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

HOLOGIC

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**.[1-3]

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**.

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.[4]

> *"...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., clinical-collected cervical specimens)."*
>
> *– FDA[2,3]*

Clinician-Collected Cervical Specimens are **Preferred – ASCCP[4]**

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.[4]

Triage Testing: Cannot be performed on a vaginal specimen. A speculum exam for clinician collection of a cervical specimen for triage testing is recommended.[4]

Repeat Testing: Recommended every 3 years following HPV-negative results using self-collected vaginal specimens due to lack of longitudinal safety and effectiveness data.[4]

Cytology is needed in the following scenarios[4]:

- 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.

> *"...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..."*
>
> *– ASCCP[4]*

Screening with HPV-Alone† Misses Cervical Cancer

1 in 5
cervical cancers were missed with HPV-Alone†[5,6]

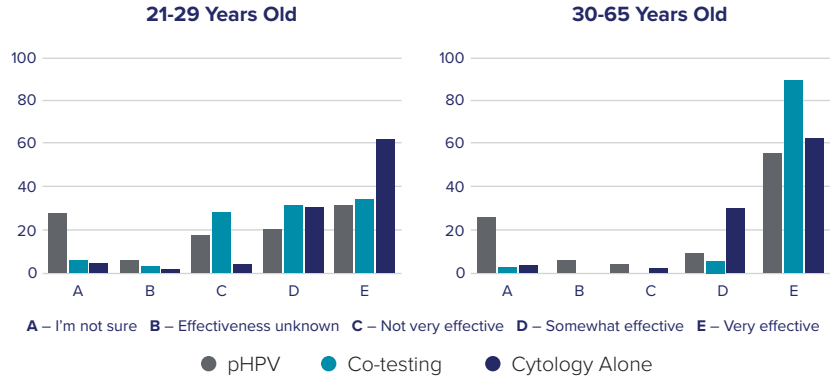
Screening with Pap + HPV Together (Co-testing) identified
70%
of the cancers missed by HPV-Alone†[7]

95%
of cervical cancers were detected with Pap + HPV Together (Co-testing)[5,6]

Provider Beliefs of Screening Modality Effectiveness[8]

*"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, 2023[8]



Patient Preferences for HPV Self-Collect[9]

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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