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Self-Collected Vaginal Specimens for HPV Testing: Recommendations From the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee

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Objective: The Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee developed recommendations for the use of self-collected vaginal specimens for human papillomavirus (HPV) testing in health care settings.

Methods: A comprehensive literature search was performed, external systematic reviews were evaluated, and HPV genotype agreement between self-collected vaginal and clinician-collected cervical specimens was summarized. Recommendations considered available data, public comments, and expert consensus. Recommendations were ratified through a vote by the Consensus Stakeholder Group.

Results: Clinician-collected cervical specimens are preferred and self-collected vaginal specimens are acceptable for primary HPV screening of asymptomatic average-risk individuals. Repeat testing in 3 years is recommended following HPV-negative screens using self-collected vaginal specimens. Colposcopy with collection of cytology and biopsies is recommended following positive tests for HPV types 16 and 18. Clinician-collected cytology or dual stain for triage testing is recommended following positive tests for HPV 45, 33/58, 31, 52, 35/39/68, or 51 or for pooled HPV other types but negative for HPV 16 or 18. Repeat HPV testing in 1 year is recommended following a positive test for HPV types 56/59/66 and no other carcinogenic types. Minimal data exist on use of self-collected vaginal specimens for surveillance following abnormal screening test results, colposcopy or treatment, and therefore, clinician-collected cervical specimens are preferred.

Conclusions: Human papillomavirus testing of self-collected vaginal specimens expands cervical cancer screening options and has potential to increase access for currently underscreened individuals. Laboratory and clinical workflows will need to be modified to ensure adequate specimen processing and follow-up.

Key Words: guidelines, cervical cancer, early detection of cancer, human papillomaviruses, self-collection

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Cervical cancer screening reduces cervical cancer incidence and mortality.[1] Cervical cytology, the first cervical screening test, is subjective and has a relatively low sensitivity, requiring frequent repeat testing to identify precancers that can be treated to prevent cancer.[2] The discovery that persistent human papillomavirus (HPV) infections are a necessary cause of almost all cervical

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cancers led to the development of HPV testing as a new primary screening method.[2] Human papillomavirus testing, an objective test with higher sensitivity and better reassurance against cancer after a negative test compared to cytology, is now the preferred screening strategy in guidelines worldwide.[3,4]

Human papillomavirus testing can also be performed using self-collected vaginal specimens,[5] extending the reach of cervical screening to sites with limited clinician access and to individuals who prefer self-collection over clinician collection for various reasons. Human papillomavirus testing of self-collected vaginal specimens has been widely evaluated and shown to perform similarly when compared to clinician-collected cervical specimens.[5,6] Several large screening programs have added self-collection to the screening options, including national programs in Australia and the Netherlands, which has increased screening participation.[7–9]

Recently, the US Food and Drug Administration (FDA) extended the indications for 2 HPV tests previously approved for primary HPV screening (cobas and Onclarity) to include self-collected vaginal specimens in health care settings where specimens can be processed by trained personnel and transported to a testing laboratory under controlled conditions.[10] Clinical guidance is needed for use of HPV self-collection in the United States.

The Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee was established as a standing committee with representatives from 19 national organizations to evaluate new technologies for cervical screening and management that have received regulatory approval for clinical use and to provide recommendations for use of these new technologies.[11] This manuscript summarizes the US recommendations for use of HPV testing using self-collected vaginal specimens with FDA-approved testing options in cervical screening and management.[10]

METHODS

The guiding principles and approach of the Enduring Guidelines development process have been described.[11,12] The first step of the evidence assessment is defining Population, Intervention, Comparator, and Outcomes (PICO) for specific questions.[13] Next, a systematic evaluation is conducted to determine the availability of primary data or existing systematic reviews and meta-analyses addressing the PICO questions. A de novo systematic review is performed if neither source of evidence is available. The Enduring Guidelines Risk Assessment Group adopted the following PICOs used in previous systematic reviews on HPV self-collection: Population: persons with a cervix presenting to a clinic for cervical cancer screening or follow-up. Index test: HPV testing on self-collected vaginal specimens. Comparator tests: HPV testing on clinician-collected cervical specimens; cervical cytology where available. Outcome: sensitivity and specificity for detection of Cervical Intraepithelial Neoplasia grade 2 or higher (CIN2+) or grade 3 or higher (CIN3+) on index test and comparator test(s). Several large systematic reviews and meta-analyses addressing these PICOs were included in the assessment.[1,5,6,14–18] De novo systematic evidence reviews were conducted for data not adequately summarized in existing reviews. In contrast to previous Enduring Guidelines efforts,[19,20] primary risk data were not used to develop the recommendations because no large prospective US data exist for the approved HPV self-collection test configurations.

