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Clinical Validation of a Vaginal Cervical Cancer Screening Self-Collection Method for At-Home Use

A Nonrandomized Clinical Trial

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Abstract

IMPORTANCE One-quarter of US women who are at risk for cervical cancer delay screening. Self-collected (SC) cervical screening was recently US Food and Drug Administration (FDA)–approved in the US for use in a health care setting only; an at-home SC option is crucial to address clinic-related barriers to screening.

OBJECTIVE To clinically validate the use of an SC device that was designed for optimal at-home performance, safety, ease-of-use, and dry storage and transport.

DESIGN, SETTING, AND PARTICIPANTS This nonrandomized clinical trial used a prospective method comparison study design. Participants aged 25 to 65 years were recruited from 16 clinical sites in the US including community and academic practices from November 20, 2023, to April 5, 2024. Data analysis was conducted from April to August 2024.

INTERVENTION Eligible participants collected a sample with the SC method, followed by a clinician-collected (CC) sample. The SC sample was eluted into PreservCyt at the laboratory and both samples were tested on an FDA-approved high risk human papillomavirus (hrHPV) test approved for primary screening. Participants were followed up for safety and completed usability and screening preference surveys.

MAIN OUTCOME AND MEASURES The primary outcome measures were positive percentage agreement (PPA) and negative percentage agreement for detection of hrHPV between the SC and CC samples. Other study measures included clinical sensitivity for high grade cervical dysplasia and usability.

RESULTS Of 609 screening-eligible participants, 599 (262 aged 30-39 years [43.7%]; 583 identified as female [97.3%]) had paired SC-CC samples, of which 582 had valid paired samples included in the end point analysis. Among the 582 evaluable paired samples, the PPA between SC compared with paired CC samples for detection of hrHPV was 95.2% (95% CI, 92.1%-97.1%; 278 of 292 participants). The absolute clinical sensitivity for detection of high-grade cervical dysplasia was 95.8% (95% CI, 86.0%-98.8%; 46 of 48 participants), equivalent to the CC (relative sensitivity, 1.00). Nearly all participants (555 of 601 participants [92.3%]) reported that the device instructions were easy or very easy to understand and also that they would choose SC if they knew the results were comparable to CC results (560 of 602 participants [93.0%]).

(continued)

Key Points

Question What is the agreement for the detection of high-risk human papillomavirus (hrHPV) between clinician-collected (CC) and self-collected (SC) vaginal samples using a device designed for at-home use among a US population?

Findings In this nonrandomized clinical trial of 599 individuals with paired SC-CC samples, SC samples compared with CC samples showed high positive agreement for detection of hrHPV and equivalent sensitivity for cervical dysplasia. Device safety and usability were also confirmed.

Meaning This study found that the SC device is a safe and accurate method for primary HPV cervical cancer screening, offering a preferred alternative to in-clinic cervical cancer screening.

+ Supplemental content

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Abstract (continued)

CONCLUSIONS AND RELEVANCE In this nonrandomized clinical trial, SC samples collected with the device showed equivalent clinical sensitivity and exceeded the PPA end point for cervical screening. This SC method was found to be easy to use and to be a preferred option with high clinical performance intended for use in an at-home setting.

TRIAL REGISTRATION ClinicalTrials.gov Identifier: NCT06120205

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Introduction

Prior to the development of the Papanicolaou (ie, Pap smear) screening test, cervical cancer was the leading cause of cancer-related death for US women. Papanicolaou tests, and subsequently liquid based cytology, became the cornerstone of cervical cancer screening until high-risk human papillomavirus (hrHPV) was identified as the primary cause of cervical cancer.[1-3] Testing for hrHPV is the most sensitive cervical screening technique, and after its approval by the US Food and Drug Administration (FDA) for primary screening in 2014, it was recommended by several US professional societies including the US Preventive Task Force Service (USPSTF).[1,4-7]

Cervical screening tests (Papanicolaou and co-test [Papanicolaou plus hrHPV test]) require a sample collected by a clinician during an in-clinic speculum examination, which poses both logistical barriers (eg, scheduling and access to a clinic, time off, and childcare), as well as emotional deterrents (embarrassment, fear or discomfort of the pelvic examination, or prior trauma).[8-10] As a result, the percentage of women reported overdue for cervical cancer screening in the US has increased from 14% in 2005 to 28% in 2021, which equates to more than 20 million individuals who are underscreened and are at increased risk for invasive cervical cancer.[10] More than one-half of newly diagnosed cancers occur in underscreened individuals.[11]

Cervical sampling is not required for detection of hrHPV, as supported by numerous studies evaluating the accuracy of self-collected (SC) vaginal samples for detection of hrHPV using polymerase chain reaction–based tests and that show comparable sensitivity to clinician-collected (CC) cervical sampling for detection of cervical dysplasia.[12,13] In May 2024, the FDA approved vaginal SC in health care settings, where the sample is self-collected in a clinic and immersed in preservative prior to or upon arrival at the laboratory. While this SC option can help address some of the emotional deterrents to a speculum examination, it fails to overcome the remaining substantial clinic access barriers cited among those who are underscreened, including time off work, arrangement of child or elder care, and transportation.[9,14] The updated USPSTF cervical screening draft recommendations[7] (2025) include SC as an option for screening, acknowledging that the clinical accuracy does not differ between home or clinic setting for SC, and that home-based SC has a greater positive impact on increasing screening rates.

