FOR IMMEDIATE RELEASE
February 21, 2025
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New Guidelines Released for Self-Collected HPV Screening

Nine months after the U.S. Food and Drug Administration (FDA) approved self-collected Human Papillomavirus (HPV) testing as an alternative method of cervical cancer screening, the first-ever guidelines have been released to incorporate the option into clinical practice. The guidelines, "Self-collected vaginal specimens for HPV testing: Recommendations from the Enduring Consensus Cervical Cancer Screening and Management Guidelines Committee," were published in the *Journal of Lower Genital Tract Disease* on February 21, 2025.

Self-collection for HPV screening was approved by the FDA on May 17, 2024, but until now, no specific recommendations for clinical practice had been released. The FDA approval stipulates that self-collection is performed in a controlled, medical setting, usually a doctor's office or lab. The new guidelines, developed through a collaboration of 19 national organizations, advise clinicians and patients on how to manage the test results. If the results are negative (the outcome in approximately 90 percent of cases), the patient is recommended to re-test again in three years; most women who test should make an appointment to see their doctor for a cervical cytology or dual stain test, to determine if biopsies or treatment is needed to prevent cancer. Proceeding directly to biopsy is recommended for women whose self-collection test is positive for HPV 16 or 18, the most aggressive types of HPV. If extended genotyping is performed, then women testing positive for lower risk genotypes, HPV 56/59/66, may repeat the test in 1 year.

"Self-collection helps expand access to potentially life-saving screening to patients who would prefer not to have a speculum exam or whose primary care physicians don't conduct pelvic exams," said Dr. Rebecca Perkins, Enduring Guidelines co-Chair and senior author.

Self-collection also may offer additional benefits for the U.S. healthcare system by relieving patient backlog at hospitals and healthcare centers and increasing the number of women able to obtain cervical cancer screenings during a time of significant primary care provider shortages.

Self-collection is not recommended for those who experience abnormal bleeding or discharge, take medication that suppresses the immune system, or have had a recent abnormal HPV or Pap test results.

Cervical cancer originates in the cervix, the lower portion of the uterus, and is most frequently diagnosed in women aged 35-44. According to the American Cancer Society, more than 13,300 women will be diagnosed with and more than 4,300 will die from cervical cancer in the U.S. in 2025—despite the disease being preventable through screening and early detection.

The majority of cervical cancer cases occur in women who have not been screened," writes Dr. Nicolas Wentzensen, Enduring Guidelines co-Chair and lead author. "If you are satisfied with your current screening options, there is no need to make any changes. But with self-collection as a new, viable alternative, our hope is that everyone will have a choice that is both comfortable and convenient. If everyone gets screened, we can eliminate cervical cancer," adds Dr. Francisco Garcia, Enduring Guidelines co-Chair and ASCCP President.

The manuscript may be found here: Self Collection

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