouraged by the World Health Organization (WHO) and the US National Cancer Institute (NCI) to enhance current diagnostics for cervical cancer prevention (Tsakogiannis et al., 2017; Bhatla and Singhal, 2020; Bonde et al., 2020; National Cancer Institute, 2022; WHO, 2023). This approach has been characterized by high clinical specificity (SP) and SN. Many countries adopt the approach to perform co-testing, i.e. Pap-test in combination with HPV DNA testing (ACOG, 2023; Cancer council, 2023).

However, multiple factors could contribute to an unwillingness to undergo the screening: cultural differences, social disparities, lack of funding coverage, and unawareness (Chorleyet al., 2017; Issa et al., 2021; Asare et al., 2022; Salehiniya et al., 2021; Perez et al., 2022). Conventional cervical cancer screening requires patient presence in a clinic for cervical sampling procedures. Low cervical cancer knowledge and awareness, discomfort during sampling, lack of time to attend a clinic, absence of accessible healthcare facilities, and many other factors could contribute to the low cervical cancer screening coverage (Chorleyet al., 2017; Issa et al., 2021). Moreover, women might be not familiar with the necessity of screening procedures, considering it too invasive or frightening to go to the hospital, based on their previous experiences (Chorleyet al., 2017). For the mentioned reasons, self-sampling for cervical cancer screening could be a good option to increase attendance of cervical cancer screening and achieve a higher rate of coverage (De Pauw et al., 2021).

Many studies have reported that self-sampling procedure for cervical cancer screening can provide an inexpensive, convenient, and easily accessible method for individuals to detect oncogenic HPV infections and to seek early treatment at the precancerous stages (De Pauw et al., 2021; Ertik et al., 2021; Sechi et al., 2022). These studies have shown a high concordance for cervico-vaginal HPV testing between self-collected samples and specimens obtained by clinicians (De Pauw et al., 2021; Ertik et al., 2021; Sechi et al., 2022). Self-sampling devices are advantageous to users because of their convenience, ease of use, and privacy (De Pauw et al., 2021; Nishimura et al., 2021). Thus, to increase general participation in screening, one of the most efficient options is to integrate self-sampling for cervical cancer screening into routine clinical practice (Chorleyet al., 2017).

Multiple types of cervical self-sampling devices for the detection of HPV infection are currently available on the market (Ketelaars et al., 2017; Tiiti et al., 2021; Tranberg et al., 2018; Bishop et al., 2019; Chatzistamatiou et al., 2020; De Pauw et al., 2021; Nishimura et al., 2021; Mremi et al., 2021). They are based on a variety of sampling tools (swab, brush, lavage, and tampon) and specimen types (cervical smear and urine). However, these self-sampling devices have different diagnostic accuracy, reliability, and patients' acceptability (Ketelaars et al., 2017; Tiiti et al., 2021; Tranberg et al., 2018; Bishop et al., 2019; Chatzistamatiou et al., 2020; Mremi et al., 2021). Thus this study's aim was to compare different types of HPV self-sampling devices for cervical cancer screening to identify the most accurate and acceptable device(s). The following research questions were formulated to achieve the study goal:

a) Which of the available self-sampling devices for HPV detection and cervical cancer screening is described in the literature as the most diagnostic accurate?

b) Which of the available self-sampling devices for HPV detection and cervical cancer screening is the most acceptable for patients?

## 2. Methods

### 2.1. Study registration and methodological standards

The study was registered in the International Prospective Register of Systematic Reviews (PROSPERO) on November 25, 2022, with a registration code of CRD42022375682.

### 2.2. Information sources and search strategy

Articles for the study were manually searched using the following databases: PubMed, Google Scholar, Scopus, Web of Science, ScienceDirect, Cochrane Library, and EBSCO. Studies limited to the involvement of human subjects and published in English online for the past 10 years from 2013 to October 2023 were selected. The search was performed using keywords and medical subject headings (MeSH) unique identifiers, if available. The following keywords and combinations of these keywords were applied: "Human Papillomaviruses" (MeSH Unique ID: D000094302); "HPV" (MeSH Unique ID: D015344); "self-sampling"; "uterine cervical neoplasms" (MeSH Unique ID: D002583); "cervical cancer"; "urine sampling"; "HPV self-sampling"; "cervical self-sampling"; "urine self-sampling"; "HPV self-sampling device"; "cervical cancer screening".

Titles and/or abstracts of studies reclaimed using the search strategy, and those from additional sources, were screened independently by four review authors to identify studies that potentially meet the objectives of this systematic review. The full text of these potentially eligible articles was retrieved and independently assessed for eligibility by other four review team members. Any disagreement between them over the eligibility of particular articles was resolved through discussion with all collaborators.

### 2.3. Eligibility criteria and PICO statement

The articles were selected to meet the following eligibility requirements to be included in the study: 1) research articles, 2) human subject research, 3) women involved; 4) studies assessing HPV cervical self-sampling kits accuracy and/or acceptability, and 5) defined self-sampling device/kit (brand name). The following exclusion criteria were applied: 1) reviews and case reports, 2) irrelevance to HPV self-sampling, 3) studies with men or transgender men/women involved; 4) non-defined self-sampling device; 5) the device diagnostic accuracy or acceptability were not reported in the outcomes; 6) animal model studies. Abstracts lacking full information about predefined criteria were excluded without further review. Population, Intervention,

Comparison, Outcomes (PICO) statement: in women eligible for cervical cancer screening (P), are the self-collected cervical samples (I), compared with samples taken by healthcare specialists (C), accurate and associated with better patients' acceptance (O)?

### 2.4. Data collection and synthesis

The search was narrowed by using "HPV OR Human Papillomavirus AND cervical self-sampling", "HPV OR Human Papillomavirus AND HPV self-sampling", "HPV OR Human Papillomavirus AND urine self-sampling", "HPV self-sampling device AND cervical cancer OR uterine cervix neoplasms", "HPV AND cervical self-sampling AND cervical cancer OR uterine cervix neoplasms", "cervical cancer screening AND self-sampling". The following data were retrieved from the analyzed studies: first author, year of publication, study location, study type, number of study participants, participants' age, self-sampling device type, biological sample type, sampling approach, the test used for accuracy detection (HPV genotyping and/or cervical cytology), device diagnostic accuracy, and device acceptance.

### 2.5. Assessment of risk of bias

All studies included in the analysis were independently reviewed for inclusion eligibility by four reviewers. Any discrepancies in the evaluation of articles were resolved through discussion. The risk of bias was assessed in terms of deviations from intended interventions, measurement of the outcome criteria, missing outcome data, and selection of the reported result according to guidelines. Non-randomized studies were evaluated according to the Newcastle–Ottawa Scale (NOS), (Wells et al., 2023) and were determined to have a "mild", "moderate", or "severe" risk of bias. The risk of bias in included randomized clinical trials (RCT) was determined by the assessment of selection, comparability, and outcome criteria and assessed according to the Cochrane Handbook for Systematic Reviews of Intervention Quality (Higgins et al., 2011).

### 2.6. Ethics statement

This study does not directly involve any animal or human data or tissue, therefore due to the nature of the study, systematic review, ethical approval for this study, and informed consent are not required. Moreover, original research studies included in the analysis were checked for the compliance with the Helsinki Declaration's ethical