Comparison of Self-Collected Vaginal and Clinician-Collected Cervical Specimens

The evidence assessment relied on existing systematic reviews and meta-analyses conducted by Arbyn et al. that compared the performance of HPV testing using self-collected vaginal and clinician-collected cervical specimens.[5,6,14,17,18] The search terms and PRISMA diagrams are reported in the primary papers.[6] Additionally, we conducted a de novo analysis to evaluate the performance of HPV testing on self-collected vaginal specimens compared to HPV testing and cytology from clinician-collected cervical specimens in a paired study design. From the previous systematic reviews, five studies were identified that used polymerase chain reaction (PCR)-based HPV assays and compared HPV self-collection to provider collection HPV and cytology testing including at least 50 participants. An updated search was run through August 2024 that identified 1 additional study fulfilling these criteria.[21–26] Human papillomavirus and cytology testing from clinician-collected specimens are reference assays for cervical cancer screening. Absolute sensitivity and specificity estimates were compared across the 3 screening approaches.

Human Papillomavirus Genotype Agreement for Self-Collected Vaginal Compared to Clinician-Collected Cervical Specimens

Among the manuscripts identified by the systematic review outlined above, we identified 3 manuscripts reporting on agreement between self-collected vaginal specimens and clinician-collected cervical specimens for extended genotyping, including the Onclarity assay, one of the 2 tests with an extended indication for self-collected vaginal specimens.[27–29] Type-level and channel-level agreement statistics were extracted from manuscripts and reported individually for each study.

Important Metrics for Evaluation of HPV Testing Using Self-Collected Vaginal Specimens

Human papillomavirus testing of self-collected vaginal specimens is typically evaluated in studies with *paired samples*, including both clinician-collected cervical and self-collected vaginal specimens at the same time point. Several metrics are used to evaluate performance.

Absolute sensitivity and specificity for detection of precancer (defined variously as CIN2+ and CIN3+) is the key performance metric in individual studies and systematic reviews. In studies with *paired sampling*, performance estimates can be directly compared between both modalities. Absolute sensitivity and specificity can be calculated across multiple studies using meta-analytic methods. However, performance estimates, particularly specificity, differ between screening and referral/management settings, limiting the ability to combine heterogeneous study designs. Absolute sensitivity and specificity were used to compare HPV and cytology testing of clinician-collected cervical specimens and HPV testing of self-collected vaginal specimens in studies that had paired data for all 3 modalities to calculate performance metrics to inform recommendations about screening intervals.

Relative sensitivity and specificity for detection of precancer is the ratio of absolute performance metrics between self-collected

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TABLE 1. Summary of Relative Sensitivity and Specificity for Cervical Precancer (CIN2+ or CIN3+) for HPV Testing Using Self-Collected Vaginal Versus Clinician-Collected Cervical Specimens (Adapted From Arbyn BMJ 2018)

Assay	Outcome	No. studies	Ratio (95% CI) Sensitivity	Ratio (95% CI) Specificity
Signal amplification	CIN2+	23	0.85 (0.80–0.89)*	0.96 (0.93–0.98)*
	CIN3+	9	0.86 (0.76–0.98)*	0.97 (0.95–0.99)*
PCR	CIN2+	17	0.99 (0.97–1.02)	0.98 (0.97–0.99)*
	CIN3+	8	0.99 (0.96–1.02)	0.98 (0.97–0.99)*

Pooled relative sensitivity and specificity estimates for studies identified in systematic review conducted by Arbyn et al.

*CI does not include unity, difference is considered statistically significant.

CIN indicates cervical intraepithelial neoplasia; CIN2+, CIN 2, 3, adenocarcinoma in situ, cancer; HPV, human papillomavirus; PCR, polymerase chain reaction.

vaginal specimens and clinician-collected cervical specimens. Relative performance metrics can be calculated within studies that have a paired design and in meta-analyses for pooled performance estimates. A relative sensitivity or specificity of 1.0 indicates that both tests completely agree with respect to precancer detection. Values below 1.0 (with self-collected vaginal specimens as the comparator) indicate lower sensitivity or specificity compared to clinician-collected cervical specimens, while values above 1.0 indicate higher sensitivity or specificity for self-collected HPV. Compared to absolute performance metrics, relative performance estimates are less affected by differences in study design and underlying populations. Relative performance metrics are reported here to inform questions related to HPV assays, sampling devices, buffers and other parameters.