While prior studies have found high acceptability and usability for SC sampling in the at-home setting, the performance of samples stored without media or preservative (ie, dry swab) required for safe use at-home has shown lower sensitivity and agreement compared with samples collected by a clinician.[15-17] One option for improving performance of current SC methodology involved changing the preanalytical workflow of FDA-approved assays (eg, smaller volume of media), and thus would require additional validation.[18-20]

The goal of the Self-Collection for Cervical Cancer Screening (SELF-CERV) study was to evaluate the agreement of dry swab samples collected with an SC device (Teal Wand) for the detection of hrHPV when compared with CC samples, in consultation with FDA guidance. SC occurred in a simulated at-home environment followed by a CC sample to ensure accurate hrHPV comparisons and to assess disease status. An additional usability cohort evaluated steps specifically for at-home use.

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The SC method utilizes dry sample storage and collection with a device optimized for performance, usability, and safety in the at-home user environment.

Methods

Study Design and Oversight

This nonrandomized clinical trial used a prospective, multicenter, method comparison study design. Eligible participants within guideline-indicated screening ages (25-65 years)[1,4] were recruited from 16 US investigational sites and enrolled from November 20, 2023, to April 5, 2024. A central institutional review board (Advarra) and 2 other institutional review boards (Johns Hopkins University and New York University) approved the study and provided human participants protection oversight. The study was designed by the study sponsor (Teal Health) with feedback from the FDA. All participants provided written informed consent. The study was conducted according to the principles of the Declaration of Helsinki[21] and followed the Transparent Reporting of Evaluations With Nonrandomized Designs (TREND) guidelines. The trial protocol is available in Supplement 1.

Data management and monitoring were conducted by independent clinical research organizations (Global BioClinical and Vantage), and 2 independent statisticians (L.G. and K.H.) calculated end points, designed the interim analysis, conducted the blinded interim analysis, and analyzed the data.

Study Population

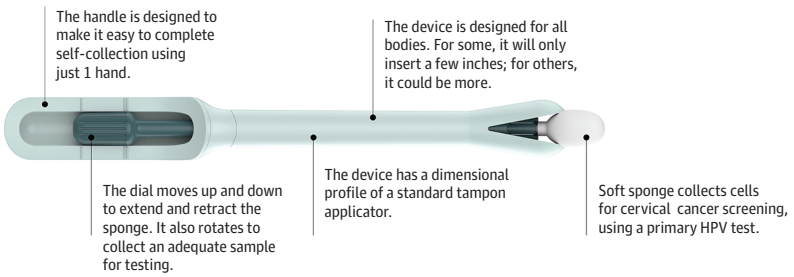
Participants were required to be within guideline screening ages for primary hrHPV screening (25-65 years) with an intact cervix. Participants from 2 groups were enrolled: (1) a general screening population and (2) an enriched group, which included people with a positive hrHPV diagnosis and/or abnormal Papanicolaou cytology result within the preceding 6 months. Abnormal cytology included diagnoses of atypical squamous cells of undetermined significance and above (≥atypical squamous cells of unknown significance) based on Bethesda criteria.[22]

Exclusionary criteria included pregnancy, vaginal bleeding, and a cervical alteration in the prior 5 months. All participants needed to be willing and able to provide informed consent. Participants received institutional review board–approved reasonable compensation for their time.

Clinical Procedures

Following informed consent and enrollment, participants were given instructions for use for the SC device (**Figure**). Participants were provided a private area for SC (simulating an at-home environment) and followed the steps in the instructions for use for collection including inserting the device in the vagina, extending the collection sponge with the dial, rotating the sponge 10 times, and removing the device. The participant then detached the sponge from the device and placed it in an empty vial. For method comparison, following SC, a sample was collected by a clinician using a

Figure. The Self-Collection Device



The device is a single patient-use, disposable device intended for the collection of vaginal cells and material to be tested with a US Food and Drug Administration–approved test indicated for high-risk human papillomavirus (HPV) primary screening for cervical cancer. The device consists of biocompatible, medical grade injection molded polymer components that are the diameter of a standard tampon. The distal-most components are fabricated from soft, atraumatic materials.

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Rovers Cervex-Brush (Rovers Medical Devices B.V.) and transferred into a 20-mL vial of PreservCyt (ThinPrep [Hologic, Inc.]).

Both the SC and CC samples were transported to the designated laboratory for processing. SC samples were stored dry in the empty vial for up to 9 days before a laboratory technician eluted the sponge into 20 mL PreservCyt. Samples were then tested using the Roche cobas hrHPV test on the Roche cobas 8800 System (Roche Molecular Systems Inc.), which detects 14 hrHPV types with partial genotyping for HPV-16, HPV-18, and 12 other hrHPVs (a pooled result inclusive of HPV-31, HPV-33, HPV-35, HPV-39, HPV-45, HPV-51, HPV-52, HPV-56, HPV-58, HPV-59, HPV-66, and HPV-68).

As a nonpowered study measure, clinical sensitivity for detection of high-grade cervical dysplasia (high-grade squamous intraepithelial lesions including cervical intraepithelial lesion grade 2 [moderate severity] or higher [CIN2+]) was evaluated as follows: if a biopsy or loop electrosurgical procedure was collected during or closely following the study visit, the deidentified histopathology results were collected and the highest severity diagnoses present were used to calculate clinical sensitivity.

Self-reported participant race, ethnicity, income, education, prior cervical screening history, and screening preferences were recorded. Race categories included American Indian or Alaska Native, Asian, Black, Native Hawaiian or Pacific Islander, multiracial (2 or more of the previously listed race categories), and other race (Brazilian, Middle Eastern, Mestiza, multiracial [2 or more races not mentioned previously], West Indian, and none listed). Ethnicity was reported according to 2016 FDA guidance[23] as a separate category from race; ethnicity categories included Hispanic or Latino and non–Hispanic or Latino. Race and ethnicity were included to evaluate any differences in preferences or usability by race or ethnicity. Usability for the SC process was tested and recorded using surveys. Safety was assessed after the collection procedures and between 6 to 14 days after study procedures.