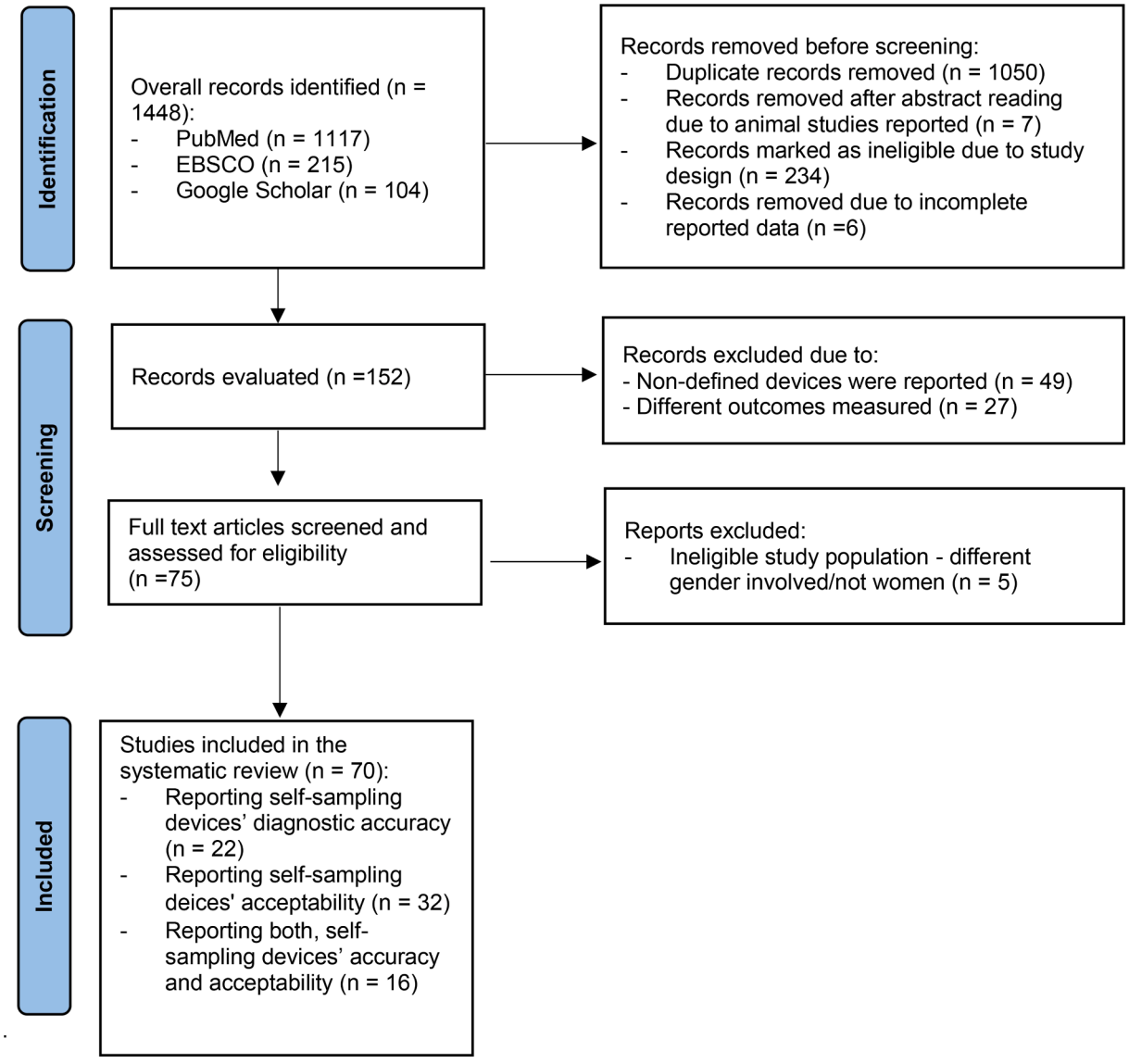


**Fig. 1.** Search strategy flow-chart.

standards.

## 3. Results

### 3.1. Study identification and selection

The initial screening on PubMed, Medline, Cochrane database, and Google Scholar identified 1,448 articles (Fig. 1). Out of all articles, 1,297 papers were excluded due to ineligibility (inappropriate study design, duplicates, and incomplete data reporting). The remaining 151 articles were assessed for eligibility based on the abstracts and 76 articles were excluded due to non-defined devices and irrelevant to this study's outcomes reporting. From the remaining 75 articles, 5 articles were excluded at this stage due to the different gender-related investigations (not women). Finally, only 70 fulfilled the inclusion and exclusion criteria (Geraets et al., 2013; Guan et al., 2013; Jentschke et al., 2013; Levinson et al., 2013; Nieves et al., 2013; Yoshida et al., 2013; Abuelo et al., 2014; Castell et al., 2014; Mahomed et al., 2014; Porras et al., 2014; Cadman et al., 2015; Crofts et al., 2015; Chan et al., 2023; Chen et al., 2016; Enerly et al., 2016; Hanley et al., 2016; Ilangovan et al., 2016; Jentschke et al., 2016; Ma'som et al., 2016; Othman et al., 2016; Qin et al., 2016; Winer et al., 2016; Chatzistamatiou et al., 2017; Ketelaars et al., 2017; Leeman et al., 2017; Mbatha et al., 2017; Jaworek et al., 2018; Leinonen et al., 2018; Phoolcharoen et al., 2018; Tranberg et al., 2018; Wong et al., 2018; Bishop et al., 2019; Brandt et al., 2019; Lorenzi et al., 2019; Pattyn et al., 2019; Behnke et al., 2020; Chatzistamatiou et al., 2020; Islam et al., 2020; Megersa et al., 2020; Saville et al., 2020; Tranberg et al., 2020; Wong et al., 2020; Andersson et al., 2021; Aranda Flores et al., 2021; De Pauw et al., 2021; Ertik et al., 2021; Inturrisi et al., 2021; Katanga et al., 2021; Klischke et al., 2021; Mremi et al., 2021; Tiiti et al., 2021; Latsuzbaia et al., 2022; Sechi et al., 2022; Van Keer et al., 2022; Veerus et al., 2022; Wedisinghe et al., 2022; Devotta et al., 2023; Ibáñez et al., 2023; Martinelli et al., 2023; Ruel-Laliberté et al., 2023; Sangrajrang et al., 2023; Shih et al., 2023; Ozawa et al., 2023; Gibert et al., 2023; Phoolcharoen et al., 2023; Fujita et al., 2023; Ploysawang et al., 2023; Sechi et al., 2023; Lichtenfels et al., 2023; Nishimura et al., 2023) and thus were selected for subsequent analysis (Fig. 1; Table 1 and 2). These comprised 22 studies reporting self-sampling devices' diagnostic accuracy (Chen et al., 2016; Geraets et al., 2013; Guan et al., 2013; Inturrisi et al., 2021; Jaworek et al., 2018; Jentschke et al., 2013; Jentschke et al., 2016; Katanga et al., 2021; Klischke et al., 2021; Latsuzbaia et al., 2022; Nieves et al., 2013; Othman et al., 2016; Pattyn et al., 2019; Porras et al., 2014; Qin et al., 2016; Saville et al., 2020; et al., 2022; Martinelli et al., 2023; Shih et al., 2023; Sangrajrang et al., 2023;; Ozawa et al., 2023; Phoolcharoen et al., 2023), 32 studies reporting self-sampling devices' acceptability (De Pauw et al., 2021; Mremi et al., 2021; Bishop et al., 2019; Chatzistamatiou et al., 2020; Abuelo et al., 2014; Andersson et al., 2021; Behnke et al., 2020; Brandt et al., 2019; Cadman et al., 2015; Castell et al., 2014; Chatzistamatiou et al., 2017; Crofts et al., 2015; Hanley et al., 2016; Ilangovan et al., 2016; Levinson et al., 2013; Lorenzi et al., 2019; Mahomed et al., 2014; Ma'som et al., 2016; Mbatha et al., 2017; Megersa et al., 2020; Phoolcharoen et al., 2018; Veerus et al., 2022; Wedisinghe et al., 2022; Winer et al., 2016; Wong et al., 2020; Yoshida et al., 2013; Wedisinghe et al., 2022; Devotta et al., 2023; Ibáñez et al., 2023; Ruel-Laliberté et al., 2023; Fujita et al., 2023; Ploysawang et al., 2023; Nishimura et al., 2023), and 16 studies reporting both, self-sampling devices diagnostic accuracy and acceptability (Chan et al., 2023; Ertik et al., 2021; Sechi et al., 2022; Ketelaars et al., 2017; Tiiti et al., 2021; Tranberg et al., 2018; Aranda Flores et al., 2021; Enerly et al., 2016; Islam et al., 2020; Leeman et al., 2017; Leinonen et al., 2018; Tranberg et al., 2020; Wong et al., 2018; Gibert et al., 2023; Sechi et al., 2023; Lichtenfels et al., 2023).

### 3.2. Study outcomes

#### 3.2.1. HPV self-sampling devices' accuracy

Out of all 70 papers analyzed in the study, 38 studies (Geraets et al., 2013; Guan et al., 2013; Jentschke et al., 2013; Nieves et al., 2013; Porras et al., 2014; Chan et al., 2023; Chen et al., 2016; Enerly et al., 2016; Jentschke et al., 2016; Othman et al., 2016; Qin et al., 2016; Ketelaars et al., 2017; Leeman et al., 2017; Jaworek et al., 2018; Leinonen et al., 2018; Tranberg et al., 2018; Wong et al., 2018; Pattyn et al., 2019; Islam et al., 2020; Saville et al., 2020; Aranda Flores et al., 2021; Ertik et al., 2021; Inturrisi et al., 2021; Katanga et al., 2021; Tiiti et al., 2021; Klischke et al., 2021; Latsuzbaia et al., 2022; Sechi et al., 2022; Tranberg et al., 2020; Van Keer et al., 2022; Martinelli et al., 2023; Sangrajrang et al., 2023; Shih et al., 2023; Gibert et al., 2023; Ozawa et al., 2023; Phoolcharoen et al., 2023; Lichtenfels et al., 2023) reported self-sampling devices' diagnostic accuracy. A comparison of the studies assessing the HPV self-sampling devices' diagnostic accuracy is presented in Table 1. Diverse self-sampling devices were utilized in the analyzed studies (Supplementary Table 1). These were tools based on cervical or urine sample collection for the subsequent HPV genotyping as a part of the cervical cancer screening procedure. All studies reported in Table 1 compared self-collected cervical or urine samples (or both) with clinician-collected samples in terms of the result concordance. For this samples were analyzed by HPV genotyping or cervical cytology (or both) methods (Table 1). Out of 38 studies analyzing self-sampling devices' diagnostic accuracy, 17 studies (44.7 %) utilized Evalyn Brush; 13 (34.2 %) used Cervex-Brush; 6 (15.8 %) - FLOQ Swab; 5 (13.2 %) - Colli-Pee; 3 (7.9 %) - Rovers Cervex-Brush, and 3 (7.9 %) - Viba Brush. Dacron swab, Qvintip, and Aptima Multitest Swab kits were used in 2 (5.3 %) studies each. The majority of studies used and compared more than one self-sampling device.