Agreement between self-collected vaginal specimens and clinician-collected cervical specimens for detection of HPV is a paired metric that measures the agreement between clinician- and self-collection for detection of HPV infections. In a 2 × 2 table, overall agreement is the sum of positive and negative agreement over all 4 cells, while positive agreement is the positive agreement over the 3 cells with any positive test result. Agreement can be evaluated for any HPV detection and for individual genotypes or channels. High agreement on HPV detection between self-collection and clinician-collection translates into high agreement on detection of cervical precancer. Agreement statistics are reported here to evaluate agreement for individual types or channels with multiple pooled type when extended genotyping is available.

EVIDENCE SUMMARY

Human Papillomavirus Test Performance in Self-Collected Vaginal Specimens Compared to Clinician-Collected Cervical Specimens

Human papillomavirus testing using self-collected vaginal specimens has been widely evaluated in studies in the United States and around the world and compared to clinician-collected cervical specimens in the same screening participants. These studies have been summarized in large systematic reviews and meta-analyses.[1,5,6,14–18] Overall, HPV testing from self-collected vaginal specimens has shown high relative sensitivity and specificity compared to HPV testing from clinician-collected cervical specimens when HPV PCR assays have been used (Table 1). The main conclusions from these systematic reviews are:

1. *High sensitivity and agreement for detection of precancer between self-collected vaginal specimens and clinician-collected cervical specimens for PCR-based HPV assays.*

Based on 56 paired clinical accuracy studies, PCR-based assays were equally sensitive on self-collected vaginal specimens as on clinician-collected cervical specimens for precancer detection (pooled ratio 0.99, 95% CI = 0.97–1.02). Relative specificity was high (0.98) for self-collected specimens compared to clinician-collected specimens when PCR-based tests were used. In contrast, HPV tests based on signal amplification or mRNA have lower sensitivity when conducted from self-collected vaginal specimens versus clinical-collected cervical specimens.[18]

2. *No demonstrated influence of sampling device or buffer*

To date, large systematic reviews have not demonstrated an impact of the choice of sampling device or sampling buffer on the agreement of HPV self-collection and clinician collection.[6,16] However, details are not included in all studies, preventing a systematic assessment. Further, different populations, assay types, sampling devices and buffers reported in the studies result in many strata with limited sample size and power. Importantly, the ***regulatory approval of self-collection in the United States prescribes the sampling devices and buffers to be used in combination with specific HPV tests; in clinical practice, these cannot be modified***.

TABLE 2. Diagnostic Accuracy for Detection of Cervical Precancer (CIN2+) of Clinician-Collected Cervical Cytology, HPV Testing Based on Clinician-Collected Cervical Specimens (Clinician HPV), and HPV Testing Using Self-Collected Vaginal Specimens (Self-HPV)

	Pooled sensitivity	Pooled specificity
Cytology	80.4 (95% CI = 73.2–86.1)	78.5 (95% CI = 69.8–85.2)
Self-HPV (PCR)	89.7 (95% CI = 84.2–93.5)	64.7 (95% CI = 44.6–80.7)
Clinician-HPV (PCR)	92.9 (95% CI = 88.6–95.5)	61.2 (95% CI = 41.2–78.1)

Pooled absolute sensitivity and specificity estimates based on 6 studies identified from the systematic literature search with available data on HPV vaginal self-collection and provider-collected HPV and cytology data.[21–26]

TABLE 3. Agreement Between HPV Test Results Using Self-Collected Vaginal and Clinician-Collected Cervical Specimens, by Overall HPV Positivity and Type-Specific HPV

	Rohner (2020)		Latsuzbaia (2022)		Martinelli (2023)	
Onclarity channel, HPV type	*n*	% agreement	*n*	% agreement	*n*	% agreement
Any hrHPV	220	83	278	89.3	188	89.5
16	62	89	73	98.1	72	95.1
18	15	97	18	98.1	7	97.9
31	21	97	55	96.9	39	94.8
45	16	97	18	98.4	9	99.0
33/58	20	98	44	96.9	23	97.9
35/39/68	37	94	50	95.7	30	95.5
51	19	99	36	97.1	13	98.3
52	30	97	42	96.1	22	97.9
56/59/66	57	97	79	94.9	50	94.4

Comparison of individual and pooled-channel–type detection in self-collected vaginal and provider-collected cervical samples.

