

ARTICLE

Self-collected vaginal specimens for human papillomavirus testing and guidance on screening exit: An update to the American Cancer Society cervical cancer screening guideline

Rebecca B. Perkins MD, MSc¹  | Andrew M. D. Wolf MD²  | Timothy R. Church PhD³  | Elena B. Elkin PhD, MPA⁴  | Steven J. Skates PhD⁵ | Ruth D. Etzioni PhD⁶ | Carmen E. Guerra MD, MSCE⁷  | Abbe Herzig PhD⁸ | Richard M. Hoffman MD, MPH⁹  | Kevin C. Oeffinger MD¹⁰  | Sana Raoof MD, PhD¹¹ | Ya-Chen Tina Shih PhD¹²  | Louise C. Walter MD¹³  | Charnita Zeigler-Johnson PhD¹⁴  | Deana Manassaram-Baptiste PhD, MPH¹⁵ | Robert A. Smith PhD¹⁵ 

¹Tufts University School of Medicine/Tufts Medical Center, Boston, Massachusetts, USA

²University of Virginia School of Medicine, Charlottesville, Virginia, USA

³Masonic Cancer Center, University of Minnesota, Minneapolis, Minnesota, USA

⁴Department of Health Policy and Management, Columbia University Mailman School of Public Health, New York, New York, USA

⁵Massachusetts General Hospital, MGH Biostatistics, Boston, Massachusetts, USA

⁶Fred Hutchinson Cancer Research Center, University of Washington, Seattle, Washington, USA

⁷Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA

⁸Patient Representative, Mathematics Department, Sarah Lawrence College, Bronxville, NY, USA

⁹Department of Medicine, Carver College of Medicine, University of Iowa, Iowa City, Iowa, USA

¹⁰Department of Medicine, Duke University School of Medicine and Duke Cancer Institute Center for Onco-Primary Care, Durham, North Carolina, USA

Abstract

This update expands the 2020 American Cancer Society (ACS) cervical cancer screening guideline for average-risk women and individuals with a cervix who are at average risk, to include self-collection for human papillomavirus (HPV) testing and revised guidance for exiting cervical cancer screening. Self-collected vaginal specimens, a method of primary HPV testing, align with the ACS cervical cancer screening guideline. When clinician-collected cervical specimens are used for HPV testing, repeat screening is recommended every 5 years for those with a negative test. For self-collected vaginal specimens, the ACS endorses the following recommendations of the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee (of which it is a member): (1) primary HPV screening using clinician-collected cervical specimens is preferred, and self-collected vaginal specimens are acceptable for average-risk individuals aged 25–65 years; and (2) repeat testing in 3 years is recommended after a negative result on a self-collected HPV screening test. These recommendations apply only to combinations of collection devices and HPV assays approved by the US Food and Drug Administration for HPV testing in a clinical setting or at home. The rationale notes that the use of self-collected vaginal specimens can overcome barriers to screening for many patients, but most patients who test HPV-positive will require extra follow-up steps, and data on long-term, real-world effectiveness

Please see related article: <https://doi.org/10.3322/caac.70047>.

This is an open access article under the terms of the [Creative Commons Attribution-NonCommercial-NoDerivs](https://creativecommons.org/licenses/by-nc-nd/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.

© 2025 The Author(s). CA: A Cancer Journal for Clinicians published by Wiley Periodicals LLC on behalf of American Cancer Society.

¹¹Department of Radiation Oncology, The Warren Alpert Medical School of Brown University, Providence, Rhode Island, USA

¹²David Geffen School of Medicine and Jonsson Comprehensive Cancer Center, University of California Los Angeles, Los Angeles, California, USA

¹³Department of Medicine, University of California San Francisco and San Francisco Veterans Affairs Medical Center, San Francisco, California, USA

¹⁴Fox Chase Cancer Center, Philadelphia, Pennsylvania, USA

¹⁵Center for Early Cancer Detection, American Cancer Society, Atlanta, Georgia, USA

Correspondence

Robert A. Smith, Center for Early Cancer Detection, American Cancer Society, 270 Peachtree Street NW, Suite, 1300 Atlanta, USA.
Email: robert.smith@cancer.org

are limited. For certain high-risk individuals, clinician-collected samples are still recommended. Furthermore, in response to high rates of cervical cancer among individuals older than 65 years and with poor implementation of current exiting screening criteria, ACS has amended the 2020 guideline to recommend HPV testing at ages 60 and 65 years, with the last HPV test at an age no younger than 65 years as a requisite to exiting screening. The revised recommendation states: *To qualify for discontinuation of screening, the ACS recommends an average-risk woman or an individual with a cervix at average risk have negative primary HPV tests (preferred) or negative co-testing using HPV tests and cytology (acceptable) at ages 60 and 65 years.* If primary HPV tests or co-testing are not available, three consecutive negative cytology (Papanicolaou) tests at the recommended screening interval with the last test at age 65 years are acceptable. If self-collected vaginal specimens are used for HPV testing, the 3-year testing interval should be followed. Additional screening exit stipulations relate to women at higher risk because of prior abnormal test results or current immune suppression.

KEYWORDS

cancer prevention, cervical cancer, early detection of cancer, guideline, human papillomavirus testing, human papillomaviruses (HPV), self-collection

INTRODUCTION

The incidence and mortality rates of cervical cancer in the United States have significantly decreased over the past 50 years, primarily because of the widespread adoption of screening practices that began in the middle 20th century.¹ Screening detects cervical pre-cancer that requires treatment to prevent cancer; up to an estimated 200,000 women in the United States require treatment for a pre-cancer each year.^{2,3} However, for various reasons that mostly relate to nonadherence to screening recommendations, it is estimated that 13,360 cases of invasive cervical cancer will be diagnosed and 4320 deaths from cervical cancer will occur in 2025.¹

Cervical cancer screening recommendations from the American Cancer Society (ACS)⁴ and other organizations⁵ have changed over time, driven by improved understanding of the disease's natural progression, the recognized role of high-risk human papillomavirus (HPV) infection, and advancements in screening technologies.⁶ Although cytology (Papanicolaou [Pap] testing) has been effective in reducing cervical cancer incidence and mortality, HPV testing has emerged as a method that offers higher sensitivity and better reassurance against cancer after a negative test, both as a co-test with cytology and as a stand-alone test.^{7,8} Primary HPV testing (i.e., stand-alone HPV test) has been recommended as the preferred screening strategy in guidelines in the United States and worldwide.^{4,9,10}

The ACS first recommended HPV testing for cervical cancer screening in the 2002 guideline update, which included a preliminary recommendation for co-testing every 3 years pending US Food and Drug Administration (FDA) approval.¹¹ After the FDA's 2003

approval of HPV testing for use in conjunction with cytology (co-testing), the ACS affirmed the use of co-testing every 3 years as an option for cervical cancer screening in women aged 30 years and older.¹² In 2012, the ACS guideline update recommended co-testing every 5 years as a preferred screening strategy.¹³ In its guideline update in 2020, the ACS recommended primary HPV testing at 5-year intervals beginning at age 25 years as the preferred strategy.⁴ The 2020 update did not include recommendations for the use of self-collected vaginal specimens for screening because the technology was not yet approved by the FDA; thus a recommendation for use outside of research studies could not be supported. However, the 2020 guideline authors stated, "we anticipate that self-sampling will play an increasingly prominent role in cervical cancer screening once regulatory and clinical prerequisites are in place and as supporting evidence continues to accumulate."⁴