Out of 38 studies analyzing self-sampling devices' diagnostic accuracy, 36 (94.7 %) studies reported that self-collected specimens provided SN and SP "comparable with clinician-collected samples" with a "good diagnostic agreement" and "good concordance rates". Good to high reliability of self-samples in comparison with clinician-collected specimens was reported by these studies (Geraets et al., 2013; Tiiti et al., 2021; Tranberg et al., 2018; Ertik et al., 2021; Inturrisi et al., 2021; Islam et al., 2020; Jaworek et al., 2018; Jentschke et al., 2013; Jentschke et al., 2016; Katanga et al., 2021; Klischke et al., 2021; Latsuzbaia et al., 2022; Leeman et al., 2017; Leinonen et al., 2018; Nieves et al., 2013; Othman et al., 2016; Porras et al., 2014; Qin et al., 2016; Saville et al., 2020; Tranberg et al., 2020; Martinelli et al., 2023; Sangrajrang et al., 2023; Shih et al., 2023; Ozawa et al., 2023; Gibert et al., 2023; Phoolcharoen et al., 2023; Sechi et al., 2023; Chan et al., 2023). The highest concordance rate between a self-collected sample and a clinician-collected specimen was found for Evalyn Brush ranging from 89.2 % to 97.5 % and SN up to 100 % (Table 1), followed by FLOQ Swab – concordance rate was 89–94 % and SN 89.7–93.8 %. The third most accurate was Colli-Pee with a concordance rate reported at 87.6 %, SN 91.1 %.

Two studies concluded that the self-sampling method is not suitable for HPV or high-grade cervical lesion detection due to a low concordance with clinician-taken samples and overall low and reliability with "somewhat lower" SP in self-sampling (Jentschke et al., 2016: Van Keer et al., 2022;).

#### 3.2.2. HPV self-sampling devices' acceptability

Studies assessing and reporting the HPV self-sampling devices' acceptability are summarized and compared in Table 2.

Among overall 48 studies analyzing self-sampling devices' acceptability (Levinson et al., 2013; Yoshida et al., 2013; Abuelo et al., 2014; Castell et al., 2014; Mahomed et al., 2014; Cadman et al., 2015; Crofts et al., 2015; Enerly et al., 2016; Ilangovan et al., 2016; Hanley et al., 2016; Ma'som et al., 2016; Winer et al., 2016; Chatzistamatiou et al., 2017; Ketelaars et al., 2017; Leeman et al., 2017; Leinonen et al., 2018;

**Table 1**
Characteristics and comparison of the studies assessing the HPV self-sampling devices' diagnostic accuracy.

| Authors/ year | Location | Study design | Participants (N) | Age (years) | Intervention description | | | Tests performed to compare self-samples and CCS for identification of diagnostic accuracy | | Reliability of self-collected samples | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling device | Sample type | Sampling approach | HPV-genotyping test used | Cervical cytology or histology test/ interpretation | Concordance with CCS, (% and/or κ), [95 % CI] | SN (ratio or %), [95 % CI] | SP ratio or %), [95 % CI] | |
| Aranda Flores et al., 2021 | Mexico/ Mexico City | Randomized clinical rtial | 505 | 30–65 | 1.XytoTest medical Device; 2.Cervex-Brush | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | Abbott RealTime HR HPV test | LBC (ThinPrep medium)/ Bethesda system | 78.2 %, κ = 0.34, p < 0.001 | Not reported | Not reported | Fair agreement of HPV positivity rates between the self-collected and CCS |
| Chan et al., 2023 | Hong Kong | Prospective study | 104 | 30–65 | 1. Cepillo Endocervical/ Cervical Brush/Cyto-Brush + DNA sample storage card; 2. Cervex-Brush | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | 1.SentisTM HPV Assay (Sentis); 2. BD OnclarityTM HPV Assay (Onclarity) | Not preformed | 1. 89.8 %, κ = 0.769; 2. 84.4 %, κ = 0.643 | Not reported | Not reported | "A substantial agreement" between the self-collected and CCS |
| Chen et al., 2016 | China/ Shanghai | Case-control | 101 cases and 101 controls | 21–79 | 1.Evalyn Brush; | 1. Vaginal smear; 2. Cervical smear; | 1.Self-sampling vs. 2. Clinician-taken sample | RealTime RT PCR | Colposcopy with cervical histology/CIN system | 97.5 %, κ = 0.95 | Not reported | Not reported | Self-sampling and CCS showed good diagnostic agreement and a very high HR-HPV positivity rate |
| Geraets et al., 2013 | Spain/ Barcelona | Not reported | 182 | 17–76 | Viba brush | 1. Vaginal smear 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | HPV SPF10 PCR-DEIA-LiPA25 version | LBC (PreservCyt solution) + Colposcopy/ Bethesda system | 89 % κ = 0.733 | 95.9 % | 42.9 % | HPV self-sampling might be valuable when a LBC cannot be used, but requires further investigation |
| Guan et al., 2013 | China/ Shanxi Province | Not reported | 2,500 | 30–59 | FTA Elute card | 1. Vaginal smear 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | HPV PCR, Roche HPV Linear Array | Not preformed | 91 % κ = 0.75 | Not reported | Not reported | Self-sampling wih FTA Elute cartridge showed high concordance rate with CCS |
| Enerly et al., 2016 | Norway/Oslo area | Cross-sectional | 267 | 25–69 | 1.Evalyn brush; 2. Delphi Screener | 1. Vaginal smear; 2. Cervical smear; | 1.Self-sampling vs. 2. Clinician-taken sample | CLART1HPV2 test Vs. Digene1HC2 | Not performed | 89.9 %, κ = 0.61 | Not reported | Not reported | Delphi Screener and the Evalyn brush had satisfactory samples concordance rate |
| Ertik et al., 2021 | Germany/ Hannover | Prospective multicenter phase II trial (CoCoss-Trial) | 65 | 24–76 | 1.Evalyn-Brush; 2. FLOQSwab; 3. Colli-Pee FV-5000 | 1. Vaginal smear; 2. Vaginal smear; | Self-sampling vs. Clinician-taken sample | Abbott RealTime High Risk HPV Test | Colposcopy with cervical histology/CIN system | 1. κ = 0.48 2.κ = 0.29 3.κ = 0.34 | 1.89.7 %; 2. 82.8 %; 3. 77.6 % | 1. 42.9 %; 2. 71.4 %; 3. 57.1 % | No significant differences in SN or SP for CIN 2 + detection between the self-smears and CCS |

(*continued on next page*)

**Table 1** (*continued*)

| Authors/ year | Location | Study design | Participants (N) | Age (years) | Intervention description | | | Tests performed to compare self-samples and CCS for identification of diagnostic accuracy | | Reliability of self-collected samples | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling device | Sample type | Sampling approach | HPV-genotyping test used | Cervical cytology or histology test/ interpretation | Concordance with CCS, (% and/or κ), [95 % CI] | SN (ratio or %), [95 % CI] | SP ratio or %), [95 % CI] | |
| | | | | | | 3. Urine sample | | | | | | | |
| Gibert et al., 2023 | Spain, Illes Balears | Cross-sectional | 120 | 40–51 | 1. Viba-Brush; 2. Mía by Xytotest; 2. Rovers Cervex-Brush | Gibert et al., 2023 | Spain, Illes Balears | Cobas® HPV test | LBC (ThinPrep medium)/ Bethesda system | 1. κ = 0.83 2.κ = 0.86 | 95.7 % | 1.88.9 % 2.91.7 % | Agreement for HPV detection between self –collected and CCS samples was very good |
| Inturrisi et al., 2021 | The Netherlands | Case-control | 30,808 cases and 456,207 controls | 30–60 | 1.Evalyn-Brush; 2. Cervex Brush | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | Cobas HPV Test | LBC (ThinPrep medium)/ CISOE-A classification | Not reported | 1. ratio = 0.88; 2. ratio = 0.94 % | ratio = 1.02 | High accuracy of HR-HPV detection in self-collected samples compared to CCS |
| Islam et al., 2020 | Kenya/ Mombasa | Cohort | 400 | 19–66 | 1. Evalyn-Brush; 2. Viba brush | 1. Vaginal smear 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | APTIMA® HPV Assay (Hologic Inc, San Diego, USA) | CC (Aptima media, Hologic, San Diego, USA) | 86.4 % | 93 % | 66 % | Self-sampling is a "viable option" for HR-HPV mRNA testing |
| Jaworek et al.,2018 | Czech | Cross-sectional | 1,198 | 17–72 | 1.Evalyn brush | 1. Vaginal smear | 1.Self-sampling vs. 2. Clinician-taken sample | 1.Cobas 4800 HPV Test 2. LMNX Genotyping Kit HPV GP | Not performed | 1. κ = 0.970; 2. κ = 0.906 | 1. ratio = 0.983; 2. ratio = 0.897 | 1. ratio = 0.992; 2. ratio = 0.989 | CCS and self-samples were highly sensitive and specific for HR-HPV detection |
| Jentschke et al., 2013 | Germany/ Hannover | Not reported | 140 | 16–68 | Delphi Screener | 1. Vaginal smear; 2. Cervical smear; | 1 and 2. Self-sampling vs. 3.Clinician-taken sample | HPV DNA detection by HC2 | Pap-test (PreservCyt solution)/ Bethesda system | κ = 0.51 | 64.5–70.6 % | 31.7–38.2 % | The study shows that self-sampling with cervicovaginal lavage with ELISA is not suitable for the detection of high-grade CIN |
| Jentschke et al., 2016 | Germany/ Hannover | Not reported | 136 | 17–78 | 1.Evalyn Brush; 2.Qvintip | 1. Vaginal smear; 2. Cervical smear; | 1 and 2. Self-sampling vs. 3.Clinician-taken sample | Abbott RealTime HighRisk HPV test | Colposcopy with cervical histology/ CIN system | 1. 91.2 %, κ = 0.822; 2. 89.0 %, κ = 0.779 | 1.89.8 %; 2. 83.7 % | 1. 66.7 %; 2. 69.0 % | Reliability of self-samples has no significant difference compared with CCS |
| Katanga et al., 2021 | Tanzania/ Kilimanjaro region | CONCEPT | 464 | 35–54 | 1.Evalyn-Brush; | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | HPV detection by HC2, QIAGEN | Not performed | 90.5 % | 61.4 % | 97.3 % | Self-sampling "seems to be a reliable alternative" to CCS |
| Ketelaars et al., 2017 | The Netherlands/ Dutch | Cross-sectional | 2,460 | 30–60 | 1.Evalyn brush; 2. Rovers Cervex-Brush | 1. Cervical smear; 2. | 1.Self-sampling vs. 2. Clinician- | Cobas 4800 HPV | LBC (ThinPrep medium)/ CISOE-A classification | 96.8 % | Not reported | Not reported | Self-sampling with the Evalyn Brush showed a high |