Performance of HPV Tests Using Self-Collected Vaginal Specimens Compared to HPV Tests and Cytology Using Clinician-Collected Cervical Specimens

A critical question related to the sensitivity of self-collected vaginal specimens for primary HPV screening is how long a negative self-collected vaginal HPV test provides reassurance against precancer and cancer. In current guidelines, a negative clinician-collected cervical HPV test in a screening setting provides sufficient reassurance for a 5-year retesting interval, while a negative cytology result provides sufficient reassurance for a 3-year testing interval.[30] Long-term follow-up data after self-collection testing are very limited, but baseline performance in the context of established tests can be used to estimate return intervals. To address the retesting interval, we conducted systematic review and meta-analysis of absolute sensitivity in studies comparing HPV testing in self-collected vaginal specimens, HPV testing in clinician-collected cervical specimens (both using PCR-based tests), and clinician-collected cervical cytology, including a subset of studies from the greater systematic review comparing HPV self-collection and HPV clinician collection (Table 2). Both self-collected vaginal and clinician-collected cervical HPV testing were substantially more sensitive than cytology. In this subset of studies, the sensitivity of self-collected vaginal specimens appeared to be slightly lower (90%) than the sensitivity of clinician-collected cervical specimens (93%), but the difference was not statistically significant (Table 2).

Genotype Agreement

To address whether recommendations for extended genotyping based on clinician-collected cervical specimens could be adapted to self-collected vaginal specimens for HPV testing, we evaluated HPV type- and channel-specific concordance between self- and clinician-collected specimens. There was good agreement for all types and channels between self- and clinician-collected specimens (Table 3). This allowed the guidelines developed for extended HPV genotyping of clinician-collected cervical specimens to be applied to self-collected vaginal specimens.

Recommendations

Several key points apply when employing recommendations for self-collected vaginal specimens for cervical cancer screening.

1. Recommendations only apply to tests (collection kits and HPV assays) with an FDA indication for primary HPV screening using self-collected vaginal specimens. At the time of writing, the combinations of the BD Onclarity HPV Assay with the Copan 522C.80 swab and the Roche cobas assay with the Evalyn brush or Copan 522C.80 swab have received FDA approval for self-collected vaginal specimens. The performance of assays and collection devices that were not FDA-approved for self-collected vaginal specimens may not be similar, and such assays should not be used for clinical care.

TABLE 4. Clinical Scenarios for Which Self-Collection Cannot be Used as HPV Testing Alone Is Not Currently Recommended

Clinical scenario	Current recommended screening test	Reference
People living with HIV	Cytology with or without HPV testing, depending on age	Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. CDC. Published online August 18, 2021. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/
In utero diethylstilbestrol exposure	Cytology	ASCCP Clinical Consensus: Screening Recommendations for Clear Cell Adenocarcinomas in People Exposed to DES In Utero. Marcus J, Nelson E. Linder, M et al. Journal of Lower Genital Tract Disease 28(4):p 351–355, October 2024.
Surveillance after colposcopy for atypical glandular cells in which no CIN2+ found	Cytology with HPV testing (cotesting)	2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines Committee. J Low Genit Tract Dis. 2020 Apr;24(2):102–131.
Surveillance after diagnosis of adenocarcinoma in situ*	Cytology with HPV testing (cotesting)	2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP Risk-Based Management Consensus Guidelines Committee. J Low Genit Tract Dis. 2020 Apr;24(2):102–131.

*After excision with negative margins and no cancer found in patients not undergoing hysterectomy.

2. The 2019 Guidelines and previously published Enduring Guidelines represent the standards for management recommendations. Changes are recommended when data for new tests and test combinations justify new recommendations. When evidence is lacking or inconsistent for specific assays or in relevant populations, recommendations default to the 2019 and Enduring Guidelines.[19,30,31]

3. These recommendations apply only to results obtained in asymptomatic, average-risk individuals with a cervix undergoing screening or surveillance. Symptomatic patients, particularly those with abnormal bleeding or discharge, should be managed according to relevant protocols.[32,33] Due to limited data, self-collected vaginal specimens are not a screening option for patients with immunosuppression and other high-risk conditions (Table 4).

The following recommendations address the use of self-collected vaginal specimens for cervical cancer screening and the subsequent management of test results.

RECOMMENDATION #1: Clinician-collected cervical specimens are preferred, and self-collected vaginal specimens are acceptable for cervical cancer screening (AII).

Rationale. Clinician-collected cervical specimens have been the standard of care in the United States for cervical cancer screening for over half a century, and over 80% of women report participating in regular screening.[34] Clinician-collected cervical samples have the advantage that cervical cells are obtained, allowing laboratories to perform both HPV testing (primary screen) and reflex cytology or p16/ki67 dual-stain testing (triage) from the same sample. In contrast, self-collected vaginal samples do not directly sample the cervix, and therefore, most individuals screening positive on the initial self-collected vaginal HPV test must return for clinician collection of cervical cytology or dual-stain testing.