The ACS cervical cancer screening guideline includes only FDA-approved combinations of HPV assays and collection devices. The ACS does not endorse any specific manufacturer or product. In 2024 and 2025, the FDA approved new options for self-collection of vaginal specimens for HPV testing, marking a significant advance in cervical cancer screening accessibility. In May 2024, the FDA expanded approvals for two primary HPV tests—the Onclarity HPV assay (Becton, Dickinson and Company) and the cobas HPV test (Roche Molecular Systems, Inc.)—to include self-collected vaginal specimens obtained in health care settings, in addition to clinician-collected cervical specimens, which were previously approved.¹⁴ This approach allows individuals to collect their own samples for cervical cancer screening in any clinical setting without the need for a speculum examination. At the

time of this publication, FDA-approved use is restricted to the following HPV test and collection device combinations: Roche cobas HPV test with either the FLOQSwab (COPAN Diagnostics Inc.) or Evalyn Brush (Rovers Medical Devices) collection devices, or the BD Onclarity HPV test with the FLOQSwab collection device, *or the Abbott Alinity m with the Evalyn Brush or Qvintip swab (part of simpli-COLLECT kit)*. Separately, the FDA approved an at-home self-collection kit (Teal Wand; Teal Health) to be used with the Roche cobas HPV test within a proprietary telehealth primary care network.^{15–17}

The Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee (hereafter referred to as the *Enduring Guidelines Committee*) was established with the primary purpose of assessing newly approved technologies for cervical cancer screening and management and to issue recommendations for their clinical use.¹⁸ The committee is comprised of members from 19 national organizations, including the ACS. In 2025, the Enduring Guidelines Committee issued recommendations for HPV testing using self-collected vaginal specimens with FDA-approved testing options for cervical cancer screening and management in the United States.¹⁹ Below, we present the ACS Guideline Development Group's (GDG's) evaluation and endorsement of the Enduring Guidelines Committee recommendations for self-collected vaginal specimens for HPV testing, which serves as an amendment to incorporate self-collected vaginal specimens for cervical cancer screening into the 2020 ACS guideline recommendations. Recognizing that many women discontinue cervical cancer screening before or after age 65 years without meeting exit criteria, the GDG also includes an amendment to its 2020 guideline recommendation for new exit criteria that should be fulfilled before screening is stopped.

Recommendations for cervical cancer screening and screening exit apply only to average-risk individuals. For the purposes of cervical cancer screening, average-risk individuals are those who fulfill the criteria listed in Table 1.²⁰ Recommendations for average-risk individuals do not apply to those under surveillance for abnormal past results or cervical precancer or to those with a history of cervical cancer; those at increased risk for cervical cancer because of solid organ or stem cell transplantation, human immunodeficiency virus infection, or immunosuppression from other causes; or those with in utero exposure to diethylstilbestrol. Management of these individuals is outlined in Table 2.^{20–25}

METHODS

ACS endorsement process

The GDG (a volunteer group of clinicians, methodologists, and public health experts) is responsible for developing cancer screening guidelines for the ACS (see Supporting Materials).²⁶ Although the ACS does not collaborate with other organizations on cancer screening guidelines under the current process for guideline development,²⁶ a formal process was established in 2016 to allow for the endorsement or adaptation of recommendations from other groups directed at interventions related to cancer prevention or cancer screening.²⁷ The process, as described elsewhere,^{27,28} includes a content review of the guideline by members of the GDG, a methodologic review of the published guideline using the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument,²⁹ and a literature search for relevant evidence published since publication of the guideline under consideration. For this endorsement, the methodological review was independently conducted by four individuals, including the GDG chairperson, a guideline development staff person, and members of the ACS Cancer-Related Evidence Synthesis Team. A written summary of this assessment, including scores and comments, was provided to the GDG cervical cancer workgroup for review.

Although several shortcomings were identified during the review process using the AGREE II tool, the methodological assessment concluded that the Enduring Guidelines Committee's recommendations and rationale were clearly articulated and supported by suitable development methods. The recommendations considered for endorsement were evidence-based, with extensive summaries of the evidence on primary HPV test performance using self-collected vaginal specimens versus clinician-collected cervical specimens.

The GDG cervical cancer screening workgroup conducted a content review of the Enduring Guideline Group's publication, focusing on the two recommendations (Table 3) regarding the use of self-collected vaginal specimens for cervical cancer screening that were considered for endorsement. Based on the evidence considered by the Enduring Guidelines Committee, the GDG cervical cancer workgroup voted on whether to fully endorse the recommendations

TABLE 1 Definition of average-risk individuals.

Criteria for average risk (must fulfill all three)
1. Has a cervix (i.e., women or transgender men who have not undergone hysterectomy with removal of the cervix)
2. Asymptomatic (i.e., does not have abnormal bleeding or other symptoms concerning cervical cancer for which a more thorough workup is required)
3. Screening for the first time or has a history of all normal cervical cancer screening results in the past; OR has a remote history of abnormal results that has been followed by a sufficient amount of normal testing that the individual fulfils criteria to resume routine cervical cancer screening based on follow-up recommendations from the Risk-Based Management Consensus Guidelines (Perkins 2020, 2024 ^{20,21}).

Note: A the time of this report, the definition of average risk is not modified by whether an individual received human papillomavirus vaccination nor by their current or past sexual history.

TABLE 2 Patient scenarios that do not meet average-risk criteria: Recommendations for average-risk screening and screening exit do not apply.

Patient scenario	Guidelines recommended for management (references)	Screening exit considerations	Self-collection considerations
Surveillance after abnormal screening test results without high-grade disease (i.e., worst diagnosis was CIN1/LSIL or negative/normal)	Refer to the 2019 ASCCP Risk-Based Management Consensus Guidelines for Abnormal Cervical Cancer Screening Tests and Cancer Precursors (Perkins 2020, 2024 ^{20,21}).	Exit may be considered if a patient is 65 years or older and has at least 10 years of normal results after their abnormal result.	Clinician-collection is preferred, self-collection is acceptable after shared decision making.
Surveillance after treatment or resolution of high-grade disease/cervical precancer (HSIL, CIN2, CIN3, AIS)	Refer to the 2019 ASCCP risk-based management consensus guidelines for abnormal cervical cancer screening tests and cancer precursors (Perkins 2020, 2024 ^{20,21}).	Exit may be considered if a patient is 65 years or older and has at least 25 years of normal results after treatment.	Clinician-collection is preferred, self-collection is acceptable after shared decision making.
Individuals with HIV or significant iatrogenic immunosuppression (e.g., solid organ transplantation, autoimmune disease on biologics)	Refer to the guidelines for the prevention and treatment of opportunistic infections in adults and adolescents with HIV (Clinicalinfo.HIV.gov 2021 ²²).	Does not qualify for screening exit	Does not qualify for self-collection
In utero diethylstilbestrol (DES) exposure	Refer to the ASCCP clinical consensus: Screening recommendations for clear cell adenocarcinomas in people exposed to DES in utero (Marcus 2024 ²³).	Does not qualify for screening exit; very limited data	Does not qualify for self-collection; vaginal cancers related to DES exposure are not HPV-related.
Symptoms of abnormal bleeding	Refer to the ACOG committee's opinion. number 557: Management of acute abnormal uterine bleeding in nonpregnant, reproductive-aged women (ACOG 2013 ²⁴).	Patients should undergo evaluation, including assessment for both cervical and uterine malignancy.	Patients should undergo evaluation, including assessment for both cervical and uterine malignancy.
History of cervical cancer	Refer to the Society of Gynecologic Oncology recommendations (Salani 2017 ²⁵).	Patients should be followed initially by a gynecologic oncologist who determines long-term plan regarding screening exit.	Patients should be followed initially by a gynecologic oncologist who determines long-term plan regarding screening modalities.