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**Table 1** (*continued*)

| Authors/ year | Location | Study design | Participants (N) | Age (years) | Intervention description | | | Tests performed to compare self-samples and CCS for identification of diagnostic accuracy | | Reliability of self-collected samples | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling device | Sample type | Sampling approach | HPV-genotyping test used | Cervical cytology or histology test/ interpretation | Concordance with CCS, (% and/or κ), [95 % CI] | SN (ratio or %), [95 % CI] | SP ratio or %), [95 % CI] | |
| | population of Nijmegen | | | | | Cervical smear; | taken sample | | | | | | concordancewith CCS, |
| Klischke et al., 2021 | Germany/ Hannover | Cross-sectional | 87 | >18 | 1.Evalyn-Brush; | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | GynTect® and Abbott RealTime HighRisk HPV assay | LBC (ThinPrep medium) | $\kappa = 0.394$, $p < 0.001$ | 26.1 % | 95.6 % | The results of the self-collected samples differed clearly in comparison to the CCS |
| Latsuzbaia et al., 2022 | Belgium/not specified | The VALHUDES framework | 486 | 31–49 | 1. Coli-Pee; 2.Multi-Collect swab 3.Evalyn Brush; 4.Qvintip; 5. Cervex-Brush | 1.Urine sample; 2. Cervical smear; 3. Vaginal smear; 4. Vaginal smear; 5. Cervical smear | 1–4. Self-sampling vs. 5. Clinician-taken sample | Abbott RT HPV test | LBC (ThinPrep medium)/ Bethesda system | 3 and 4. Hr-HPV 87.65 %, $\kappa = 0.748$; 3 and 5. 89.04 %, $\kappa = 0.774$ | 3 and 4. ratio = 0.92; 3 and 5. ratio = 0.95 | 3 and 4. ratio = 1.04; 3 and 5. ratio = 1.11 | Self-collected samples give similarly accurate result with CCS for CIN |
| Leeman et al., 2017 | Spain | Cross-sectional | 91 | ≥18 | 1.Colli-Pee™; 2. Evalyn brush | 1.Urine sample; 2. Vaginal smear; | 1 and 2. Self-sampling vs. 3.Clinician-taken sample | SPF10-DEIA-LiPA25 assay and GP5+/6+-EIA-LMNX | LBC (PreservCyt solution)/ Bethesda system | $\kappa = 0.85$ | 100 % | 33 % | High concordance between self-collected and CCS samples was found |
| Leinonen et al., 2018 | Norway/ South East region population | Cross-sectional | 310 | 21–80 | 1.Evalyn brush; 2. FLOQSwab | 1. Vaginal smear; 2. Vaginal smear; | 1 and 2. Self-sampling vs. 3.Clinician-taken sample | Anyplex™ II HPV28, Cobas® 4800 HPV Test and Xpert®HPV | LBC (ThinPrep medium)/ Bethesda system | 1. 94 %, $\kappa = 0.68$; 2. 87.9 %, $\kappa = 0.50$ | 1. 91–95 %; 2. 86–88 % | Not reported | Self-collection is comparable to CCS for detecting cervical carcinoma |
| Lichtenfels et al., 2023 | Brazil, São Paulo | Not reported | 73 | 25–65 | SelfCervix | Vaginal smear 2. Cervical smear | Self-sampling Vs. Clinician collected | HPV DNA detection by HC2, QIAGEN | PreservCyt® (Hologic, MA, USA) | 87 % | 86 % | 90 % | Self-sampling using the SelfCervix® "is not inferior in HPV-DNA detection rate" compared with CCS |
| Martinelli et al., 2023 | Italy, Monza | Not reported | 245 | 17–67 | 1. Colli-pee; 2. FLOQSwab | 1.Urine sample; 2. Vaginal smear; | 1 and 2. Self-sampling vs. 3.Clinician-taken sample | Anyplex™II HPV28 (Seegene) | LBC (ThinPrep medium)/ Bethesda system | 1. $\kappa = 0.715$; 2. $\kappa = 0.898$ | 1.90.9 % 2.95.5 % 3.95.5 % | 1.39.8 % 2.36.3 % 3.40.8 % | High accuracy of self-collected samples confirmed in detecting HSIL |

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**Table 1** (*continued*)

| Authors/ year | Location | Study design | Participants (N) | Age (years) | Intervention description | | | Tests performed to compare self-samples and CCS for identification of diagnostic accuracy | | Reliability of self-collected samples | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling device | Sample type | Sampling approach | HPV-genotyping test used | Cervical cytology or histology test/ interpretation | Concordance with CCS, (% and/or κ), [95 % CI] | SN (ratio or %), [95 % CI] | SP ratio or %), [95 % CI] | |
| Nieves et al., 2013 | Mexico, Michoacán | Not reported | 2,049 | 30–50 | POI/NIH self-sampler | 1. Vaginal smear; 2. Cervical smear; | 1 and 2. Self-sampling vs. 3.Clinician-taken sample | HPV DNA detection by HC2 | Pap-test (PreservCyt solution)/ Bethesda system | 97 % | 62.5 % | 90.5–93 % | Self-sampling applications are explored and showed a high agreement and SN with CCS |
| Othman et al., 2016 | Malaysia | Cross-sectional | 367 | 22–65 | 1.Evalyn Brush; 2.Cervex-Brush | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | Not performed | LBC (PreservCyt solution)/ Bethesda system | $\kappa = 0.568$,p = 0.040 | 71.9 % | 86.6 % | Self-sampling and CCS have "good diagnostic agreement" |
| Ozawa et al., 2023 | Japan | Not reported | 165 | 20–50 | 1.Home Smear Set Plus; 2. Cervex Brush | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | HPV testing - Cobas 4800 HPV system (Roche Diagnostics KK) | Cytology and hystology; Bethesda system | 88.5 % $\kappa$ = 0.76 | 1.81.4 % 2.89.8 % | – | High concordance rate between self-collected and CCS |
| Pattyn et al., 2019 | Belgium/not specified | Randomized | 33 (258 samples) | 27–37 | Colli-Pee | 1. Urine sample; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | Riatol qPCR HPV genotyping assay | Not performed | 1.7.14 (IQR: 2.87–17.85); 2.4.5 (IQR: 1.88–9.15) ng | Not reported | Not reported | Colli-Pee collected samples show higher HPV concentrations than cup collected samples |
| Porras et al., 2014 | Costa Rica/ not specified | Costa Rica Vaccine Trial | 7,466 | 18–25 | Dacron swab | 1. Vaginal smear; 2. Cervical smear; | 1.Self-sampling vs. 2. Clinician-taken sample | HPV DNA detection by HC2 | LBC (PreservCyt solution)/ Bethesda system | $\kappa = 0.78$, McNemar $\chi^2 = 0.62$ | 88.7 % | 68.9 % | Self-collected specimens provided SN and SP comparable with CCS |
| Phoolcharoen et al., 2023 | Thailand, Bangkok | Not reported | 494 | Not available | Aptima Multitest Swab | 1. Vaginal smear; 2. Cervical smear; | 1.Self-sampling vs. 2. Clinician-taken sample | APTIMA® HPV Assay (Hologic Inc, San Diego, USA) | Colposcopy and biopsy; Bethesda system | – | 1.87 % 2.90.2 % | 1.28.5 % 2.36.1 % | Self-collected samples for HPV detection demonstrated good sensitivity |
| Sechi et al., 2023 | Italy/ Sardinia | Cross-sectional | 185 | 34–51 | FLOQSwab; | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | Anyplex™ II HPV HR (Seegene | – | $\kappa = 0.98$ | – | – | High reliability and accuracy of HPV-DNA tests self-collected samples via FLOQSwabs was shoen |
| Qin et al., 2016 | China/ Yunnan Province | Cross-sectional | 300 | 25–65 | FTA Elute card | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | Abbott RealTime High RiskHPV assay | Colposcopy with cervical histology/CIN system | 87 %, $\kappa = 0.731$ | 100 % | 61.39 % | FTA Elute card demonstrated good performance on self-collected sample for HR-HPV |