Statistical Analysis

The primary outcome measures were agreement (positive and negative) for detection of hrHPV between the SC and CC samples. Agreement for detection of hrHPV provides an acceptable end point for SC validation studies because hrHPV assays are validated and approved based on clinical accuracy for detection of precancerous lesions (CIN2+).[13] The point estimates for agreement for detection of hrHPV were derived from published SC data using threshold analysis to establish the agreement point estimates corresponding to a relative sensitivity exceeding 0.95 and relative specificity exceeding 1.00.[13] Point estimates of 87% for positive percentage agreement (PPA) and 88% for negative percentage agreement (NPA) with a lower bound of 80% (95% CI) were used to compute the targeted minimum sample size for HPV-positive and HPV-negative CC samples in the trial (225 HPV-positive and 198 HPV-negative). Additional primary measures included device design adequacy for primary safety and usability. Participants' general willingness to use an SC device and concerns or preferences for SC were assessed using survey instruments.

Planned interim analysis at 291 participants showed acceptable safety and accuracy to continue the study to conclusion without sample size adjustments. Enrollment continued beyond minimum sample sizes to obtain requisite numbers of participants with HPV-16–positive results requested by the FDA.

Statistical analysis was conducted from April to August 2024 using SPSS Statistics version 29.0.2.0 (20; IBM). Descriptive statistics were used to summarize participant characteristics. Basic summaries of diagnostic test results were tabulated, including the dichotomized test result and adequacy of the sample collected. Adverse events were evaluated for relatedness and severity. Invalid results were reported in aggregate. Usability was assessed using patient-completed surveys and invalid rate or false-negative results to ensure at least 90% valid sample collection and success for critical steps. The threshold for statistical significance was a 2-sided $P < .05$.

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Results

A total of 609 eligible participants from 16 clinical sites in the US (eTable 1 and eTable 2 in Supplement 2) were consented and 599 paired SC-CC samples (262 aged 30-39 years [43.7%]; 583 identified as female [97.3%]) were analyzed. Ten participants were excluded for inclusion or exclusion reasons or if a paired sample was not obtained. Nearly 60% of participants (362 participants [59.4%]) were recruited from the hrHPV enriched group, while the remaining 40% (247 participants [40.6%]) were recruited from the general screening population (eFigure in Supplement 2). While not required for the primary analysis of agreement, each participant's active involvement in the study was confined to a single collection visit and subsequent safety follow-up via email or phone contact between 6 to 14 days post visit. Follow-up compliance was 98.2% (585 of 599 participants). All participants who used the SC device were evaluated for safety and usability end points using survey responses. Participants were recruited from 16 clinical sites across the US, representing diverse geography, sociodemographic diversity, and a mixture of academic and community settings (**Table 1**; eTable 1 and eTable 2 in Supplement 2).

Paired SC and CC samples from 599 eligible participants were analyzed for detection of hrHPV. The rates of invalid results for the SC (14 participants [2.3%]) and CC (3 participants [0.5%]) resulted in 582 valid sample pairs for analysis (eFigure in Supplement 2). Efforts to evaluate the most likely causes of the invalid samples did not show any one prevailing cause (eTable 3 and eTable 4 in Supplement 2). Of note, an invalid sample result requires recollecting a sample but is not reported as a negative (eg, false negative). The invalid rate reported here is comparable to that of the other FDA-approved devices.[24]

As shown in **Table 2**, PPA for any of the 14 hrHPVs was 95.2% (95% CI, 92.1%-97.1%; 278 of 292 participants), including high agreement for HPV-16 and/or HPV-18 genotypes (69 of 72 HPV-16– or HPV-18–positive samples [95.8%]), exceeding the point estimate and lower bound end points in the protocol (Supplement 1 and eTable 5 in Supplement 2). The positive agreement for hrHPV was significantly higher among those who did not receive the HPV vaccine but remained high in both groups (132 of 136 unvaccinated participants [97.1%] vs 82 of 91 vaccinated participants [90.1%]; $P = .04$). This difference is expected given decreased HPV-16 and HPV-18 genotypes (targeted in all vaccines and causative of the majority of cervical dysplasia and cancer) are less prevalent in vaccinated individuals, with a proportional decreased burden of CIN2+ causing a lower positive predictive value of an hrHPV.[17] There were no statistically significant differences in PPA by prior cervical tissue alteration, body mass index, presence of blood in the sample (eg, menses), or among those with an intrauterine device in place.

Clinical Accuracy

Of the enrolled participants, 245 underwent a colposcopy with a biopsy or excisional procedure (eg, loop electrosurgical procedure or conization) and an additional 19 underwent an excisional procedure following the study procedure yielding histopathology results. A total of 48 participants had high grade squamous intraepithelial lesions or CIN2+, and 29 of the 48 had a diagnosis of cervical intraepithelial lesion grade 3 or higher (CIN3+).

The absolute clinical sensitivity of SC was 95.8% (95% CI, 86.0%-98.8%) for CIN2+ (46 of 48 participants). The relative sensitivity compared with CC was 1.00. The SC method demonstrated absolute clinical sensitivity for CIN3+ of 96.6% (95% CI, 82.8%-99.4%; 28 of 29 participants), with a relative sensitivity of 0.97 (**Table 3**; eTable 6 and eTable 7 in Supplement 2). There were no statistically significant differences in clinical sensitivity by prior cervical tissue alteration, body mass index, or among those with an intrauterine device in place. The relative specificity for CIN grade 1 or lower was 0.97 among group 2.