Abbreviations: ACOG, American College of Obstetricians and Gynecologists; AIS, adenocarcinoma in situ, cancer; ASCCP, American Society of Colposcopy and Cervical Pathology; CIN, cervical intraepithelial neoplasia; CIN2+, cervical intraepithelial neoplasia grade 2 or worse; CIN3, adenocarcinoma in situ, cancer; HIV, human immunodeficiency virus; HPV, human papillomavirus; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion.

as stated; endorse the recommendations with commentary, qualifying statements, or exceptions for clarification; or reject them if their judgments on the evidence and recommendations differed significantly from those of the Enduring Guidelines Committee.

The draft endorsement statements were presented to the full GDG for review, discussion, and approval and subsequently were reviewed by four expert advisors to the GDG before submitting for publication.

ACS guidelines and conflicts of interest

All participants in the guideline development process, including the endorsement of an externally produced guideline, are required to disclose all financial and nonfinancial (including personal, intellectual, and practice-related) relationships and activities that could be

perceived as potential conflicts of interest in the development of cancer screening and related guidelines (see Supporting Materials).²⁶ Disclosures from ACS staff and GDG members are made available to all committee members for review. The chairpersons of the ACS GDG and the cervical cancer screening workgroup were responsible for ensuring that balanced perspectives were considered during discussions and decision making.

The Enduring Guidelines Committee recommendations and ACS endorsement

ACS content review

The content review assessed the two recommendations considered for endorsement and the extent to which the available evidence

TABLE 3 Summary of American Cancer Society-endorsed recommendations.

The American Cancer Society endorses the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee recommendations for self-collected vaginal specimens for HPV testing according to current FDA approvals.

The recommendations apply only to average-risk individuals (see Table 1 for definition of average risk and Table 2 for high-risk clinical situations).

Recommendations* for self-collected vaginal specimens for cervical cancer screening:

1. Clinician-collected cervical specimens are preferred, and self-collected vaginal specimens are acceptable for cervical cancer screening.
2. When self-collected vaginal specimens are HPV-negative in the screening setting, repeat testing in 3 years is recommended.

*Recommendations only apply to tests (collection kits and HPV assays) with an FDA indication for primary HPV screening using self-collected vaginal specimens. Note: Tests and collection devices should be used in the settings for which they have FDA approval (in a clinical setting or at home).

*Recommendations are intentionally conservative to provide a margin of safety during the initial implementation of self-collection in the United States.

This may be updated if long-term follow-up data indicate that the incidence of CIN3+ after a negative self-collected screen is sufficiently low to warrant a 5-year testing interval.

Abbreviations: CIN3+, cervical intraepithelial neoplasia grade 3 or worse; FDA, US Food and Drug Administration; HPV, human papillomavirus; HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion.

supports the recommendation. In the evaluation of the content and evidence presented for the two Enduring Guideline Committee recommendations, the GDG members considered the following questions:

- Are the results of the studies supporting these recommendations interpreted and applied according to the GDG's judgments about the data?
- Is the evidence presented in support of each recommendation sufficient?
- Are the recommendations clear, and will they be easily understood by the intended audience?
- Is the assessment of the balance between benefits and harms acceptable as reflected in the recommendations, and how confident is the GDG in the underlying estimates of effect?
- Do the recommendations adequately take into consideration patient values and preferences?

Upon completing the content review, the GDG concluded that the quality, strength, and consistency of evidence related to self-collected vaginal samples (Table 4) supported the conclusion that the benefits of self-collected vaginal specimens for cervical cancer screening outweigh the limited harms.^{30–36} The GDG elected to fully endorse the recommendations for self-collection from the Enduring Guidelines Committee without qualifying statements or exceptions and thus to update the ACS guideline to include self-collected vaginal specimens for primary HPV testing as a valid option for cervical cancer screening.

Recommendations and rationale

1. Enduring guidelines: Clinician-collected cervical specimens are preferred and self-collected vaginal specimens are acceptable for cervical cancer screening

Historically, clinician-collected cervical samples for cytology testing have served as the benchmark for cervical cancer screening. With the emergence of newer screening strategies—first co-testing (cytology

combined with HPV testing) and, later, primary HPV testing alone—clinician-collected specimens have remained the standard of care in the United States. These approaches have proven effective, contributing to nearly 80% of women participating in regular cervical cancer screening and a reduction in cervical cancer mortality by >50% in the past 50 years.¹

HPV testing using self-collected vaginal specimens has been extensively evaluated in studies among varied populations in the United States and around the world.^{30,31,33,37–39} The findings from these studies indicate that HPV testing with polymerase chain reaction (PCR) using self-collected vaginal specimens demonstrates similar sensitivity and specificity compared with clinician-collected specimens. High-quality evidence from multiple systematic reviews and meta-analyses supports the use of self-collected vaginal specimens for PCR-based HPV testing as an acceptable alternative, offering comparable sensitivity and specificity to clinician-collected specimens for detecting high-risk HPV infections and associated cervical precancer.¹⁹ The evidence establishes the clinical validity and reliability of self-collected vaginal specimens for HPV testing and supports their inclusion in cervical cancer screening guidelines.

Implementation of self-collection of vaginal samples for cervical cancer screening also has the potential to improve screening participation among individuals who face barriers to traditional screening methods.⁴⁰ There is evidence that using at-home, self-collected vaginal specimens or offering patients a choice of collection methods in a clinical setting increases uptake of primary HPV testing for cervical cancer screening.⁴⁰ One systematic review reported that, in 40 of 42 studies, self-collected primary HPV testing increased the proportion of participants completing cervical cancer screening (range, 2%–63%).⁴¹ Moreover, screening rates were generally greater among individuals who were underscreened or from traditionally underscreened populations.⁴¹ As such, self-collection provides a viable and evidence-supported option within cervical cancer screening programs to enhance access, equity, and adherence.

Cervical specimen collection by a clinician, however, is the preferred sampling protocol for cervical cancer screening because of its established performance across all screening modalities. Clinician-collected specimens provide direct access to the transformation zone

TABLE 4 Summary of key studies.