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**Table 1** (*continued*)

| Authors/ year | Location | Study design | Participants (N) | Age (years) | Intervention description | | | Tests performed to compare self-samples and CCS for identification of diagnostic accuracy | | Reliability of self-collected samples | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling device | Sample type | Sampling approach | HPV-genotyping test used | Cervical cytology or histology test/ interpretation | Concordance with CCS, (% and/or κ), [95 % CI] | SN (ratio or %), [95 % CI] | SP ratio or %), [95 % CI] | |
| Sangrajrang et al., 2023 | Thailand, Bangkok | Not reported | 268 | 30–60 | Aptima Multitest Swab Specimen Collection Kit | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | APTIMA® HPV Assay (Hologic Inc, San Diego, USA) | – | 92.8 % κ = 0.57 | – | – | Self-sampling is a reliable alternative to CCS |
| Saville et al., 2020 | Australia/not specified | Cross-sectional | 303 | ≥18 | 1. FLOQSwab 552C; 2. Cervex-Brush | 1. Vaginal smear 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | 1.Cobas 4800 HPV; 2. Gene Xpert HPV test; 3. BD Onclarity HPV assay; 4. Anyplex II HPV HR Detection; 5. Abbott HPV test | Not performed | κ = 0.73 | 1. 93.8–100 %; 2. 82.15–82.4 % 3. 83.3–100 %; 4. 84.9–100 %; 5. 80–88.5 % | 1. 96.5—99 % 2. 97.7–97.5 % 3. 97.8—99.3 % 4. 98.5—99.3 % 5. 98.9—99.3 % | Self-collection for HPV-based cervical screening shows good concordance and relative SN when compared with CCS |
| Sechi et al., 2022 | Italy/Monza | Not reported | 40 | 39.5 (mean) | 1.FLOQ Swab; 2. Evalyn Brush; 3.Her swab | 1–3. Vaginal smear; 4. Cervical smear | 1–3.Self-sampling vs. 4. Clinician-taken sample | AnyplexI HPV28 | LBC (ThinPrep medium)/ Bethesda system | 1. κ = 0.89; 2. κ = 0.79; 3. κ = 0.90 | Not reported | Not reported | Self-collected samples showed overall high concordance with CCS |
| Shih et al., 2023 | Taiwan, Taichung | Not reported | 167 | ≥20 | 1. Urine sampler 2.Rovers Cervex-Brush 3. Digene cervical brush | 1.Urine test 2. Vaginal smear 3. Cervical smear | 1 and 2. Self-sampling vs. 3.Clinician-taken sample | 1. HPV DNA Tests by Cervista 2.HPV DNA Tests by HC II | – | κ = 0.22–0.26 | 1.75 % 2.49 % | 1.74.5 % 2.71.1 % | HPV tests self-samples had around 60 % SN to HPV tests on CCS |
| Tiiti et al., 2021 | South Africa/ Gauteng Province (black Africans) | Cross-sectional | 527 | ≥18 | 1.SelfCerv Self-Collection Cervical Health Screening Kit; 2. Cervex-Brush Combi | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | Abbott RealTime HR-HPV and Aptima HR-HPV mRNA assays | Not performed | 87.1 %, κ = 0.74 | 86.2 % | 88 % | Self-collected samples had good agreement with the CCS for the detection of HR-HPV |
| Tranberg et al., 2018 | Denmark/ Central Region | Cross-sectional | 213 | 30–59 | Evalyn brush | Vaginal smear | 1.Self-sampling vs. 2. Clinician-taken sample | Cobas 4800 assay | LBC (not specified)/ Bethesda system | 89.2 % | 80.9 % | 91.6 % | A good concordance between self-samples and CCS in terms of HPV detection |

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**Table 1** (*continued*)

| Authors/ year | Location | Study design | Participants (N) | Age (years) | Intervention description | | | Tests performed to compare self-samples and CCS for identification of diagnostic accuracy | | Reliability of self-collected samples | | | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling device | Sample type | Sampling approach | HPV-genotyping test used | Cervical cytology or histology test/ interpretation | Concordance with CCS, (% and/or κ), [95 % CI] | SN (ratio or %), [95 % CI] | SP ratio or %), [95 % CI] | |
| Tranberg et al., 2020 | Denmark/ Central Denmark Region | Cross-sectional | 216 | 30–59 | 1. Cervex-Brush; 2. Evalyn Brush; 3. Genelock | 1. Cervical smear 2. Vaginal smear 3. Urine sample | 1–3.Self-sampling vs. 4. Clinician-taken sample | GENOMICA CLART® Vs.COBAS® 4800 assays | Not performed | 1.κ = 0.59; 2.κ = 0.66 | 1.51.6 %; 2.63.9 % | 1.92.4 %; 2.96.5 % | With COBAS, higher concordance between urine and vaginal self-sampling and CCS HR-HPV detection |
| Van Keer et al., 2022 | Belgium/not specified | The VALHUDES framework | 492 | 19–72 | 1. Colli-Pee 2. Cervex-Brush | 1. Urine sample; 2. Cervical smear | 1. SelSelf-sampling Clinician-taken sample | BD Onclarity HPV Assay | LBC, BD Viper LT System/ Bethesda system | κ = 0.678 | 1.90.9–91.1 %; 2. 90.9 %-93.3 % | 1. 46.3 %; 2. 50.5 % | BD Onclarity HPV Assay on first-void urine has similar SN and "somewhat lower" SP in self-sampling and CCS |
| Wong et al., 2018 | China, Hong Gong/sex-workers | Cross-sectional | 68 | 22–59 | 1.Dacron swab 2. Cytobrush | 1. Vaginal smear 2. Cervical sample | Self-sampling vs. Clinician-taken sample | Genotyping assay type not psecified | Papanicolaou test/ Bethesda system | 85.3 %, κ = 0.69 | 66.7 % | 66.1 % | High concordance rate |

Table footnotes: CC – conventional cytology; CCS - clinician-collected specimens; CIN - cervical intraepithelial neoplasia; CISOE-A - composition, inflammation, squamous epithelium, other and endometrium, endocervical columnar epithelium, and adequacy of the smear; CONCEP - Comprehensive Prevention of Cervical Cancer in Tanzania; HC2 - Hybrid Capture 2; HPV – human papillomavirus; HR-HPV – high-risk human papillomavirus; HSIL – high-grade squamous intraepithelial lesion; LBC – liquid-based cytology; κ - Cohen's Kappa; RT - real-time; SN – sensitivity; SP – specificity; POI/NIH - Preventive Oncology International/National Institutes of Health.

**Table 2**
Characteristics and comparison of the studies assessing the HPV self-sampling devices' acceptability.

| Authors/study | Location/ population | Study design | Participants (N) | Age (years) | Intervention description | | | | Acceptance of self-collection | Additional information | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling tool type | Sample type | Sampling approach | Survey used | | | |
| Abuelo et al., 2014 | Peru/urban communities along the Amazon | Not reported | 320 | 30–45 | "Just for Me"self-administered cervicovaginal sampling brush | 1.Vaginal smear | 1. Self-sampling vs. 2.Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 99.7 % | – | The self-sampling technique may be appropriate for large-scale cervical cancer preventative interventions |
| Andersson et al., 2021 | Sweden/ Stockholm County | Case-control | 43 cases, 479 controls | ≥34 | Female Swab Sample Packet (Cobas) | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 100 % | Acceptance of women from the control group was 74 % | Educating women regarding cervical cancer and HPV testing will improve attendance |
| Aranda Flores et al., 2021 | Mexico/Mexico City | Randomized clinical rtial | 505 | 30–65 | 1.XytoTest medical Device; 2.Cervex-Brush | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2.Clinician-taken sample | A questionnaire (type is not specified) | 96.8 % | 88.8 % reported no discomfort at all performing the procedure | A high acceptance is reported |
| Behnke et al., 2020 | Ghana/ North Tongu district | Mixed-method | 52 | 23–59 | 1.Delphi Screener; 2.Evalyn Brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 98.1 % | All responders found self-sampling to be 'Easy' or 'Very Easy' | Self-sampling for cervical cancer screening is highly acceptable |
| Bishop et al., 2019 | USA/Hispanic, non-Hispanic white, non-Hispanic black | Cross-sectional | 605 | 21–65 | 1.EvalynBrush; 2. HerSwab; 3.Catch-All Swab; 4.Qvintip | Vaginal smear | Self-sampling | Online survey | 1.67.6 %<br>2.49.4 %<br>3.73.9 %<br>4.72.1 % | 53.1 % of participants concerned about the self-sampling test accuracy | Acceptability of HPV self-sampling as a cervical cancer screening strategy was high |
| Brandt et al., 2019 | Ethiopia/ Northwest rural district | Qualitative | 41 | 20–65 | Evalyn Brush | Vaginal smear | Self-sampling | Community-based focus group discussions | High | High level of misconceptions and low awareness about cervical cancer and screening among respondents | Home-based self-sampling for cervical cancer screening is a socially acceptable and feasible method |
| Cadman et al., 2014 | England and Wales/Indian (Hindu) | Mixed methods | 185 | 25–64 | 1.Dacron swab; 2. Evalyn brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | Low | Self-collected sampling had a mixed reception | Familiar barriers to screening; Lack of women's confidence |
| Castell et al., 2014 | Germany/ Hamburg and Hanover | Cross-sectional | 162 | 20–69 | Delphi Screener | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 98 % | – | The self-sampling was very well accepted |
| Chan et al., 2023 | Hong Kong | Prospective study | 104 | 30–65 | 1. Cepillo Endocervical/ Cervical Brush/ Cyto-Brush + DNA sample storage card; 2. Cervex-Brush | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2.Clinician-taken sample | A questionnaire (self-administered) | 65 % | 68 % - not feeling embarrassed; 58 % - convenient | Self-sampling was shown to be a generally well-accepted method of cervical cancer screening |