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Table 1. Summary of Demographics

Response category	No./ total No. (%)[a]
Race	
American Indian or Alaska Native	4/599 (0.7)
Asian	23/599 (3.8)
Black	151/599 (25.2)
Native Hawaiian or Pacific Islander	3/599(0.5)
White	346/599 (57.8)
Multiracial[b]	21/599 (3.5)
Other[c]	23/599 (3.8)
Missing	28/599 (4.7)
Ethnicity	
Hispanic or Latino	114/599. (19.0)
Not Hispanic or Latino	471/599 (78.6)
Missing	14/599 (2.3)
Gender identity	
Female	583/599 (97.3)
Gender queer or nonconforming	8/599 (1.3)
Transgender man or male	3/599 (0.5)
Additional gender category	1/599 (0.2)
Missing	4/599 (0.7)
Age, y	
25-29	148/599 (24.7)
30-39	262/599 (43.7)
40-49	113/599 (18.9)
≥50	76/599 (12.7)
Body mass index[d]	
<18.5	5/599 (0.8)
18.5-24	206/599 (34.4)
25-29	157/599 (26.2)
30-39	176/599 (29.4)
≥40	46/599 (7.7)
Missing	9/599 (1.5)
Annual income	
<$9999	69/599 (11.5)
$10 000-$19 999	35/599 (5.8)
$20 000-$49 999	135/599 (22.5)
$50 000-$99 999	172/599 (28.7)
$100 000-$149 999	66/599 (11.0)
≥$150 000	67/599 (11.2)
Do not know or prefer not to say	55/599 (9.2)
Education level	
No formal schooling	4/599 (0.7)
Up to middle school (grade 8)	13/599 (2.2)
High school or general educational development	160/599 (26.7)
Associates degree (2 y)	101/599 (16.9)
Vocational or technical school	41/599 (6.8)
Bachelor's degree (4 y)	188/599 (31.4)
Master's or professional degree	90/599 (15.0)
Missing	2/599 (0.3)

(continued)

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Table 1. Summary of Demographics (continued)

Response category	No./ total No. (%)[a]
Human papillomavirus vaccination status	
Not vaccinated	266/599 (44.7)
1 Dose	22/599 (3.7)
2 Doses	45/599 (7.6)
3 Doses	122/599 (20.5)
Unknown number of doses	70/599 (11.8)
Missing or unknown vaccination status	74/599 (12.4)

[a] Each category includes the number of responses based on the number of participants who answered each question who were included in the paired analysis.

[b] Multiracial is defined as identifying with 2 or more race categories listed previously, therefore is not additive toward the total.

[c] Other included Brazilian (14 participants), as well as Middle Eastern (5 participants), Mestiza (1 participant), multiracial (2 or more race categories not previously listed; 1 participant), West Indian (1 participant), and none (1 participant).

[d] Calculated as weight in pounds divided by height in inches.

Table 2. HPV Agreement, Including Genotype Group, Between Self-Collected and Clinician-Collected Samples

Agreement groups	Agreement, No./total No. (%) [95% CI]
PPA for any high-risk HPV	278/292 (95.2) [92.1-97.1]
PPA for HPV-16 or HPV-18 only	69/72 (95.8) [88.5-98.6]
PPA for other high-risk HPV only	207/220 (94.1) [90.2-96.5]
Negative percentage agreement for any high-risk HPV	261/290 (90.0) [86.0-92.9]

Abbreviations: HPV, human papillomavirus; PPA, positive percentage agreement.

Table 3. Clinical Sensitivity for Detection of CIN2+ and CIN3+ and Relative Sensitivity Between Self-Collected and Clinician-Collected Samples

	Sensitivity, No./total No. (%) [95% CI]		
Sensitivity	Self-collected sample	Clinician-collected sample	Relative sensitivity
CIN2+	46/48 (95.8) [86.0-98.8]	46/48 (95.8) [86.0%-98.8]	1.00
CIN3+	28/29 (96.6) [82.8-99.4]	29/29 (100) [88.3-100.0]	0.97

Abbreviations: CIN2+, positive results for cervical intraepithelial neoplasia grade 2 or higher; CIN3+, positive results for cervical intraepithelial neoplasia grade 3 or higher.

Safety

The clinicians collecting the study sample conducted a visual examination of the cervix and vagina following use of the SC device and again following the cervical collection; any observations were recorded. All observed events were anticipated, and the majority of reported events were mild and attributed to CC procedures and/or the nonstudy subsequent colposcopy, biopsy, or excisions. Only 2 adverse events (2 of 602 participants [0.3%]) were solely attributed to the SC device; one event was a minor cervical abrasion without associated bleeding or pain, and the other involved a participant report of spotting after collection, while no spotting was noted on the clinician examination. Additionally, mild spotting or bleeding attributed to either or both collection types was reported in 0.5% of cases (3 of 602 participants).

Usability

Usability testing showed high user comprehension and task execution across all study demographics (601 participants). Instructions were written at a fifth to sixth grade level with 92.3% of participants (555 of 601 participants) reporting easy or very easy understanding.