However, speculum examination for clinician-collected cervical specimens may be difficult to access or undergo for certain individuals, and current screening programs fail to reach all individuals at risk for cervical cancer.[35] Data from other countries indicate that incorporating self-collected vaginal specimens into screening programs can increase screening rates.[7,8] Barriers that may be overcome by self-collection include those related to health system (e.g., lack of available clinicians, difficulty accessing gynecologic care), clinician (e.g., clinician does not perform pelvic exams, lack of time in visit), and patient (e.g., limited mobility, vaginismus, history of sexual trauma, gender dysphoria, not comfortable with clinician, prefers self-collection).[35,36] Thus, self-collected vaginal specimens provide an important tool to expand screening access.

RECOMMENDATION #2: When self-collected vaginal specimens are HPV-negative in the screening setting, repeat testing in 3 years is recommended (AII).

Rationale. Based on all data available, we have strong evidence that HPV testing of self-collected vaginal specimens has better sensitivity and overall accuracy than cytology for detection of CIN3+ in the screening setting.[5,14] Patients in the screening setting are asymptomatic individuals presenting for screening with a history of all normal results, no history of high-grade abnormal results, a remote history of low-grade abnormal results with at least 3 subsequent HPV-negative results, or without available history. Data are somewhat heterogeneous regarding agreement between the results of self-collected vaginal and clinician-collected cervical specimens for precancer detection. Some studies suggest equivalence although others suggest a small decrease in sensitivity[5,14] (Table 2). Studies are heterogeneous with respect to populations, sampling devices, sample handling, and HPV assays used. The cross-sectional data summarized in systematic reviews strongly support a 3-year interval. Five-year data following a negative self-collected HPV test result are currently not available to estimate risks that would directly inform longer intervals. Three-year intervals provide a margin of safety in the interim while additional data accrue. If additional data support the equivalence of self-collected vaginal specimens and clinician-collected cervical specimens, the recommended interval can be extended to 5 years in the future.

RECOMMENDATION #3: When self-collected vaginal specimens are positive for HPV 16 and/or 18, direct referral for colposcopy with concurrent cytology collection is recommended (AII).

Rationale. Human papillomavirus 16 and 18 infections confer an elevated risk of CIN3+. Colposcopy has therefore been recommended in prior guidelines; these recommendations are continued for self-collection.[20,30,37] The recommendation to perform colposcopy when HPV 16 and/or HPV 18 are detected applies in all settings (e.g., screening, after colposcopy, after treatment). Evidence supports concordance of self- and clinician-collected specimens for HPV 16 and 18 (Table 3), and therefore equivalent management is warranted. As described in the 2019 guidelines, collection of cervical cytology at the colposcopy visit is recommended because additional diagnostic testing and surveillance is recommended for Atypical Glandular Cells (AGC), and for Atypical Squamous Cells cannot exclude High-grade (ASC-H) or High-grade Squamous Intraepithelial Lesion (HSIL) cytology with colposcopic biopsy results of less than CIN2.[30] (See Figures 1 and 2)

RECOMMENDATION #4: When self-collected vaginal specimen HPV test results are: a) positive for HPV (untyped), b) negative for HPV 16/18 and positive for HPV HR12 (other); or c) negative for HPV 16/18 and positive for HPV 45, 33/58, 31, 52, 35/39/68, 51 or combinations thereof, obtaining a clinician-collected cervical specimen for cytology or dual stain is recommended. Subsequent management of cytology or dual-stain results per management guidelines is recommended (AII).

Rationale. Evidence supports concordance of self- and clinician-collected specimens for partial and extended HPV genotyping (Table 3). The immediate CIN3+ risk for HR12 or untyped is above the colposcopy threshold when triage testing is abnormal, defined as a positive dual-stain result or a cytology result of Atypical Squamous Cells of Undetermined Significance (ASC-US) or more severe. Immediate CIN3+ risks are below the colposcopy threshold when triage testing is normal, defined as a negative dual-stain or cytology result of Negative for Intraepithelial Lesion or Malignancy (NILM).[19] Triage testing (i.e., cytology or dual stain) cannot be performed on a vaginal specimen. Therefore, a speculum exam for clinician collection of a cervical specimen on which to perform the triage test is recommended. Management using the 2019 guidelines is recommended when HPV test results are untyped or HR12 HPV and cytology is used for triage testing.[30] Management using the dual-stain guidelines is recommended when HPV test results are untyped or HR12 HPV and dual stain is used for triage testing.[19] Management using the extended genotyping guidelines is recommended for management when the HPV test results are negative for HPV 16 and 18 and positive for HPV 45, 33/58, 31, 52, 35/39/68, 51 or combinations thereof and cytology and/or dual-stain results are used for triage testing. Briefly