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**Table 2** (*continued*)

| Authors/study | Location/ population | Study design | Participants (N) | Age (years) | Intervention description | | | | Acceptance of self-collection | Additional information | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling tool type | Sample type | Sampling approach | Survey used | | | |
| Chatzistamatiou et al., 2017 | Greeece/rural Greek | Cross-sectional | 346 | 25–60 | 1.Evalyn brush | 1. Vaginal smear; | Self-sampling vs. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 82.4 % | 92.3 % were positive towards self-sampling | Self-sampling is well-accepted for HPV-based screening |
| Chatzistamatiou et al., 2020 | Greece/rural Greek | Cross-sectional | 13,111 | 25–60 | Self-sampling collection kit (dry cotton swab and sterile vial | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 67.9 % | 74.4 % of the women felt adequately confident about self-sampling | Self-sampling is highly acceptable |
| Crofts et al., 2015 | Cameroon/East Province of | Not reported | 540 | 30–65 | Copan ESwab® | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 95.6 % | Acceptance of self-sampling had no correlation with socio-demographic factors | The self-sampling approach was very well accepted |
| De Pauw et al., 2021 | Belgium/not specified | The VALHUDES framework - Diagnostic test accuracy study following STARD guideline | 515 | 25–64 | 1. Multi-Collect swab; 2. Evalyn-Brush; 3. Qvintip; 4.Colli-Pee | 1. Vaginal smear; 2. Vaginal smear; 3. Vaginal smear 4. Urine specimen | Self-sampling | A questionnaire (self-administered paper questionnaire) | >95 % | Among women preferring self-sampling, 53 % would choose urine collection, 38 % vaginal self-collection and 9 % had no preference | Both urine and vaginal self-samples are well accepted by the study participants |
| Devotta et al., 2023 | Canada, Ontario | Mixed methods | 69 | 30–69 | HerSwab | Vaginal sampling | Self-sampling | A an interviewer-administered survey | – | Some women found HPV self-sampling to be acceptable alternative to CCS | Self-sampling is an alternative to clinical cervical cancer screening |
| Enerly et al., 2016 | Norway/Oslo area | Cross-sectional | 267 | 25–69 | 1.Evalyn brush; 2. Deplphi Screener | 1. Vaginal smear; 2. Vaginal smear | Self-sampling vs. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 88 % | The majority of women found the self-sampling procedure to be easy | Self-sampling has the potential to improve cervical cancer screening attendance |
| Ertik et al., 2021 | Germany/ Hannover | Prospective multicenter phase II trial (CoCoss-Trial) | 65 | 24–76 | 1.Evalyn-Brush; 2. FLOQSwab; 3. Colli-Pee FV-5000 | 1. Vaginal smear; 2. Vaginal smear; 3. Urine sample | Self-sampling vs. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 95 % | Only 4.6 % of women preferred the CCS over the self-samples | All devices were considered easy to use without any difficulties following the written instructions |
| Fujita et al., 2023 | Japan | Randomized | 1,196 | 30–59 | Evalyn-Brush | 1. Vaginal smear; 2. Cervical smear | Self-sampling vs. Clinician-taken sample | A questionnaire (not specified) | 75.3—81.3 % | Willingness to undergo screening with a self-collected sample was significantly higher than with CCS | High acceptability of HPV self-sampling was confirmed |
| Gibert et al., 2023 | Spain, Illes Balears | Cross-sectional | 120 | 40–51 | 1. Viba-Brush; 2. Mía by Xytotest; 2. Rovers Cervex-Brush | 1. Vaginal smear; 2. Vaginal smear; 3.Cervical smear | Self-sampling vs. Clinician-taken sample | A questionnaire (survey) | 91.7 % | The majority of participants considered self-sampling to be beneficial on CCS | Self-sampling was well-accepted by patients |
| Hanley et al., 2016 | Japan/Sapporo | Not reported | 203 | 20–49 | Evalyn brush; | Vaginal smear; | Self-sampling vs. Clinician- | A questionnaire (self-administered | 90 % | Compared with CCS, women found self-sampling significantly | Self-sampling was highly acceptable |

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**Table 2** (*continued*)

| Authors/study | Location/ population | Study design | Participants (N) | Age (years) | Intervention description | | | | Acceptance of self-collection | Additional information | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling tool type | Sample type | Sampling approach | Survey used | | | |
| | | | | | | | taken sample | paper questionnaire) | | less painful and less embarrassing | in the studied population |
| Ibáñez et al., 2023 | Spain, Catalonia and Canary Islands | Randomized | 1,158 | 30–65 | Evalyn brush; | Vaginal smear; | Self-sampling vs. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 87 % | The majority of all participants "favoured home-based self-sampling approach" for cervical cancer screening | Self-sampling was a highly accepted in Spain |
| Ilangovan et al., 2016 | USA/Florida/ Haitian and Latina women | Not reported | 180 | 30–65 | POI/NIH self-sampler | Vaginal smear; | Self-sampling vs. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 67 % | Over 80 % of women agreed HPV self-sampling was "faster, more private, easy to use, and would prefer to use again" | HPV self-sampling was acceptable and feasible to the study participants |
| Islam et al., 2020 | Kenya/ Mombasa | Cohort study | 400 | 19–66 | 1. Evalyn-Brush; 2. Viba brush | 1.Vaginal smear 2. Cervical smear | Self-sampling vs. Clinician-taken sample | Questionnaire (type of survey not specified) | 36 % | 88 % of women agreed that the Evalyn brush was comfortable to use | The possibility self-sampling would improve the utility of cervical cancer screening |
| Ketelaars et al., 2017 | The Netherlands/ Dutch population of Nijmegen and 's-Hertogenbosch regions | Cross-sectional | 2,460 | 30–60 | 1.Evalyn brush; 2. Rovers Cervex-Brush | 1. Vaginal smear; 2. Vaginal smear; | Self-sampling vs. Clinician-taken sample | A questionnaire (online) | 97.1 % | 62.8 % preferred self-sampling over a CCS for the next screening round | Self-sampling is highly acceptable to women, and a well-accepted alternative to CCS |
| Leeman et al., 2017 | Spain | Cross-sectional | 91 | ≥18 | 1.Colli-Pee™; 2. Evalyn brush | 1.Urine sample; 2. Vaginal smear; | Self-sampling vs. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 90.1 % | The overall rating by all 91 women resulted in an average score of 7.6 out of 10 for CCS, 8.1 for self-sampling ($P < 0.005$) | The self-sampling technique was rated as excellent by most of the women |
| Leinonen et al., 2018 | Norway/South East region population | Cross-sectional | 310 | 21–80 | 1.Evalyn brush; 2. FLOQSwab | 1.Vaginal smear; 2. Vaginal smear; | 1 and 2.Self-sampling vs. 3.Clinician-taken sample | A questionnaire (type is not specified) | 90–94.5 % | Patients considered Evalyn Brush easier than FLOQSwab | Both devices were well accepted |
| Levinson et al., 2013 | Peru/Manchay and Iquitos | Not reported | 632 | 30–45 | "Just for Me"self-administered cervicovaginal sampling brush | 1.Vaginal smear; 2.Cervical smear; | 1. Self-sampling vs. 2.Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 98 % | – | Self-sampling approach had high satisfaction among patients |
| Lichtenfels et al., 2023 | Brazil, São Paulo | Not reported | 73 | 25–65 | SelfCervix | Vaginal smear 2.Cervical smear | Self-sampling Vs. Clinician collected | Questionnaire (not specified) | 79.7 % | – | The majority of the study participants would recommend self-sampling to other women |
| Lorenzi et al., 2019 | Brazil/Caucasian, non-Caucasian | Cross-sectional | 116 | ≥21 | Evalyn Brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 76.7 % | 12.9 % would prefer CCS | Regardless of age, the participants found self-collection easy to accept |