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Screening Preferences

Of the 602 participants who completed the survey, 192 (31.9%) reported having delayed their screenings. Of the multiple response options provided, the following 3 reasons were reported in participants who delayed screening: (1) uncomfortable with the examination, (2) lack of time, and (3) financial issues. Other reasons for delaying their screening included having experienced sexual trauma, other health or life crises, pain or embarrassment, lack of awareness, or lack of access. When participants were asked to select 1 option for preferred screening option and location, nearly one-half preferred at-home SC (276 participants [45.8%]), followed by in-clinic speculum collection (206 participants [34.2%]), with in-clinic SC least preferred (118 participants [19.6%]). When asked if an at-home screening would make them more likely to stay up to date with screening, 516 participants (85.7%) responded yes. Furthermore, 560 participants (93.0%) indicated they would prefer an at-home SC option if they knew the results were equivalent to CC.

Discussion

The evolution of cervical screening tests from Papanicolaou tests to polymerase chain reaction–based hrHPV DNA testing has not only improved screening sensitivity for detection of disease, but also enables SC samples to be used for screening.[6,10,12,25-28] This nonrandomized clinical trial was designed to validate this SC method by demonstrating the performance for cervical screening for use in an at-home setting. Among the 599 individuals from 16 US clinical sites, samples obtained with the SC device showed excellent agreement and clinical sensitivity when compared with CC. Overall, this SC method was acceptable to the diverse study population, who found that this option would help address several of the barriers they face to regular cervical cancer screenings. Based on participants' survey responses, 32% reported having delayed or avoided their cervical cancer screening, while 93% indicated that they would prefer an SC option if they knew the results were equivalent to CC. Racial and ethnic minority individuals and socioeconomically disadvantaged groups have lower participation in guideline-based screening, but are overwhelmingly accepting of and able to perform an at-home SC of a vaginal sample, including those in the SELF-CERV study, emphasizing the importance of the option.[9,14,18,29-31] The SC procedure and device were safe and easy to use.

The updated USPSTF cervical screening draft recommendations include SC as part of the Grade A screening recommendations, recognizing that home SC increases screening.[7] Ensuring follow-up to an abnormal result is a critical consideration with implementation of at-home SC screening. Adherence to follow-up after a positive SC result across studies is typically high (85%-95%) even among those who previously did not participate in screening.[32-39] These rates are higher when engaged with a clinician, including using digital and telehealth with ordering and receiving results.[39]

In-clinic screenings became even more inaccessible during the COVID-19 pandemic, and the rates of screening have continued to lag in the post–COVID-19 pandemic period.[25-28] With the decline of in-clinic screenings, the use of at-home testing in the form of COVID-19 testing and colon cancer screenings, coupled with the massive expansion of telehealth utilization during the COVID-19 pandemic, have changed the landscape of at-home testing.[31-33,40,41] As an FDA-approved prescription device, the SC device will require a clinician order and follow the same delivery workflow for results as, for example, at-home colon cancer screening tests. At-home collection will allow participation in screening for individuals facing the multiple barriers to speculum and clinic-based collection cited in this study and the literature, and will facilitate greater compliance for those who are underscreened.

Limitations

The limitations of the study include the requirement for a simulated (vs actual) at-home environment to both assess device safety and collect a clinician sample during the same visit. This ensured an accurate measure of agreement for detection of hrHPV and histopathology outcomes.

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Conclusions

The SELF-CERV nonrandomized clinical trial used a method comparison design that clinically validated the SC device for vaginal specimens for cervical screening in a diverse US study population. The study found that the SC device was a safe and accurate option for cervical screening suitable for at-home use. The intersection of increased health autonomy and highly sensitive diagnostic tools make this an optimal time to implement at-home SC cervical cancer screening in the US, thereby improving access and accelerating progress toward cervical cancer elimination.[42-57]

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Supervision: Hwang, Sutton, Williams, Jennings, Novetsky, Saville, Depel, Aviki, Sheth, Conageski.

Conflict of Interest Disclosures: Dr Behrens reported receiving personal fees from Antiva Biosciences, having a pending patent for a device system for human papillomavirus (HPV) infection and cervical intraepithelial

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neoplasia, and owning stock in Roche outside the submitted work. Dr Crane reported receiving personal fees from Planned Parenthood outside the submitted work. Dr Kuroki reported receiving grants from the National Institutes of Health and honoraria from the National Cancer Institute Physician Data Query (Cancer Screening and Prevention Editorial Board) outside the submitted work. Dr Gillis reported receiving consulting fees from Teal Health for statistical design planning and power analysis for other studies outside the submitted work. Dr Hawkes reported receiving nonfinancial support (consumables for HPV research studies including self-collection) from Abbott, AusDiagnostics, Becton Dickinson, Cepheid, Hologic, Roche, and Seegene; nonfinancial support (consumables for self-collection) from Copan, Rovers, and Qiagen; and grants from Copan (commercially funded validation of self-collection device) and V-Veil (commercially funded validation of self-collection device) outside the submitted work. Dr Saville reported receiving nonfinancial support from Abbott, AusDiagnostics, Becton Dickinson, Cepheid, Hologic, Roche, Seegene, Rovers, and Qiagen and grants from Copan (commercially funded validation study) and V-Veil (commercially funded validation study) outside the submitted work. Dr Sheth reported serving on the board of directors (unpaid) for the American Society of Colposcopy and Cervical Pathology outside the submitted work. No other disclosures were reported.