HPV test result	Management of clinician- vs. self-collected collected specimens	Current HPV test result	Current cytology result	Past history	Management
HPV 16/18	Clinician-collected: Laboratory performs cotest or reflex cytology. Self-collected: Colposcopy recommended. Collect cytology at colposcopy.	16	HSIL	Noncontributory	Treatment preferred; colposcopy acceptable
		16	ASC-H	Noncontributory	Treatment or colposcopy
		16	NILM, ASC-US, LSIL, AGC, or no cytology	Noncontributory	Colposcopy[1]
		18	HSIL	Noncontributory	Treatment or colposcopy
		18	NILM, ASC-US, LSIL, ASC-H, AGC, or no cytology	Noncontributory	Colposcopy[1,2]
HPV 45, 33/58, 31, 52, 35/39/68, 51 Untyped or "other" types when 16 and 18 are not present	Clinician-collected: Laboratory performs cotest or reflex cytology. Self-collected: Patient returns for collection of cytology unless current test is 2nd consecutive HPV+ in which case colposcopy recommended.	45, 33/58, 31, 52, 35/39/68, 51 or untyped/other	HSIL, ASC-H, AGC	Noncontributory	Colposcopy[1,2]
		45, 33/58, 31, 52, 35/39/68, 51	ASC-US, LSIL	Noncontributory	Colposcopy
		Other/untyped	ASC-US, LSIL	Documented HPV negative screen in past 5 years or colposcopy <CIN2 within past 1 year	Repeat HPV test in 1 year
		Other/untyped	ASC-US, LSIL	Any history other than above	Colposcopy
		45, 33/58, 31, 52, 35/39/68, 51 or untyped/other	NILM	Normal[3] or colposcopy <CIN2 within past 1 year	Repeat HPV test in 1 year
		45, 33/58, 31, 52, 35/39/68, 51 or untyped/other	Not available	HPV+ without colposcopy (i.e. current test is 2nd consecutive HPV+)	Colposcopy
HPV 59/56/66	Clinician- collected: No additional immediate testing needed. Laboratory may run cytology if cotesting is performed.[4] Self-collected: No additional immediate testing needed	59/56/66	ASC-H, AGC, or HSIL	Noncontributory	Colposcopy[1,2]
		59/56/66	No cytology or NILM, ASC-US, LSIL	Normal or colposcopy <CIN2 within past 1 year	Repeat HPV test in 1 year
		59/56/66	Not available	HPV+ without colposcopy (i.e., current test is 2nd consecutive HPV+)	Colposcopy

FIGURE 1. Summary of management for positive HPV screening test results with self-collected and clinician-collected specimens for settings using cytology (either as a cotest or triage test). Abbreviations: AGC indicates atypical glandular cells; ASC-H, atypical squamous cells, cannot exclude HSIL; ASC-US, atypical squamous cells of undetermined significance; CIN, cervical intrepithelial neoplasia;HPV, human papillomavirus; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; NILM, negative for intraepithelial lesion or malignancy; <CIN2, CIN1 or less; CIN2+, CIN2, CIN3, adenocarcinoma in situ, cancer.[1] In nonpregnant patients, endocervical curettage recommended for AGC; endometrial biopsy recommended if cytology specifies atypical endometrial cells and for nonpregnant patients aged ≥35 and patients aged <35 if risk factors for endometrial neoplasia present (e.g., abnormal uterine bleeding, conditions suggesting anovulation, obesity).[2] Colposcopy or treatment is acceptable for results of untyped HPV with ASC-H or HSIL cytology; expedited treatment is preferred for nonpregnant patients 25 years or older with HSIL cytology and concurrent positive testing for HPV genotype 16 (HPV 16) (i.e., HPV 16-positive HSIL cytology) and for never or rarely screened patients with HPV-positive HSIL cytology regardless of HPV genotype.[3] Normal screening history documented in medical record, and/or patient is in the general screening population and has no known history of CIN2+.[4] Cytology triage is not recommended for primary HPV screening with results positive for HPV59/56/66; this guideline may be used if cytology results are obtained. *Note: For patients with a history of high-grade histology, high-grade cytology (HSIL or persistent ASC-H) or following treatment (or observation of CIN2), 2019 guidelines should be followed.*

summarized, these guidelines are: if dual-stain–negative or NILM cytology, repeat testing in 1 year is recommended. If dual-stain–positive or cytology result of ASC-US or higher, colposcopy is recommended. For patients with initial results of dual-stain–negative or NILM cytology who undergo repeat HPV testing or cotesting at 1 year, colposcopy is recommended if the repeat test is HPV-positive for any type (See Figures 1 and 2).

