

Evaluating the *Tradeoffs* of HPV Self-Collect for Cervical Cancer Screening



A self-collect vaginal swab is collected by the patient in a health care or private setting; and **should only be considered when the patient and healthcare provider (HCP) determine that it is not possible for the clinician to collect a cervical specimen and when notification, documentation, and follow-up processes are in place.**¹⁻⁴



HPV self-collect is **for individuals currently not participating or engaging in routine screening.** The lack of an organized screening program in the **US makes it difficult to identify under-screened or never-screened individuals.**⁴⁻⁸



Screening alone does not prevent cancer; positive HPV test results must be managed and treated. This requires communication with patients and ensuring all follow-up visits are conducted.⁹

Clinician-Collected Cervical Specimens are Preferred – ASCCP⁹

Patient and Provider Tradeoffs of HPV Self-Collection

Loss to Follow-Up: Notable concern with nearly 4-fold higher loss to follow-up compared to clinician-collection, as seen in the Dutch national program.⁹

Triage Testing: Cannot be performed on a vaginal specimen. A speculum exam for clinician collection of a cervical specimen for triage testing is recommended.⁹

Repeat Testing: Recommended every 3 years following HPV-negative results using self-collected vaginal specimens due to lack of longitudinal safety and effectiveness data.⁹

Cytology is needed in the following scenarios⁹:

- HPV 16/18 positive: requires immediate diagnostic evaluation (e.g. colposcopy) and ongoing surveillance.*
- HPV-positive, genotyping unknown.
- HPV HR12 (other) positive.
- HPV 45, 33/58, 31, 52, 35/39/68, 51 positive.

“...the primary risk associated with self-collected vaginal specimens may arise if regularly-screened individuals electively switch from clinician-collected cervical specimens to self-collected vaginal specimens, which could result in potential missed cervical disease cases that could have otherwise been detected and prevented using the current standard of care (i.e., clinician-collected cervical specimens).”

– FDA^{2,3}

“It is important to note that much of the evidence on self-collection (ie, patient collection) is from non-U.S. settings and involves patient-collected samples outside of the clinician office environment. The currently available patient-collected hrHPV tests are approved solely for samples ordered or approved by a clinician for patients aged 25–65 years.”

– ACOG⁴

“...self-collect vaginal specimens appear less sensitive and specific in comparison to clinician-collected cervical specimens.”

– FDA regarding HPV self-collect^{2,3}

“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 clinician-collected cervical samples have the advantage that cervical cells are obtained...”

– ASCCP⁹

Screening with HPV-Alone[†] Misses Cervical Cancer

1 in 5

cervical cancers were missed with HPV-Alone^{†10,11}

Screening with Pap + HPV Together (Co-testing) identified

70%

of the cancers missed by HPV-Alone^{†12}

95%

of cervical cancers were detected with Pap + HPV Together (Co-testing)^{†10,11}

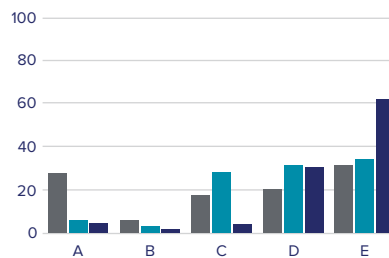
Provider Beliefs of Screening Modality Effectiveness¹³

“Fewer providers believed in the effectiveness of pHPV [Primary HPV] to reduce cervical cancer mortality and were less likely to recommend pHPV [Primary HPV] in the correct age group and screening interval compared with cytology-based screening modalities.”

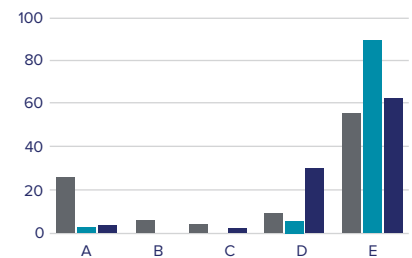
– Kruse, 2023¹³

”

21-29 Years Old



30-65 Years Old



A – I'm not sure B – Effectiveness unknown C – Not very effective D – Somewhat effective E – Very effective

● pHPV ● Co-testing ● Cytology Alone

Patient Preferences for HPV Self-Collect¹⁴



All women regardless of screening modality prefer to start screening at the age of 21.



Co-testing was the preferred screening method among adequately and under-screened women.



HPV self-collect was the least preferred method of screening among adequately screened women.



Under-screened women prefer co-testing over HPV self-collect.



Increasing cervical cancer screening by an HCP and educating women about improvements in accuracy is critical to help women avoid this preventable cancer.

^{*} As described in the 2019 ASCCP guidelines, collection of cervical cytology at the colposcopy visit is recommended because additional diagnostic testing and surveillance are required.

[†] A positive HPV screening result may lead to further evaluation with cytology and/or colposcopy.

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