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Role of the Funder/Sponsor: Teal Health (sponsor) designed the trial, developed the protocol, and determined the statistical plan with input from the US Food and Drug Administration. Data were entered by participating study sites through a cloud based electronic data capture (EDC) system, Castor. Global Bioclinical Consulting, the data management consultant, maintained the study database, entered laboratory data, and verified data. The sponsors were blinded to the laboratory data during enrollment and data entry of these results. At interim analysis, the study statistician was provided the data for analysis and shared the predefined data to the sponsor, per the predefined interim analysis plan. Site good clinical practice compliance monitoring was performed by Vantage Clinical Advisors and also by Global Bioclinical Consulting. Upon study completion, the EDC data were downloaded and provided to the study statistician for final analysis. All analyses for scientific publication were performed by the study statistician, Mr Hibler. The first author, Dr Fitzpatrick, wrote drafts of the manuscript and these were reviewed, with edits suggested, by all authors prior to submission.

Data Sharing Statement: See Supplement 2.

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REFERENCES

1. Curry SJ, Krist AH, Owens DK, et al; US Preventive Services Task Force. Screening for cervical cancer: US preventive services task force recommendation statement. *JAMA*. 2018;320(7):674-686. doi:10.1001/jama.2018.10897

2. Walboomers JMM, Jacobs MV, Manos MM, et al. Human papillomavirus is a necessary cause of invasive cervical cancer worldwide. *J Pathol*. 1999;189(1):12-19. doi:10.1002/(SICI)1096-9896(199909)189:1<12::AID-PATH431>3.0.CO;2-F

3. Burd EM. Human papillomavirus and cervical cancer. *Clin Microbiol Rev*. 2003;16(1):1-17. doi:10.1128/CMR.16.1.1-17.2003

4. Marcus JZ, Cason P, Downs LSJ Jr, Einstein MH, Flowers L. The ASCCP cervical cancer screening task force endorsement and opinion on the American Cancer Society updated cervical cancer screening guidelines. *J Low Genit Tract Dis*. 2021;25(3):187-191. doi:10.1097/LGT.0000000000000614

5. Fontham ETH, Wolf AMD, Church TR, et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2020;70(5):321-346. doi:10.3322/caac.21628

6. Wright TC, Stoler MH, Behrens CM, Sharma A, Zhang G, Wright TL. Primary cervical cancer screening with human papillomavirus: end of study results from the ATHENA study using HPV as the first-line screening test. *Gynecol Oncol*. 2015;136(2):189-197. doi:10.1016/j.ygyno.2014.11.076

7. United States Preventive Services Taskforce. Draft evidence review—cervical cancer: screening. Published December 10, 2024. Accessed April 14, 2025. https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-evidence-review/cervical-cancer-screening-adults-adolescents

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8. Healthy People 2030. Increase the proportion of females who get screened for cervical cancer—C-09. Office of Disease Prevention and Health Promotion. Accessed April 14, 2025. https://health.gov/healthypeople/objectives-and-data/browse-objectives/cancer/increase-proportion-females-who-get-screened-cervical-cancer-c-09

9. Zeno EE, Brewer NT, Spees LP, et al. Racial and ethnic differences in cervical cancer screening barriers and intentions: the my body my test-3 HPV self-collection trial among under-screened, low-income women. *PLoS One*. 2022;17(10):e0274974. doi:10.1371/journal.pone.0274974

10. Suk R, Hong YR, Rajan SS, Xie Z, Zhu Y, Spencer JC. Assessment of US Preventive Services Task Force guideline-concordant cervical cancer screening rates and reasons for underscreening by age, race and ethnicity, sexual orientation, rurality, and insurance, 2005 to 2019. *JAMA Netw Open*. 2022;5(1):e2143582. doi:10.1001/jamanetworkopen.2021.43582

11. Francoeur AA, Liao CI, Caesar MA, et al. The increasing incidence of stage IV cervical cancer in the USA: what factors are related? *Int J Gynecol Cancer*. 2022;32(9):1115-1122. doi:10.1136/ijgc-2022-003728

12. Arbyn M, Smith SB, Temin S, Sultana F, Castle P; Collaboration on Self-Sampling and HPV Testing. Detecting cervical precancer and reaching underscreened women by using HPV testing on self samples: updated meta-analyses. *BMJ*. 2018;363:k4823. doi:10.1136/bmj.k4823

13. Arbyn M, Castle PE, Schiffman M, Wentzensen N, Heckman-Stoddard B, Sahasrabuddhe VV. Meta-analysis of agreement/concordance statistics in studies comparing self- vs clinician-collected samples for HPV testing in cervical cancer screening. *Int J Cancer*. 2022;151(2):308-312. doi:10.1002/ijc.33967

14. Allen-Leigh B, Uribe-Zúñiga P, León-Maldonado L, et al. Barriers to HPV self-sampling and cytology among low-income Indigenous women in rural areas of a middle-income setting: a qualitative study. *BMC Cancer*. 2017;17(1):734. doi:10.1186/s12885-017-3723-5

15. Catarino R, Vassilakos P, Bilancioni A, et al. Accuracy of self-collected vaginal dry swabs using the Xpert human papillomavirus assay. *PLoS One*. 2017;12(7):e0181905. doi:10.1371/journal.pone.0181905

16. Saville M, Hawkes D, Keung M, et al. Analytical performance of HPV assays on vaginal self-collected vs practitioner-collected cervical samples: the SCoPE study. *J Clin Virol*. 2020;127:104375. doi:10.1016/j.jcv.2020.104375

17. Jun JK, Lim MC, Hwang SH, et al. Comparison of dry and wet vaginal swabs with cervical specimens in Roche Cobas 4800 HPV and Abbott RealTime high risk HPV tests. *J Clin Virol*. 2016;79:80-84. doi:10.1016/j.jcv.2016.04.012

18. Winer RL, Lin J, Tiro JA, et al. Effect of mailed human papillomavirus test kits vs usual care reminders on cervical cancer screening uptake, precancer detection, and treatment: a randomized clinical trial. *JAMA Netw Open*. 2019;2(11):e1914729. doi:10.1001/jamanetworkopen.2019.14729