RECOMMENDATION #5: When self-collected vaginal specimen HPV test results are positive for HPV types 56/59/66 and no other carcinogenic types, 1 year repeat testing is recommended (AII). If HPV-positive for any HPV type at the 1-year follow-up, colposcopy is recommended (CIII).

Rationale. Evidence supports concordance of self- and clinician-collected samples for partial and extended HPV genotyping (Table 3). The extended genotyping guidelines are recommended for management of HPV types 56/59/66 when no other carcinogenic types are present.[20] To summarize briefly, the CIN3 + risk for HPV 56/59/66 is below the colposcopy threshold for dual-stain–positive or cytology of ASC-US or higher, therefore triage testing (i.e., cytology or dual stain) does not change management and a visit to obtain a triage test is not needed. Therefore, repeat testing in 1 year is recommended. If the patient remains HPV-positive at the 1-year follow-up, colposcopy is recommended (See Figures 1 and 2).

RECOMMENDATION #6: In the surveillance setting, clinician-collected cervical specimens are preferred. If a clinician-collected cervical specimen cannot be obtained, a self-collected vaginal specimen is acceptable following shared decision-making. If a self-collected vaginal specimen is obtained, management per 2019 guidelines is recommended (CIII).

Rationale. Sensitivity comparisons between self- and clinician-collected HPV results show near equivalence in different settings (i.e., screening and colposcopy).[6] However, data are very limited for individuals in the surveillance setting, defined as those with prior HPV-positive test results, those who are postcolposcopy, and those who are posttreatment.[6] In addition, the surveillance

HPV test result	Management of clinician- vs. self-collected collected specimens	Current HPV result	Current dual stain result	Past history	Management
HPV 16/18	Clinician- and self-collected: same management	16 and/or 18	Noncontributory	Noncontributory	Colposcopy *with collection of cytology if available*
HPV 45, 33/58, 31, 52, 35/39/68, 51 or untyped	Clinician-collected: Laboratory performs reflex dual stain. Self-collected: Patient returns for collection of dual stain.	45, 33/58, 31, 52, 35/39/68, 51 or untyped	Dual stain negative[1]	Normal[2] or colposcopy <CIN2 within past 1 year	Repeat HPV test in 1 year
		45, 33/58, 31, 52, 35/39/68, 51 or untyped	Dual stain positive[3]	Noncontributory	Colposcopy
		45, 33/58, 31, 52, 35/39/68, 51 or untyped	Noncontributory	HPV+ without colposcopy (i.e., current test is 2nd consecutive HPV+)	Colposcopy
HPV 59/56/66	Clinician- and self-collected: same management	59/56/66	Noncontributory	Normal[2] or colposcopy <CIN2 within past 1 year	Repeat HPV test in 1 year[1]
		59/56/66	Noncontributory	HPV+ without colposcopy (i.e., current test is 2nd consecutive HPV+)	Colposcopy

FIGURE 2. Summary of management for positive HPV screening results with self-collected and clinician-collected specimens for settings using reflex testing with $p16^{ink4a}$/Ki-67 dual stain. Abbreviations: CIN indicates cervical intraepithelial neoplasia; HPV, human papillomavirus; <CIN2, CIN1 or less; CIN2+, CIN2, CIN3, adenocarcinoma in situ, cancer; NILM, negative for intraepithelial lesion or malignancy[1]If cytology is performed in a cotesting setting and a dual-stain result is negative, repeat HPV testing in 1 year is recommended for NILM, ASC-US, or LSIL results. Colposcopy is recommended for ASC-H, AGC, or HSIL cytology results.[2] Normal screening history documented in medical record, and/or patient is in the general screening population and has no known history of CIN2+[3] If cytology is performed in a cotesting setting, colposcopy is recommended for all results including NILM *Note: For patients with a history of high-grade histology, high-grade cytology (HSIL or persistent ASC-H), following surveillance of CIN2 or treatment of CIN2+, 2019 guidelines should be followed.*

population has a higher risk of CIN3+ and HPV infection.[38] Higher HPV-positivity rates lead to more patients requiring speculum exams for triage testing. Therefore, clinician-collected cervical specimens are preferred. However, there was consensus within the Enduring Guidelines committee that using a self-collected vaginal specimen was preferable to no testing. If self-collected vaginal specimens for HPV testing are used in the surveillance setting, utilization of the risk management thresholds outlined in the 2019 guidelines is recommended (i.e., treatment, colposcopy, or repeat HPV testing in 1 or 3 years according to CIN3+ risk). Self-collection data are not available to directly assess these scenarios, and recommendations may change when additional data accrue.