Study (reference)	Sample size	Type of study	Place of self-collection (home or clinic)	Sensitivity (self-collected vs. clinician-collected)	Agreement between self-collected and clinician collected samples	Key takeaway
Meta-analysis, multiple platforms (Arbyn 2014 ³⁰)	≥154,000	Meta-analysis	Home and clinic	76% vs. 91% (CIN2+)	—	PCR-based self-collected tests were comparable to clinician collected tests; self-collection showed lower sensitivity.
Meta-analysis, multiple platforms (Arbyn 2022 ³¹)	10,071	Meta-analysis	Home and clinic	—	88.7% overall agreement; 90.4% overall agreement for PCR-based tests	Most studies showed strong concordance between self-collected and clinician-collected samples for detecting high-risk HPV types, particularly PCR-based assays.
SCoPE study, 2020 (Saville 2020 ³²)	303	National program	Clinic	Relative sensitivity self-collected 80%–100% (high-risk HPV types)	83%–99% agreement	Reliable across multiple HPV assays
Netherlands study, 2017–2018 (Inturrisi 2021 ³³)	≥487,000, of whom 30,000 had self-collection	National program	Home	Modeled relative sensitivity self-collected 91% (CIN2+) and 94% (CIN3+)	—	Slightly lower sensitivity of self-collected vs. clinician-collected samples in rollout of a national program
Roche cobas (Asciutto 2017 ³⁴)	218	Diagnostic accuracy	Clinic	92.8% vs. 92.8% (HSIL/AIS)	—	Equal efficacy in detecting high-grade lesions
BD Onclarity (Martinelli 2024 ³⁵)	300	Regulatory trial Diagnostic accuracy	Clinic	90.3% vs. 89.2% (CIN2+)	—	The sensitivity of the self-collected samples for detecting CIN2+ lesions was comparable to that of clinician-collected samples.
Teal Wand (Fitzpatrick 2025 ³⁶)	599	Regulatory trial	Clinic (simulated home environment)	96% vs. 96% (CIN2+)	—	High accuracy and user preference for self-collection

Abbreviations: AIS, adenocarcinoma in situ; CIN2+, cervical intraepithelial neoplasia grade 2 or worse; CIN3+, cervical intraepithelial neoplasia grade 3 or worse (adenocarcinoma in situ, cancer); HSIL, high-grade squamous intraepithelial lesion; LSIL, low-grade squamous intraepithelial lesion; PCR, polymerase chain reaction.

of the cervix, the primary site of HPV-related precancerous lesions; therefore, the same sample can be used for both HPV testing and subsequent cytologic evaluation of an HPV-positive result. Because self-collected vaginal specimens do not directly capture cells from the cervix, a positive HPV test result from self-collected vaginal specimens requires a follow-up speculum examination to obtain clinician-collected cervical cytology samples for triage in most cases.²⁰ In addition, although clinician collection is adequate to screen all patients, self-collection requires assessing patient eligibility to ensure that patients with HIV/immunosuppression, exposure to diethylstilbestrol in utero, or a history of cervical cancer are offered appropriate testing (Table 2).

2. Enduring guidelines: When self-collected vaginal specimens are HPV-negative in the screening setting, repeat testing in 3 years is recommended

The evidence evaluating the concordance between self-collected vaginal and clinician-collected cervical specimens for the detection

of cervical precancer is somewhat heterogeneous. Some studies demonstrate equivalent sensitivity, whereas others report a modest reduction in sensitivity for self-collected samples.^{30,31,33,42} Variability in findings is attributable to differences in study populations, sampling devices, sample processing protocols, and the specific HPV assays used. Despite this heterogeneity, cross-sectional data summarized in multiple systematic reviews support a 3-year screening interval after a negative HPV test result from a self-collected vaginal specimen when PCR-based assays are used.^{42,43}

Currently, 5-year longitudinal risk data after a negative self-collected HPV test result are limited.⁴⁴ This evidence gap poses a challenge because long-term risk estimates are essential for determining appropriate screening intervals and ensuring that self-collection strategies provide a level of safety comparable to clinician-collected testing. Therefore, in alignment with risk-based screening principles, a 3-year screening interval is recommended to ensure patient safety while longer term data in the US accrues. This interval may be reconsidered and extended to 5 years if future

evidence supports the clinical equivalence of self-collected vaginal specimens with clinician-collected cervical specimens for long-term risk prediction.

Self-collected vaginal specimens that test negative for HPV using an FDA-approved, PCR-based assay provide reassurance that the risk of cervical precancer or cancer is sufficiently low to support a 3-year screening interval. This recommendation is consistent with risk-based management principles and parallels the follow-up interval recommended for HPV-negative results obtained from clinician-collected cervical specimens in primary HPV screening.²¹ Evidence from large cohort studies and meta-analyses demonstrates that the negative predictive value of self-collected HPV testing with validated PCR assays is high and is comparable to that of clinician-collected samples.^{42,43} Therefore, average-risk individuals who test negative for high-risk HPV on a self-collected sample can defer further screening for 3 years with assurance, maintaining both effectiveness and efficiency in cervical cancer prevention. Importantly, adopting this approach supports broader screening access and adherence while maintaining safety and alignment with established clinical standards.

Clarification of ACS guideline recommendation to discontinue cervical cancer screening

The ACS 2020 guideline found sufficient evidence of a favorable balance of benefits and harm when stopping screening if an individual aged 65 years or older meets the following criteria: *no history of cervical intraepithelial neoplasia grade 2 or more severe disease within the past 25 years and documented, adequate, negative prior screening in the 10-year period before age 65 years, with adequate screening defined as two consecutive negative primary HPV tests, two consecutive negative co-tests, or three consecutive negative cytology tests within the past 10 years, with the most recent test occurring within the recommended interval for the test used.*⁴ Likewise, other organizations acknowledge that it is reasonable for some individuals to stop cervical cancer

screening, but they stress the importance of doing so on an individual basis and only if the above criteria are met.^{5,10}

It is critical that the guidance for exiting screening be clear and easily implemented to maximize the benefits of screening and minimize harm. In the United States, approximately one in four cervical cancers occurs in women older than 65 years, and their mortality is double that of younger women.⁴⁵ Studies of cervical cancer screening uptake demonstrate that screening use decreases with age, with individuals aged 60–64 years less than one half as likely to be screened as those aged 30–39 years.⁴⁶ Nonadherence to screening recommendations at older ages also contributes to the discrepancies between models that predict low cancer rates after screening exit—which assume perfect adherence to screening—and real-world experience.⁴⁷ Studies of adherence to exit screening guideline recommendations indicate substantial underscreening during the years before screening exit, with only one in three women aged 64–66 years fulfilling criteria to discontinue screening.⁴⁸ Furthermore, lower rates of follow-up colposcopy in practice increase the risk of undetected abnormalities progressing to cancer.⁴⁹ Women who do not fulfill exit criteria before age 65 years have a two-fold risk of developing cervical cancer before age 85 years compared with those who have been adequately screened.⁵⁰

The 2020 ACS guideline recommendation language regarding exiting criteria for cervical cancer screening has been viewed by many as difficult to interpret and challenging to operationalize in the clinical practice, largely because of the limited availability of complete screening records for many patients.⁵¹ Existing recommendations that specify to “discontinue screening if” require clinicians to verify prior screening history before making a decision, which, although conceptually sound, often impedes implementation and may result in missed opportunities for appropriate screening.⁵¹ In consideration of these factors, the GDG updated the wording for the ACS recommendations for exiting cervical cancer screening for individuals aged 65 years and older as follows: to qualify for discontinuation of screening, the ACS recommends that an average-risk woman, or an individual with a cervix at average risk, should have

TABLE 5 Updated American Cancer Society recommendation for exiting cervical cancer screening.