19. Ejegod DM, Pedersen H, Alzua GP, Pedersen C, Bonde J. Time and temperature dependent analytical stability of dry-collected Evalyn HPV self-sampling brush for cervical cancer screening. *Papillomavirus Res*. 2018;5:192-200. doi:10.1016/j.pvr.2018.04.005

20. Inturrisi F, Aitken CA, Melchers WJG, et al. Clinical performance of high-risk HPV testing on self-samples versus clinician samples in routine primary HPV screening in the Netherlands: An observational study. *Lancet Reg Health Eur*. 2021;11:100235. doi:10.1016/j.lanepe.2021.100235

21. World Medical Association. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2013;310(20):2191-2194. doi:10.1001/jama.2013.281053

22. Nayer R, Wilbur DC, eds. *The Bethesda System for Reporting Cervical Cytology: Definitions, Criteria, and Explanatory Notes*. 3rd ed. Springer; 2015. doi:10.1007/978-3-319-11074-5

23. Department of Health and Human Services. Collection of race and ethnicity data in clinical trials: guidance for Food and Drug Administration staff. Published October 26, 2016. Accessed April 18, 2025. https://www.fda.gov/media/75453/download

24. US. Food and Drug Administration. Summary Of safety and effectiveness data (SSED). Published May 14, 2024. Accessed April 14, 2025. https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190028S009B.pdf

25. Castle PE, Stoler MH, Wright TC Jr, Sharma A, Wright TL, Behrens CM. Performance of carcinogenic human papillomavirus (HPV) testing and HPV16 or HPV18 genotyping for cervical cancer screening of women aged 25 years and older: a subanalysis of the ATHENA study. *Lancet Oncol*. 2011;12(9):880-890. doi:10.1016/S1470-2045(11)70188-7

26. Rao A, Young S, Erlich H, et al. Development and characterization of the cobas human papillomavirus test. *J Clin Microbiol*. 2013;51(5):1478-1484. doi:10.1128/JCM.03386-12

Downloaded from jamanetwork.com by guest on 05/31/2026

27. Ronco G, Dillner J, Elfström KM, et al; International HPV screening working group. Efficacy of HPV-based screening for prevention of invasive cervical cancer: follow-up of four European randomised controlled trials. *Lancet*. 2014;383(9916):524-532. doi:10.1016/S0140-6736(13)62218-7

28. Stoler MH, Wright TC Jr, Parvu V, et al. The Onclarity human papillomavirus trial: design, methods, and baseline results. *Gynecol Oncol*. 2018;149(3):498-505. doi:10.1016/j.ygyno.2018.04.007

29. Beavis AL, Gravitt PE, Rositch AF. Hysterectomy-corrected cervical cancer mortality rates reveal a larger racial disparity in the United States. *Cancer*. 2017;123(6):1044-1050. doi:10.1002/cncr.30507

30. Montealegre JR, Mullen PD, L Jibaja-Weiss M, Vargas Mendez MM, Scheurer ME. Feasibility of cervical cancer screening utilizing self-sample human papillomavirus testing among Mexican immigrant women in Harris County, Texas: a pilot study. *J Immigr Minor Health*. 2015;17(3):704-712. doi:10.1007/s10903-014-0125-5

31. Kung TH, Gordon JR, Abdullahi A, et al. "My husband says this: If you are alive, you can be someone…": facilitators and barriers to cervical cancer screening among women living with HIV in India. *Cancer Causes Control*. 2019;30(4):365-374, 365-374. doi:10.1007/s10552-019-01145-7

32. Léniz J, Barriga MI, Lagos M, Ibáñez C, Puschel K, Ferreccio C. HPV vaginal self-sampling among women non-adherent to Papanicolaou screening in Chile. *Salud Publica Mex*. 2013;55(2):162-169. doi:10.1590/S0036-36342013000200007

33. Sultana F, Roeske L, Malloy MJ, McDermott TL, Saville M, Brotherton JML. Implementation of Australia's renewed cervical screening program: preparedness of general practitioners and nurses. *PLoS One*. 2020;15(1):e0228042. doi:10.1371/journal.pone.0228042

34. Gupta S, Palmer C, Bik EM, et al. Self-sampling for human papillomavirus testing: increased cervical cancer screening participation and incorporation in international screening programs. *Front Public Health*. 2018;6:77. doi:10.3389/fpubh.2018.00077

35. Enerly E, Bonde J, Schee K, Pedersen H, Lönnberg S, Nygård M. Self-sampling for human papillomavirus testing among non-attenders increases attendance to the Norwegian cervical cancer screening programme. *PLoS One*. 2016;11(4):e0151978. doi:10.1371/journal.pone.0151978

36. Giorgi Rossi P, Fortunato C, Barbarino P, et al; HPV Self-sampling Italian Working Group. Self-sampling to increase participation in cervical cancer screening: an RCT comparing home mailing, distribution in pharmacies, and recall letter. *Br J Cancer*. 2015;112(4):667-675. doi:10.1038/bjc.2015.11

37. Gök M, van Kemenade FJ, Heideman DA, et al. Experience with high-risk human papillomavirus testing on vaginal brush-based self-samples of non-attendees of the cervical screening program. *Int J Cancer*. 2012;130(5):1128-1135. doi:10.1002/ijc.26128

38. Gök M, Heideman DA, van Kemenade FJ, et al. HPV testing on self collected cervicovaginal lavage specimens as screening method for women who do not attend cervical screening: cohort study. *BMJ*. 2010;340:c1040. doi:10.1136/bmj.c1040