DISCUSSION

Use of self-collected vaginal specimens for primary HPV screening is an effective approach to expand access to cervical cancer screening.[6–8] Self-collection may reduce barriers at the patient level (e.g., discomfort with speculum exams), clinician level (e.g., clinician does not perform pelvic exams or lacks time in a health care visit to perform the exam), and systems level (e.g., lack of screening appointments).[35] The FDA approval of 2 HPV assays for primary HPV screening using self-collected vaginal specimens is an important step toward broader screening coverage in the United States. The majority of cervical cancers in the United States occur among individuals who do not participate in cervical screening,[39] and self-collection can expand screening to those who have not participated in traditional screening programs.[7,8] This manuscript summarizes strong evidence showing that HPV test performance is similar for self-collected vaginal HPV specimens and clinician-collected cervical specimens. Based on these performance characteristics, guidelines for HPV screening using self-collected vaginal and clinician-collected cervical specimens are very similar.

However, there are operational differences between the approaches that must be considered. Human papillomavirus self-collection may require different order sets, laboratory processes, and clinical workflows; examples are available at the following references.[40,41] Importantly, currently approved triage tests, cervical cytology, and dual stain cannot be performed on self-collected specimens. Therefore, a clinic visit for a clinician-collected cervical specimen is required when triage tests are indicated. In a screening population, approximately 90% of patients will test HPV-negative and not require further testing, and 3% will test positive for HPV 16 and/or 18 and require direct colposcopy referral.[38,42] If extended genotyping is not available, triage is needed for the remaining 7%. If extended genotyping is available, those who test positive for HPV 56/59/66 and no other carcinogenic types can repeat HPV testing in 1 year, further reducing the need for obtaining additional triage specimens.[20]

Importantly, screening alone does not prevent cancer; HPV-positive test results need to be followed up to detect and treat precancers for successful cancer prevention. Thus, HPV self-collection can only effectively improve cervical screening when all downstream steps of management and treatment are completed. This requires that self-collection test results are communicated back to the screening participants and all needed follow-up visits are completed; this may include collection of triage cytology or dual stain, colposcopy, and excisional treatment. Data from the Dutch national program indicate a nearly 4-fold higher loss to follow-up following self- compared to clinician-collection.[43] Contributing factors may include the need for an extra clinic visit for cytology or dual-stain collection when self-collection is used and also higher levels of barriers to obtaining health services among those who have not previously participated in screening. Therefore, improving tracking within the electronic medical record as well as patient navigation services to ensure completion of care through diagnostic biopsy and treatment of precancer is paramount.

The initial regulatory approval of HPV self-collection has some limitations, including the need to collect the specimen in a controlled setting that allows for immediate sample handling. Although this currently limits the realization of the full potential of self-collection to expand screening in the United States, regulatory trials evaluating HPV self-collection as a home collection are underway.[44] The Enduring Guidelines process will update recommendations for other HPV assays and for HPV self-collection at

home following regulatory approval. Home collection will address additional barriers to screening, but will also raise additional challenges around ensuring that kits are returned, similar to those encountered in at-home colorectal cancer screening.[45]

There is a continued need to study HPV self-collection in screening and management to fill current evidence gaps. Long-term prospective data comparing self- and clinician-collection will be critical to inform screening intervals. The current recommendation for a 3-year interval after a negative self-collected HPV test result can be considered an interim recommendation that was made because of a lack of long-term prospective data. The cross-sectional data summarized in systematic reviews support that a 3-year interval is safe. This recommendation may be expanded to a 5-year interval recommended for negative clinician-collected HPV test result if more data accrue that support the equivalence of self-collected vaginal specimens and clinician-collected cervical specimens, for example from the IMPROVE trial.[46] Additional data in the surveillance setting are needed to determine the utility of self-collection for individuals following positive HPV test results, colposcopy, and treatment of precancer. More data are also needed to evaluate whether HPV self-collection is equally sensitive across a wide age range, particularly among postmenopausal individuals, as well as among those with obesity. In addition, screening of people living with HIV or other immunosuppressive disorders currently requires a cytology component, and more research is needed on the applicability of primary HPV screening, including self-collected vaginal specimens, in this population.[47] Further, data are limited for the sensitivity of self-collection for detection of glandular cancers and cancer precursors.

Despite these questions, the availability of HPV self-collection in the United States is a major advance toward expanding the reach of screening and making it more accessible, particularly for individuals with barriers to clinician-collected screening.[48] Implementation of HPV self-collection according to currently approved indications needs to consider access to clinical office or laboratory settings for specimen collection, education of clinical and laboratory staff, as well as new laboratory and clinical workflows to ensure proper specimen processing and adequate follow-up through diagnostic resolution. The Enduring Guidelines process was developed to rapidly respond to new data and will update recommendations when additional data become available indicating that changes are needed.

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