To qualify for discontinuation of screening, the ACS recommends an average-risk woman, or individual with a cervix at average risk, have negative primary HPV tests (*preferred*) or negative co-testing using HPV tests and cytology (*acceptable*) at ages 60 and 65 years. If primary HPV tests or co-testing are not available, three consecutive negative cytology (Pap) tests at the recommended screening interval with the last test at age 65 years are acceptable.

Screening should continue until two consecutive negative, primary HPV tests (preferred), or co-tests are obtained. Alternatively, three consecutive negative cytology (Pap) tests at the recommended 3-year interval are acceptable. If self-collected vaginal specimens are used for HPV testing, the 3-year testing interval should be followed. Although the resultant ages of testing may deviate slightly from the 60-year and 65-year age marks, these tests should follow the recommended screening intervals for that modality, with the last test at age 65 years or older.

- Cervical cancer screening may be discontinued by individuals of any age with limited life expectancy.
- Screening is not recommended for individuals who have undergone hysterectomy with removal of the cervix for benign indications.
- Individuals should continue screening after age 65 years if they have the following risk factors (see Table 2):
 - a. HIV-positive or immunosuppression;
 - b. History of a positive HPV test or abnormal cytology (Pap test) result of low-grade squamous intraepithelial lesion or higher in the past 10 years;
 - c. History of cervical precancer in the past 25 years (cervical intraepithelial neoplasia grade 2 or grade 3 or adenocarcinoma in situ); and/or
 - d. History of cervical cancer at any time.

negative primary HPV tests (*preferred*) or negative co-testing using HPV tests and cytology (*acceptable*) at ages 60 and 65 years. If HPV tests or co-testing are not available, then three consecutive negative cytology (Pap) tests at the recommended screening interval with the last test at age 65 years are acceptable (for details, see Table 5). If self-collected vaginal specimens are used for HPV testing, the 3-year testing interval should be followed. Adhering to the recommended screening interval for the test used is important, even if the resultant ages of testing deviate slightly from the 60-year and 65-year marks, provided that the last test occurs at an age no younger than 65 years. This approach prioritizes risk-based management over rigid age cutoffs, offering flexibility while maintaining patient safety.

DISCUSSION

Cervical cancer is a highly preventable disease, and, although age-adjusted rates for new cervical cancer cases have been stable over 2013–2022,⁵² recent trends reveal concerning increases in rates in some population subgroups.⁵³ This is attributable in part to inadequate screening and follow-up, including a documented decline in screening participation in recent years.^{54,55} Recent reports indicate that up-to-date cervical cancer screening rates have declined since 2021 and, notably, have not rebounded in the postpandemic period, with this downward trend persisting in 2023 data.⁵⁵ Cervical cancer incidence and mortality are significantly higher among underserved populations, including people living in rural or medically underserved areas, individuals from minoritized racial and ethnic groups, and those with lower socioeconomic status.^{56–61}

Self-collection of specimens for HPV testing offers a promising strategy to help improve disparities in screening by reaching more of those who need it, with one study of self-collection noting a doubling of screening uptake among under-screened patients in the United States.⁴⁰ Self-collection can overcome screening barriers related to patients (e.g., discomfort, cultural factors), clinicians (e.g., some primary care providers do not perform pelvic examinations), and systems (e.g., lack of appointments). Currently, for those with negative HPV test results from self-collected vaginal specimens, repeat screening is recommended in 3 years. Recommending repeat testing at 3 years rather than 5 years provides a margin of safety to allow additional data to accrue on the real-world performance of HPV self-collection in the United States, at which time screening intervals can be re-assessed.¹⁹

In addition to the potential benefits of self-collection of vaginal specimens for HPV testing, self-collection also raises some important implementation concerns related to communication about eligibility, patient workflows, and system capacity. Current guidelines for high-risk individuals (see Table 2), including those with immunosuppression, recommend both HPV and cytology testing for screening; cytology cannot be performed on self-collected vaginal specimens.

Therefore, it will be important to clearly inform these patients that self-collection is not a recommended option for cervical cancer screening. In addition, self-collection will necessitate new clinical workflows and tracking procedures. Because laboratories cannot perform cytology testing from a self-collected vaginal specimen, implementation of self-collection will create a category of patients: those who test HPV-positive and require a second visit to obtain a clinician-collected cervical specimen for cytology or p16/Ki67 dual stain (hereafter referred to as *dual stain*) to determine whether colposcopy is needed.

By contrast, when a screening specimen is collected from the cervix by a clinician, if the HPV test is positive, the laboratories can perform the cytology test or dual-stain test from the original specimen. In an average-risk screening population, approximately 10%–15% of individuals will test HPV-positive. Approximately one half of them will have a negative cytology or dual-stain result, for which repeat testing is recommended in 1 year.⁶² In a hypothetical population with a 10% HPV-positive rate, approximately 5% of patients would have positive cytology or dual-stain testing and would require colposcopy, and 5% would have negative cytology or dual-stain testing and return in 1 year. Thus, when clinician-collected cervical specimens are used, approximately 5% of the screening population will need immediate follow-up. In contrast, when self-collected vaginal HPV testing is used, all patients with HPV-positive results (10% of our hypothetical population) will need immediate follow-up either for cytology, dual-stain testing, or colposcopy.⁶³

Wide implementation of self-collection can be expected to improve cervical cancer screening rates, especially in unscreened and underscreened populations. Although this increase is desirable, introducing additional follow-up clinical appointments into the pathway will likely generate greater demand for clinical resources and may strain existing systems. This has the potential to create barriers to timely screening and follow-up of positive results if additional resource needs are not anticipated and addressed. Thus it is important to anticipate the need for increased capacity to meet this greater demand, particularly tracking systems to ensure reliable patient callbacks and coordination of in-person visits.

Although the opportunity for self-collection of vaginal specimens at home can address barriers to care and expand access to cervical cancer screening, its broader implementation will require further evaluation to assess real-world effectiveness and address any shortcomings that are identified. At the time of this publication, the widely available HPV test kits for self-collected vaginal specimens are designed to be used within health care settings, with orders initiated by the patient's primary care or gynecology provider, results are to be integrated directly into the electronic health record, and health maintenance tracking is to be facilitated through existing clinical workflows. This integration allows for streamlined follow-up, minimizes manual record entry, and ensures that screening and management remain aligned with the patient's

referring clinician. The only FDA-approved option for at-home collection at the time of this publication, the Teal Wand, currently has limited availability and is offered through a proprietary telehealth primary care service.¹⁵

At-home self-collection for HPV testing is being evaluated in the National Cancer Institute-sponsored *Self-Collection for HPV Testing to Improve Cervical Cancer Prevention* (SHIP) trial—a national, multi-center study conducted at 25 sites across the United States.⁶⁴ The trial objectives include determining whether self-collected vaginal specimens yield accuracy on HPV detection comparable to clinician-collected cervical specimens. Results from the SHIP trial are expected to provide robust, US-based evidence on the performance of unsupervised, at-home self-collection and will inform future guideline recommendations for primary HPV-based cervical cancer screening.