39. Smith LW, Booth A, Racey CS, et al. Self-screening for cervical cancer offered through a digital platform in a region of British Columbia with lower screening rates. *Curr Oncol*. 2024;31(9):5399-5411. doi:10.3390/curroncol31090399

40. Mast C, Munoz del Rio A. Delayed cancer screenings—a second look. Epic Research. Published July 17, 2020. Accessed April 14, 2025. https://www.epicresearch.org/articles/delayed-cancer-screenings-a-second-look/

41. Akinlotan M, Bolin JN, Helduser J, Ojinnaka C, Lichorad A, McClellan D. Cervical cancer screening barriers and risk factor knowledge among uninsured women. *J Community Health*. 2017;42(4):770-778. doi:10.1007/s10900-017-0316-9

42. Rebolj M, Brentnall AR, Cuschieri K. Predictable changes in the accuracy of human papillomavirus tests after vaccination: review with implications for performance monitoring in cervical screening. *Br J Cancer*. 2024;130(11):1733-1743. doi:10.1038/s41416-024-02681-z

43. Fedewa SA, Star J, Bandi P, et al. Changes in cancer screening in the US During the COVID-19 Pandemic. *JAMA Netw Open*. 2022;5(6):e2215490. doi:10.1001/jamanetworkopen.2022.15490

44. Lozar T, Nagvekar R, Rohrer C, Dube Mandishora RS, Ivanus U, Fitzpatrick MB. Cervical cancer screening postpandemic: self-sampling opportunities to accelerate the elimination of cervical cancer. *Int J Womens Health*. 2021;13:841-859. doi:10.2147/IJWH.S288376

45. Fuzzell L, Lake P, Brownstein NC, et al. Examining the perceived impact of the COVID-19 pandemic on cervical cancer screening practices among clinicians practicing in federally qualified health centers: a mixed methods study. *Elife*. 2023;12:e86358. doi:10.7554/eLife.86358

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46. Winstead E. For cancer screening, COVID-19 pandemic creates obstacles, opportunities. National Cancer Institute. Published March 10, 2021. Accessed April 14, 2025. https://www.cancer.gov/news-events/cancer-currents-blog/2021/cancer-screening-decreases-coronavirus-pandemic

47. Bose S, Dun C, Zhang GQ, Walsh C, Makary MA, Hicks CW. Medicare beneficiaries in disadvantaged neighborhoods increased telemedicine use during the COVID-19 pandemic. *Health Aff (Millwood)*. 2022;41(5):635-642. doi:10.1377/hlthaff.2021.01706

48. Franciosi EB, Tan AJ, Kassamali B, et al. The impact of telehealth implementation on underserved populations and no-show rates by medical specialty during the COVID-19 pandemic. *Telemed J E Health*. 2021;27(8):874-880. doi:10.1089/tmj.2020.0525

49. Hoppe KK, Williams M, Thomas N, et al. Telehealth with remote blood pressure monitoring for postpartum hypertension: a prospective single-cohort feasibility study. *Pregnancy Hypertens*. 2019;15:171-176. doi:10.1016/j.preghy.2018.12.007

50. Bestsennyy O, Gilbert G, Harris A, Rost J. Telehealth: a quarter-trillion-dollar post-COVID-19 reality? McKinsey. Published July 9, 2021. Accessed April 14, 2025. https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality#

51. Weltin A, Etcher L. The role of telemedicine in gynecologic healthcare: a narrative review. *Nurse Pract*. 2021;46(5):24-31. doi:10.1097/01.NPR.0000742912.87293.02

52. World Health Organization. Global strategy to accelerate the elimination of cervical cancer as a public health problem. Published November 17, 2020. Accessed April 14, 2025. https://www.who.int/publications-detail-redirect/9789240014107

53. Burger EA, Smith MA, Killen J, et al. Projected time to elimination of cervical cancer in the USA: a comparative modelling study. *Lancet Public Health*. 2020;5(4):e213-e222. doi:10.1016/S2468-2667(20)30006-2

54. Grimes DR, Corry EMA, Malagón T, O'Riain C, Franco EL, Brennan DJ. Modeling cervical cancer screening strategies with varying levels of human papillomavirus vaccination. *JAMA Netw Open*. 2021;4(6):e2115321. doi:10.1001/jamanetworkopen.2021.15321

55. Broberg G, Gyrd-Hansen D, Miao Jonasson J, et al. Increasing participation in cervical cancer screening: offering a HPV self-test to long-term non-attendees as part of RACOMIP, a Swedish randomized controlled trial. *Int J Cancer*. 2014;134(9):2223-2230. doi:10.1002/ijc.28545

56. Pretsch PK, Spees LP, Brewer NT, et al. Effect of HPV self-collection kits on cervical cancer screening uptake among under-screened women from low-income US backgrounds (MBMT-3): a phase 3, open-label, randomised controlled trial. *Lancet Public Health*. 2023;8(6):e411-e421. doi:10.1016/S2468-2667(23)00076-2

57. Catarino R Jr, Vassilakos P, Stadali-Ullrich H, Royannez-Drevard I, Guillot C, Petignat P. Feasibility of at-home self-sampling for HPV testing as an appropriate screening strategy for nonparticipants in Switzerland: preliminary results of the DEPIST study. *J Low Genit Tract Dis*. 2015;19(1):27-34. doi:10.1097/LGT.0000000000000051

SUPPLEMENT 1.
Trial Protocol

SUPPLEMENT 2.
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SUPPLEMENT 3.
Data Sharing Statement

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