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**Table 2** (*continued*)

| Authors/study | Location/ population | Study design | Participants (N) | Age (years) | Intervention description | | | | Acceptance of self-collection | Additional information | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling tool type | Sample type | Sampling approach | Survey used | | | |
| Mahomed et al., 2014 | South Africa/ urban and rural | Not clarified | 106 | >18 | 1.Evalyn Brush; 2. Delphi Screener | 1.Vaginal smear; 2. Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 75 % | – | Self-sampling may be an acceptable way to improve cervical cancer screening coverage |
| Ma'som et al., 2016 | Malaysia/Malays, Indian, Chinese | Cross-sectional | 839 | 30–48 | "Just for Me"self-administered cervicovaginal sampling brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 68.2 % | Acceptance depends on patients' age | Urban Malaysian women found self-sampling to be an acceptable alternative to Pap-test |
| Mbatha et al., 2017 | South Africa/ KwaZulu-Natal | Cross-sectional | 91 | 16–22 | 1. Dacron swab; 2 Viba Brush | 1.Vaginal smear; 2. Vaginal smear; | 1.Self-sampling vs. 2.Clinician-taken sample | A questionnaire (type is not specified) | 56 % | 44 % indicated preference for CCS | Self-sampling was acceptable to the majority of participants |
| Megersa et al., 2020 | Ethiopia /North Gondar Zone | Qualitative descriptive | 47 | Average age – 36 | Evalyn Brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | Low | Fear of using Evalyn brush for self-sampling was found to be the main barrier | Educating women regarding cervical cancer and HPV testing is required |
| Mremi et al., 2020 | Tanzania/ rural Kilimanjaro | Combined cross-sectional and cohort | 1,108 | 25–60 | Evalyn Brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) +text messages | 98.9 % | 94.5 % would recommend it to a friend | Self-sampling may have potential to improve cervical cancer screening in LMICs |
| Nishimura et al., 2023 | Japan, Muroran City | Not reported | 953 | 20–50 | 1.Evalyn Brush; 2.Colli-Pee | 1.Vaginal smear; 2.Urine sample; | 1 and 2.Self-sampling | A questionnaire (self-administered) | 88.8 % | 85.5 % - the collection method was easy, 12.9 % - "somewhat challenging" | The self-sampling method was found to be acceptable |
| Phoolcharoen et al., 2018 | Thailand, Bangkok | Not reported | 247 | 30–70 | 1. Evalyn Brush; 2. Rovers Cervex-Brush | 1. Vaginal smear; 2. Cervical smear | Self-sampling vs. 2. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 90 % | 80 % of participants reported the overall very good experience of using the self-sample in comparison with CCS | Self-sample HPV testing appears to be highly accepted |
| Ploysawang et al., 2023 | Thailand, Bangkok | Cross-sectional | 265 | 30–60 | Aptima Multitest Swab Specimen Collection Kit | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | A questionnaire (self-administered paper questionnaire) | 66.4–93.6 % | 66.4 % preferred self-sampling for the next screening | Most of the study participants accepted HPV self-sampling |
| Ruel-Laliberté et al., 2023 | Canada, Québec | Cross-sectional | 310 | 21–65 | Roche Dry swab | Cervico-vaginal smear | Self-sampling | A questionnaire (in-person, paper based) | 84.2–95.8 % | 84.2 % - very satisfied and 95.8 % - choose self-sampling as a primary screening method | HPV self-sampling could increase access to cervical cancer screening |
| Sechi et al., 2022 | Italy/Monza | Not specified | 40 | >18 | 1.FLOQSwab; 2. Evalyn Brush; 3.Her swab | 1–3. Vaginal smear; | 1–3.Self-sampling vs. 4.Clinician- | A questionnaire (not specified) | 100 % | Almost all the patients would prefer to use vaginal self-sampling | Good acceptance was reported |

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**Table 2** (*continued*)

| Authors/study | Location/ population | Study design | Participants (N) | Age (years) | Intervention description | | | | Acceptance of self-collection | Additional information | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling tool type | Sample type | Sampling approach | Survey used | | | |
| | | | | | | 4. Cervical smear | taken sample | | | compared CCS | |
| Sechi et al., 2023 | Italy/Sardinia | Cross-sectional | 185 | 34–51 | FLOQSwab; | 1. Vaginal smear; 2. Cervical smear | 1.Self-sampling vs. 2. Clinician-taken sample | A questionnaire (not specified) | "higher than 60 %" | – | High acceptability of self-collection among women was reported |
| Tiiti et al., 2021 | South Africa/ Gauteng Province (black Africans) | Cross-sectional | 527 | ≥18 | 1.SelfCerv Self-Collection Cervical Health Screening Kit; 2. Cervex-Brush Combi | 1. Vaginal smear; 2.Cervical smear; | 1.Self-sampling vs. 2. Clinician-taken sample | A questionnaire (in-person, paper based) | 90.5 % | 88.4 % of women preferred self-collection | Self-sampling is a potential way to increase primary screening coverage |
| Tranberg et al., 2018 | Denmark/Central Region | Cross-sectional | 213 | 30–59 | Evalyn brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 97.2 % | 94.8 % of women reported that self-sampling was comfortable | A high acceptability of home-based self-sampling was reported |
| Tranberg et al., 2020 | Denmark/ Central Denmark Region | Cross-sectional | 216 | 30–59 | 1. Cervex-Brush®; 2. Evalyn® Brush; 3. Genelock | 1.Cervical smear 2. Vaginal smear 3. Urine sample | Self-sampling vs. Clinician-taken sample | Questionnaire (self-administered paper questionnaire) | 97.3 % | – | Urine collection provides a well-accepted screening option |
| Veerus et al., 2022 | Estonia | Randomized | 1,920 | 37–62 | 1.Qvintip; 2. Evalyn-Brush | Vaginal smear | Self-sampling | Online questionnaire | High | 98 % of women agreed that self-sampling was easy, 88 % preferred it as a future screening method | The good acceptance of HPV self-sampling among long-term screening non-attenders in Estonia was reported |
| Wedisinghe et al., 2022 | Scotland/ Dumfries and Galloway | Prospective cohort | 313 | 30–60 | Evalyn-Brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 70 % | 97 % of women would regularly participate in cervical screening if self-sampling was offered | Offering self-sampling appears to increase cervical cancer screening coverage |
| Winer et al., 2016 | USA/Arizona American Indian | Not reported | 329 | 21–65 | Dacron swab | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 96 % | 62 % of women indicated that they preferred HPV self-sampling to CCS | HPV self-sampling is feasible and acceptable |
| Wong et al., 2018 | China, Hong Gong | Cross-sectional | 68 | 22–59 | Dacron swab | Vaginal smear | Self-sampling vs. Clinician-taken sample | A questionnaire (in-person, paper based) | 70.6 % | Positive attitudes toward self-sampling, however, with some confidence expressed | The study findings showed that self-sampling could improve cervical cancer screening |
| Wong et al., 2020 | China/ Hong Kong | Cross-sectional | 177 | 25–35 and aged ≥ 45 | Evalyn Brush | Vaginal smear | Self-sampling | Questionnaire (type of survey not specified) | 95 % | Acceptance of HPV self-sampling was fairly positive | HPV self-sampling was found to be a good solution to overcome low screening coverage |

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**Table 2** (*continued*)

| Authors/study | Location/ population | Study design | Participants (N) | Age (years) | Intervention description | | | | Acceptance of self-collection | Additional information | Conclusion |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Self-sampling tool type | Sample type | Sampling approach | Survey used | | | |
| Yoshida et al., 2013 | Lao People's Democratic Republic | Not reported | 290 | 18–80 | Viba brush | Vaginal smear | Self-sampling | A questionnaire (self-administered paper questionnaire) | 62 % | – | Self-sampling for cervical cancer screening is highly acceptable |

Table footnotes: CCS – clinician-collected sample; LMIC – low- and middle-income countries;

Mbatha et al., 2017; Phoolcharoen et al., 2018; Tranberg et al., 2018; Wong et al., 2018; Bishop et al., 2019; Brandt et al., 2019; Lorenzi et al., 2019; Behnke et al., 2020; Chatzistamatiou et al., 2020; Islam et al., 2020; Megersa et al., 2020; Tranberget al., 2020; Wong et al., 2020; De Pauw et al., 2021; Ertik et al., 2021; Mremi et al., 2021; Tiiti et al., 2021; Sechi et al., 2022; Andersson et al., 2021; Aranda Flores et al., 2021; Veerus et al., 2022; Wedisinghe et al., 2022; Wedisinghe et al., 2022; Devotta et al., 2023; Ibáñez et al., 2023; Ruel-Laliberté et al., 2023; Gibert et al., 2023; Fujita et al., 2023; Ploysawang et al., 2023; Sechi et al., 2023; Lichtenfels et al., 2023; Chan et al., 2023; Nishimura et al., 2023), the most commonly used self-sampling device was Evalyn Brush – 27 studies (56.3 %) followed by Cervex-Brush – 7 (14.6 %). Viba Brush, FLOQ Swab, Colli-Pee, and Dacron swab devices were utilized in 4 (8.3 %) studies each, while Delphi Screener in 3 studies (6.3 %). Most of the studies assessing self-sampling devices' acceptability utilized more than one device.