It is not clear when additional options for self-collection at home will become available or whether self-collection in health care settings will increase or diminish once more home testing options become available. Regardless, it is important that there is an ongoing evaluation of self-collection to assess real-world effectiveness, any fragmentation of care, or persistent loss to follow-up among individuals with positive test results.

Lack of screening is especially concerning among postmenopausal women who may stop seeking gynecologic care, including cervical cancer screening examinations. Low screening rates among this population contribute to higher cervical cancer incidence and mortality among women aged 65 years and older. The exit screening criteria developed in 2012, although sensible, were complex and placed too much emphasis on a look-back at 10 years of medical records at age 65 years, a cumbersome activity which, in the United States, is difficult to achieve because records may be unavailable.⁵¹ Thus these prior guidelines are very difficult to implement in practice and have not resolved the problem of inadequate screening in this age group. Emphasizing a simple but specific, forward-looking approach more feasibly lays the foundation for decision making for exiting screening. This observation prompted the proactive ACS guideline recommendation contained herein—perform HPV testing at ages 60 and 65 years as the preferred strategy for fulfilling criteria for discontinuing screening. This wording retains the evidence and logic framework of prior guidelines, but we believe that these recommendations will be easier for clinicians and patients to understand and implement in practice.

Our goal with this guideline revision is to further expand and simplify cervical cancer screening in the United States to move toward our goal of the elimination of cervical cancer as a public health problem. Data indicate a 90% reduction in cervical cancer among women who received HPV vaccination before age 17 years, with significantly reduced effectiveness for vaccination at older ages.⁶⁵ However, some women were ineligible for vaccination because of their age at the time of vaccine introduction, and others remain unvaccinated for various reasons; all women and individuals with a cervix who reach adulthood without receiving HPV vaccination will continue to require cervical

cancer screening. If all eligible patients with a cervix have access to and avail themselves of primary and secondary preventive strategies, with the technologies we have today, including HPV vaccines, clinician-collected and self-collected primary HPV screening tests, and improved diagnostic and treatment modalities, achieving the elimination goal for cervical cancer is within our reach in the United States.⁶⁵

ACKNOWLEDGMENTS

Members of the ACS Guideline Development Group (GDG) serve as volunteers and receive no compensation from the ACS. Current members are: Timothy R. Church, PhD; Elena B. Elkin, PhD, MPA; Ruth D. Etzioni, PhD; Carmen E. Guerra, MD, MSCE; Abbe Herzig, PhD (Patient Representative); Richard Hoffman, MD, MPH; Kevin C. Oeffinger, MD; Rebecca B. Perkins, MD, MSc; Sana Raoof, MD, PhD; Steven J. Skates, PhD; Ya-Chen Tina Shih, PhD; Louise C. Walter, MD; Charnita Zeigler-Johnson PhD; and Andrew M. D. Wolf, MD (Chair).

We thank the group of expert advisors for their time reviewing the draft manuscript before publication: Beverly B. Green, MD, MPH - Senior Investigator, Kaiser Permanente Washington Health Research Institute; Kathy L. MacLaughlin, MD - Associate Professor of Family Medicine, Mayo Clinic; Ritu Nayar, MD - Professor of Pathology & Medical Education, Northwestern University, Feinberg School of Medicine; Nicolas Wentzensen, MD, PhD, MS - Deputy Director, Clinical Genetics Branch at National Cancer Institute.

CONFLICT OF INTEREST STATEMENT

Carmen E. Guerra reports grants/contracts from Genentech; personal/consulting or advisory fees from Guardant Health, Natera, and Roche outside the submitted work; and owns stock in Bean Therapeutics, CRISPER, Editas, and Intellia Therapeutics. Richard M. Hoffman reports support for professional activities from Wolters Kluwer outside the submitted work. Sana Raoof reports personal/consulting or advisory fees from C the Signs, Exact Sciences, and Grail outside the supported work and owns stock in Illumina, Inc. Ya-Chen Tina Shih reports personal/consulting or advisory fees from Sanofi outside the submitted work. Deana Manassaram-Baptiste and Robert A. Smith are employed by the American Cancer Society, which receives grants from private and corporate foundations, including foundations associated with companies in the health sector, for research outside of the submitted work. They are not funded by or key personnel for any of these grants, and their salary is solely funded through American Cancer Society funds. The remaining authors disclosed no conflicts of interest.

ORCID

Rebecca B. Perkins  <https://orcid.org/0000-0002-7054-3014>

Andrew M. D. Wolf  <https://orcid.org/0009-0004-5510-7224>

Timothy R. Church  <https://orcid.org/0000-0003-3292-5035>

Elena B. Elkin  <https://orcid.org/0000-0001-8833-4213>

Carmen E. Guerra  <https://orcid.org/0000-0002-9164-6370>

Richard M. Hoffman  <https://orcid.org/0000-0002-4714-7726>

Kevin C. Oeffinger  <https://orcid.org/0000-0003-0806-7894>

Ya-Chen Tina Shih  <https://orcid.org/0000-0001-7290-3864>

Louise C. Walter  <https://orcid.org/0000-0002-9642-6238>

Charnita Zeigler-Johnson  <https://orcid.org/0000-0003-2641-7755>

Robert A. Smith  <https://orcid.org/0000-0003-3344-2238>

REFERENCES

1. Siegel RL, Kratzer TB, Giaquinto AN, Sung H, Jemal A. Cancer statistics, 2025. *CA Cancer J Clin*. 2025;75(1):10-45. doi:10.3322/caac.21871
2. Henk HJ, Insinga RP, Singhal PK, Darkow T. Incidence and costs of cervical intraepithelial neoplasia in a US commercially insured population. *J Low Genit Tract Dis*. 2010;14(1):29-36. doi:10.1097/LGT.0b013e3181ac05e9
3. Gargano JW, Park IU, Griffin MR, et al. Trends in high-grade cervical lesions and cervical cancer screening in 5 states, 2008–2015. *Clin Infect Dis*. 2018;68(8):1282-1291. doi:10.1093/cid/ciy707
4. 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
5. Curry SJ, Krist AH, Owens DK, et al. Screening for cervical cancer: US Preventive Services Task Force recommendation statement. *JAMA*. 2018;320(7):674-686. doi:10.1001/jama.2018.10897
6. Perkins RB, Wentzensen N, Guido RS, Schiffman M. Cervical cancer screening: a review. *JAMA*. 2023;330(6):547-558. doi:10.1001/jama.2023.13174
7. Salazar KL, Duhon DJ, Olsen R, Thrall M. A review of the FDA-approved molecular testing platforms for human papillomavirus. *J Am Soc Cytopathol*. 2019;8(5):284-292. doi:10.1016/j.jasc.2019.06.001
8. Lata K, Bhatla N. HPV testing for cervical cancer screening: time for a new paradigm. *Natl Med J India*. 2014;27(4):212-213.
9. World Health Organization (WHO), ed. *WHO Guideline for Screening and Treatment of Cervical Pre-Cancer Lesions for Cervical Cancer Prevention*. 2nd ed. World Health Organization; 2021.
10. U.S. Preventive Services Task Force (USPSTF). Draft Recommendation Statement. Screening for Cervical Cancer. USPSTF; 2024. Accessed June 4, 2025. <https://www.uspreventiveservicestaskforce.org/uspstf/draft-recommendation/cervical-cancer-screening-adults-adolescents>
11. Saslow D, Runowicz CD, Solomon D, et al. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. *CA Cancer J Clin*. 2002;52(6):342-362. doi:10.3322/canjclin.52.6.342
12. Smith RA, Cokkinides V, Eyre HJ. American Cancer Society guidelines for the early detection of cancer, 2004. *CA Cancer J Clin*. 2004;54(1):41-52. doi:10.3322/canjclin.54.1.41
13. Saslow D, Solomon D, Lawson HW, et al.; ACS-ASCCP-ASCP Cervical Cancer Guideline Committee. American Society for Colposcopy and Cervical Pathology and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin*. 2012;62(3):147-172. doi:10.3322/caac.21139
14. US Food and Drug Administration (FDA). *FDA roundup: May 17, 2024 [FDA News Release]*. FDA; 2024. Accessed June 4, 2025. <https://www.fda.gov/news-events/press-announcements/fda-roundup-may-17-2024>
15. Teal Health. *FDA Approves Teal Health's Teal Wand*. Teal Health; 2025. Accessed November 4, 2025. <https://www.getteal.com/news/fda-approves-teal-healths-teal-wand-tm---the-first-and-only-at-home-self-collection-device-for-cervical-cancer-screening-introducing-a-comfortable-alternative-to-in-person-screening>
16. US Food and Drug Administration (FDA). *Device Classification Under Section 513(f)(2)(De Novo)*. Device for home collection and transport of vaginal specimens by lay users for use in an approved HPV molecular assay. FDA; 2025. Accessed August 20, 2025. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN240045>
17. Teal Health. *At-Home Self-Collect Cervical Cancer Screening*. Teal Health; 2025. Accessed July 30, 2025. <https://getteal.com>
18. Wentzensen N, Garcia F, Clarke MA, et al. Enduring Consensus guidelines for cervical cancer screening and management: introduction to the scope and process. *J Low Genit Tract Dis*. 2024;28(2):117-123. doi:10.1097/lgt.0000000000000804
19. Wentzensen N, Massad LS, Clarke MA, et al. Self-collected vaginal specimens for HPV testing: recommendations from the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee. *J Low Genit Tract Dis*. 2025;29(2):144-152. doi:10.1097/lgt.0000000000000885
20. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP risk-based management consensus guidelines: updates through 2023. *J Low Genit Tract Dis*. 2024;28(1):3-6. doi:10.1097/lgt.0000000000000788
21. Perkins RB, Guido RS, Castle PE, et al. 2019 ASCCP risk-based management consensus guidelines for abnormal cervical cancer screening tests and cancer precursors. *J Low Genit Tract Dis*. 2020;24(2):102-131. doi:10.1097/lgt.0000000000000525
22. Clinicalinfo.HIV.gov. *Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV*. Office of AIDS Research, National Institutes of Health; 2021. Accessed June 4, 2025. <https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/>
23. Marcus JZ, Nelson E, Linder M, Chelmow DP. ASCCP clinical consensus: screening recommendations for clear cell adenocarcinomas in people exposed to DES in utero. *J Low Genit Tract Dis*. 2024;28(4):351-355. doi:10.1097/lgt.0000000000000842
24. ACOG committee opinion no. 557: management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. *Obstet Gynecol*. 2013;121(4):891-896. doi:10.1097/01.AOG.0000428646.67925.9a
25. Salani R, Khanna N, Frimer M, Bristow RE, Chen LM. An update on post-treatment surveillance and diagnosis of recurrence in women with gynecologic malignancies: Society of Gynecologic Oncology (SGO) recommendations. *Gynecol Oncol*. 2017;146(1):3-10. doi:10.1016/j.ygyno.2017.03.022
26. Brawley O, Byers T, Chen A, et al. New American Cancer Society process for creating trustworthy cancer screening guidelines. *JAMA*. 2011;306(22):2495-2499. doi:10.1001/jama.2011.1800
27. Saslow D, Andrews KS, Manassaram-Baptiste D, et al. Human papillomavirus vaccination guideline update: American Cancer Society guideline endorsement. *CA Cancer J Clin*. 2016;66(5):375-385. doi:10.3322/caac.21355
28. Saslow D, Andrews KS, Manassaram-Baptiste D, Smith RA, Fontham ETH; American Cancer Society Guideline Development Group. Human papillomavirus vaccination 2020 guideline update: American Cancer Society guideline adaptation. *CA Cancer J Clin*. 2020;70(4):274-280. doi:10.3322/caac.21616
29. Brouwers MC, Kho ME, Browman GP, et al. AGREE II: advancing guideline development, reporting, and evaluation in health care. *Prev Med*. 2010;51(5):421-424. doi:10.1016/j.ypmed.2010.08.005
30. Arbyn M, Verdoodt F, Snijders PJ, et al. Accuracy of human papillomavirus testing on self-collected versus clinician-collected samples: a meta-analysis. *Lancet Oncol*. 2014;15(2):172-183. doi:10.1016/s1470-2045(13)70570-9