Based on the data analyzed, a similar acceptability of 84.2–100 % was reported for Evalyn Brush, Cervex-Brush, Dacron swab, Delphi Screener, FLOQ Swab, Colli-Pee, and Female Swab Sample Packet. However, it is worth mentioning, although the acceptability of the Female Swab Sample Packet was reported at 100 %, it was a single study that used this device. The acceptance of the Cervex-Brush and Dacron swab devices was also high – 90.5–97.3 % (Table 2).

Self-sampling had a mixed reception. The vast majority of studies found the self-sampling procedure to be easy and with a good potential to improve cervical cancer screening attendance, which resulted in a high acceptance of the approach. However, four studies reported a low acceptance (Abuelo et al., 2014; Cadman et al., 2015; Jaworek et al., 2018; Megersa et al., 2020). Factors affecting the acceptance rate were the following: family-related barriers to screening (husband's permission), lack of women's confidence while using a self-sampling device, and lack of knowledge and awareness of cervical cancer screening. Moreover, self-sampling acceptance depended on patients' age, education, and social status.

### *3.3. Risk of bias*

Out of 70 studies analyzed, 65 studies were non-randomized and 5 were randomized. Of 65 non-randomized studies analyzed, 55 were rated as "mild" risk of bias, 8 as "moderate" risk of bias, and 2 as "severe" risk of bias in terms of quality determined by the comparability and outcome criteria (Supplementary Table 2). The bias was mainly caused by the ambiguity of intervention reporting, discrepancy in the measurement of outcome, and selection of the reported results. All 5 RCTs included in the study had "mild" risk of bias related to data reporting (Supplementary Table 3).

## 4. Discussion

Although cervical cancer is a preventable disease, it remains one of the actual healthcare problems worldwide (Arbyn et al., 2020; Akhatova et al., 2022; Serrano et al., 2022). Elimination of this condition largely depends on proper screening practices and vaccination. As recommended by WHO, HPV testing is considered one of the effective cervical cancer screening approaches (Rizzo and Feldman, 2018; WHO, 2023). Increasing evidence supports the feasibility of self-sampling as an alternative to clinician-taken specimen collection for HPV/cervical cancer screening (Serrano et al., 2022). Self-sampling potentially could engage long-term non-attenders and can be an effective strategy for LMICs. Convenient and easy-to-use self-sampling screening devices could be utilized for the screening and contribute to the reduction of cervical cancer mortality and morbidity. In this study, different types of HPV self-sampling devices were compared to identify the most accurate and acceptable device(s).

To the best of our knowledge, this is the first systematic review analyzing and comparing HPV self-sampling devices' diagnostic

accuracy and acceptance to define the most reliable and patient-acceptable tool. Previously performed systematic reviews and *meta*-analyses investigated HPV self-sampling approach evaluated the "uptake of cervical cancer screening services", "frequency of cervical cancer screening", "social harms/adverse events" (Yeh et al., 2019), long-term non-attenders engagement (Aasbø et al., 2022) or logistical values/devices acceptability (Nishimura et al., 2021; Dartibale et al., 2022) and diagnostic accuracy (Chao and McCormack, 2019) separately, however, none of them evaluated HPV self-sampling devices' diagnostic accuracy and acceptance simultaneously.

Our findings show multiple differences in various aspects and criteria among the studies that considered the HPV self-sampling strategy for primary cervical cancer screening such as study design, target population, number of participants, device type, study setting, HPV genotyping and cytological tests used, and interpretation of the results. As was seen in some studies reported in this review (Cadman et al., 2015; Mbatha et al., 2017), patients' sociodemographic, ethnic, and cultural factors should be taken into consideration as it may acceptance of and preferences for self-sampling or clinician-taken sampling.

Based on the eligible papers analyzed, in this systematic review Evalyn Brush, Cervex-Brush, FLOQ Swab, and Delphi Screener self-sampling devices were found to be widely used, the most reliable and patient-acceptable for HPV detection, thus, could be effectively utilized to improve cervical cancer screening programs worldwide. In terms of diagnostic accuracy, the self-sampling method had no significant difference compared with the conventional method performed by healthcare providers.

A previous *meta*-analysis by Arbyn et al. (2014), which examined the accuracy and reliability of self-collected samples for HPV genotyping, concluded the superiority of clinician-taken samples' SN and SP (Arbyn et al., 2014). HPV testing on a self-sampling basis was suggested by Arbyn et al. (2014) as an additional strategy to enroll cervical cancer screening non-attenders (Arbyn et al., 2014). Our study results show a controversial finding suggesting a fairly high concordance rate between self-collected and clinician-collected samples defined by HPV genotyping tests. This could be explained by improvements in the quality of self-sampling devices allowing the proper biological material collection within the past decade, since 2014 when the previous review was published (Arbyn et al., 2014).

Our study findings are in agreement with previous researchers, which systematically compared studies assessing the acceptability of HPV self-sampling devices and strongly support "inclusion of self-sampling for HPV testing" as an additional approach for cervical cancer screening programs where HPV DNA testing is used (Verdoodt et al., 2015; Morgan et al., 2019; Nishimura et al., 2021). However, none of those studies specified which device was the most acceptable among patients. Awareness of patients' preferences for the self-sampling approach is important; moreover, understanding the preferred device type would even more significantly improve the self-sampling-based screening coverage.

### 4.1. Strengths and imitations

One of this systematic review strengths is in the assessment and reporting of the studies using the PRISMA checklist. In this review, both randomized and non-randomized studies were analyzed. The search was performed in multiple databases, considered studies of any location, and used a systematic approach for analysis. Moreover, this is the first study that compared both important criteria for self-sampling device utilization, its diagnostic accuracy in the detection of HPV, and patients' acceptance. Based on this analysis data, the most reliable and acceptable self-sampling device could be identified by any researcher for their studies and clinical practice. The findings of this review should be analyzed in light of its limitations. No conference abstracts or sources published in other than the English language were included in this review, so the reported findings might not fully reflect the entire list of resources on HPV self-sampling diagnostic accuracy and acceptability. Taking into consideration the diversity of studies (qualitative and quantitative) and measures used in these investigations to assess patients' acceptance, it was difficult to make comparisons of some studies in terms of specific aspects of self-sampling.

### 4.2. Clinical implications

Being implemented into clinical practice, especially in LMICs, HPV self-sampling could become a widely used alternative method for cervical cancer screening to improve the screening coverage and thus contribute to the reduction of cervical cancer incidence. It has a great potential to increase the efficiency and accessibility of cervical cancer screening among non-attenders/underscreened women.

## 5. Conclusion

Self-sampling modality for cervical cancer screening has a good potential to increase cervical cancer screening coverage. The quality of HPV self-sampling devices has improved during the past decade. This systematic review shows high diagnostic accuracy and patient acceptance of the self-sampling approach for HPV screening in general. However, information and patient education on cervical cancer screening and the opportunity for HPV self-sampling are required for women of diverse backgrounds. Evidence support the validity of self-sampling modality as an alternative, which enables increasing cervical cancer screening uptake. Thus, this approach has a great potential to facilitate efforts in decreasing cervical cancer morbidity and mortality rates. In addition, before a nationwide implementation of self-sampling, especially in LMICs with low coverage of conventional screening programs, further research is required to evaluate the self-sampling approach's cost-effectiveness in specific local settings based on cultural diversity.

## 6. Funding information

There was no funding available to support this study.

## 7. Consent

This study does not directly involve any animal or human data or tissue, therefore due to the nature of the study, systematic review, the ethical approval for this study and informed consent is not required. Moreover, original research studies included in the analysis were checked for the compliance with the Helsinki Declaration ethical standards. Authors' contribution

## CRediT authorship contribution statement

**Gulzhanat Aimagambetova:** . **Kuralay Atageldiyeva:** Data curation, Formal analysis, Investigation, Validation, Writing – original draft. **Aizada Marat:** Data curation, Formal analysis, Investigation, Writing – original draft. **Assem Suleimenova:** Investigation, Visualization, Writing – original draft. **Torgyn Issa:** Data curation, Formal analysis, Software, Visualization. **Sarina Raman:** Data curation, Software, Validation, Writing – original draft. **Timothy Huang:** Data curation, Formal analysis, Software, Validation, Writing – original draft. **Ayimkul Ashimkhanova:** Data curation, Formal analysis, Investigation, Visualization, Writing – original draft. **Saida Aron:** Investigation, Writing – original draft. **Andrew Dongo:** Data curation, Formal analysis, Software, Validation. **Yerbolat Iztleuov:** Data curation, Formal analysis, Investigation. **Saykal Shamkeeva:** Data curation, Formal analysis, Investigation. **Azliyati Azizan:** Conceptualization, Methodology, Project administration, Supervision, Visualization, Writing – original draft, Writing – review & editing.

## Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

## Data availability

Data will be made available on request.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2024.102590.

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