31. Arbyn M, Castle PE, Schiffman M, Wentzensen N, Heckman-Stoddard B, Sahasrabudhe 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
32. 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
33. 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
34. Asciutto KC, Henningsson AJ, Borgfeldt H, Darlin L, Borgfeldt C. Vaginal and urine self-sampling compared to cervical sampling for HPV-testing with the Cobas 4800 HPV test. *Anticancer Res*. 2017;37(8):4183-4187. doi:10.21873/anticancer.11807
35. Martinelli M, Latsuzbaia A, Bonde J, et al.; Extended Valhudes Study Group. Performance of BD Onclarity HPV assay on FLOQSwabs vaginal self-samples. *Microbiol Spectr*. 2024;12(3):e0287223. doi:10.1128/spectrum.02872-23
36. Fitzpatrick MB, Behrens CM, Hibler K, et al. Clinical validation of a vaginal cervical cancer screening self-collection method for at-home use: a nonrandomized clinical trial. *JAMA Netw Open*. 2025;8(5):e2511081. doi:10.1001/jamanetworkopen.2025.11081
37. Arbyn M, Latsuzbaia A, Castle PE, Sahasrabudhe VV, Broeck DV. HPV testing of self-samples: Influence of collection and sample handling procedures on clinical accuracy to detect cervical pre-cancer. *Lancet Reg Health Eur*. 2022;14:100332. doi:10.1016/j.lanepe.2022.100332
38. Arbyn M, Simon M, de Sanjosé S, et al. Accuracy and effectiveness of HPV mRNA testing in cervical cancer screening: a systematic review and meta-analysis. *Lancet Oncol*. 2022;23(7):950-960. doi:10.1016/s1470-2045(22)00294-7
39. Polman NJ, Ebisch RMF, Heideman DAM, et al. Performance of human papillomavirus testing on self-collected versus clinician-collected samples for the detection of cervical intraepithelial neoplasia of grade 2 or worse: a randomised, paired screen-positive, non-inferiority trial. *Lancet Oncol*. 2019;20(2):229-238. doi:10.1016/s1470-2045(18)30763-0
40. Montealegre JR, Hilsenbeck SG, Bulsara S, et al. Self-collection for cervical cancer screening in a safety-net setting: the PRESTIS randomized clinical trial. *JAMA Intern Med*. 2025;185(9):1119-1127. doi:10.1001/jamainternmed.2025.2971
41. U.S. Preventive Services Task Force (USPSTF). *Screening for Cervical Cancer With High-Risk Human Papillomavirus Testing: A Draft Evidence Update for the U.S. Preventive Services Task Force. Evidence Synthesis, No. 244*. Agency for Healthcare Research and Quality (US); 2024. Accessed June 1, 2025. <https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-evidence-review/cervical-cancer-screening-adults-adolescents>
42. Yeh PT, Kennedy CE, de Vuyst H, Narasimhan M. Self-sampling for human papillomavirus (HPV) testing: a systematic review and meta-analysis. *BMJ Glob Health*. 2019;4(3):e001351. doi:10.1136/bmjgh-2018-001351
43. 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
44. Stanczuk GA, Currie H, Forson W, et al. Self-sampling as the principal modality for population based cervical screening: five-year follow-up of the PaVdaG study. *Int J Cancer*. 2022;150(8):1350-1356. doi:10.1002/ijc.33888
45. 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
46. Sokale IO, Montealegre JR, Oluyomi AO, Thrift AP. Trends and racial/ethnic differences in predictors of cervical cancer screening among US Women ages 30-64 years. *Cancer Epidemiol Biomarkers Prev*. 2023;32(1):82-90. doi:10.1158/1055-9965.Epi-22-0970
47. Perkins RB, Feldman S. Why are US cervical cancer screening exit criteria failing? *JAMA Netw Open*. 2025;8(3):e250488. doi:10.1001/jamanetworkopen.2025.0488
48. Mills JM, Morgan JR, Dhaliwal A, Perkins RB. Eligibility for cervical cancer screening exit: comparison of a national and safety net cohort. *Gynecol Oncol*. 2021;162(2):308-314. doi:10.1016/j.ygyno.2021.05.035
49. Benard VB, Jackson JE, Greek A, et al. A population study of screening history and diagnostic outcomes of women with invasive cervical cancer. *Cancer Med*. 2021;10(12):4127-4137. doi:10.1002/cam4.3951
50. Castanon A, Green LI, Sasieni P. Impact of screening between the ages of 60 and 64 on cumulative rates of cervical cancer to age 84y by screening history at ages 50 to 59: a population-based case-control study. *Prev Med*. 2021;149:106625. doi:10.1016/j.ypmed.2021.106625
51. Alimena S, Lykken JM, Tiro JA, et al. Accessibility of criteria to exit cervical cancer screening at age 65 years in the electronic health record. *O G Open*. 2024;1(3):032. doi:10.1097/og9.0000000000000032
52. National Cancer Institute; *Surveillance, Epidemiology, and End Results (SEER) Program*. Cancer Stat Facts: Cervical Cancer. National Cancer Institute, SEER Program; 2023. Accessed August 20, 2025. <https://seer.cancer.gov/statfacts/html/cervix.html>
53. Amboree TL, Damgacioglu H, Sonawane K, Adsul P, Montealegre JR, Deshmukh AA. Recent trends in cervical cancer incidence, stage at diagnosis, and mortality according to county-level income in the United States, 2000-2019. *Int J Cancer*. 2024;154(9):1549-1555. doi:10.1002/ijc.34860
54. American Cancer Society. *Cancer Prevention & Early Detection Facts & Figures, 2025-2026*. American Cancer Society; 2025. Accessed August 20, 2025. <https://www.cancer.org/research/cancer-facts-statistics/cancer-prevention-early-detection.html>
55. Bandi P, Star J, Mazzitelli N, et al. Prevalence and review of major modifiable cancer risk factors, HPV vaccination, and cancer screenings in the United States: 2025 update. *Cancer Epidemiol Biomarkers Prev*. 2025;34(6):836-849. doi:10.1158/1055-9965.Epi-24-1835
56. Musselwhite LW, Oliveira CM, Kwaramba T, et al. Racial/ethnic disparities in cervical cancer screening and outcomes. *Acta Cytol*. 2016;60(6):518-526. doi:10.1159/000452240
57. Roman L, Meghea C, Ford S, et al. Individual, provider, and system risk factors for breast and cervical cancer screening among underserved Black, Latina, and Arab women. *J Womens Health (Larchmt)*. 2014;23(1):57-64. doi:10.1089/jwh.2013.4397
58. Benard VB, Thomas CC, King J, et al. Vital signs: cervical cancer incidence, mortality, and screening—United States, 2007-2012. *MMWR Morb Mortal Wkly Rep*. 2014;63(44):1004-1009.
59. Yu L, Sabatino SA, White MC. Rural-urban and racial/ethnic disparities in invasive cervical cancer incidence in the United States, 2010-2014. *Prev Chronic Dis*. 2019;16:E70. doi:10.5888/pcd16.180447

60. Cohen CM, Wentzensen N, Castle PE, et al. Racial and ethnic disparities in cervical cancer incidence, survival, and mortality by histologic subtype. *J Clin Oncol*. 2023;41(5):1059-1068. doi:[10.1200/jco.22.01424](https://doi.org/10.1200/jco.22.01424)
61. Gopalani SV, Janitz AE, Campbell JE. Cervical cancer incidence and mortality among non-Hispanic African American and White Women, United States, 1999–2015. *J Natl Med Assoc*. 2020;112(6):632-638. doi:[10.1016/j.jnma.2020.06.007](https://doi.org/10.1016/j.jnma.2020.06.007)
62. Egemen D, Cheung LC, Chen X, et al. Risk estimates supporting the 2019 ASCCP risk-based management consensus guidelines. *J Low Genit Tract Dis*. 2020;24(2):132-143. doi:[10.1097/lgt.00000000000000529](https://doi.org/10.1097/lgt.00000000000000529)
63. Clarke MA, Wentzensen N, Perkins RB, et al. Recommendations for use of p16/Ki67 dual stain for management of individuals testing positive for human papillomavirus. *J Low Genit Tract Dis*. 2024;28(2):124-130. doi:[10.1097/lgt.000000000000000802](https://doi.org/10.1097/lgt.000000000000000802)
64. Division of Cancer Prevention, National Cancer Institute. *SHIP Trial—About the Study*. National Cancer Institute; 2025. Accessed July 28, 2025. <https://prevention.cancer.gov/research-areas/networks-consortia-programs/last-mile/ship-trial>
65. Lei J, Ploner A, Elfström KM, et al. HPV vaccination and the risk of invasive cervical cancer. *N Engl J Med*. 2020;383(14):1340-1348. doi:[10.1056/NEJMoa1917338](https://doi.org/10.1056/NEJMoa1917338)

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Perkins RB, Wolf AMD, Church TR, et al. Self-collected vaginal specimens for human papillomavirus testing and guidance on screening exit: An update to the American Cancer Society cervical cancer screening guideline. *CA Cancer J Clin*. 2026;e70041. doi:[10.3322/caac.70041](https://doi.org/10.3322/caac.70041)