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Addendum to Guidelines for Cervical Cancer Prevention and Screening (January 2024) – Guidance on Self-Collected Vaginal Samples for HPV testing

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1 INTRODUCTION

The HKCOG Guidelines for Cervical Cancer Prevention and Screening was last updated in 2024 (1, 2). This addendum includes guidance for the use of HPV testing using self-collected vaginal samples with approved testing options in cervical cancer screening.

Human papillomavirus (HPV) testing (either as a stand-alone or co-testing with cytology) is currently the preferred primary screening method worldwide and is one of the recommended screening strategies in Hong Kong (3, 4). HPV testing has a higher sensitivity and provides better reassurance against cervical cancer following a negative test as compared to cytology. Additionally, HPV testing can be done on the self-collected vaginal sample. Thus, it can potentially increase screening uptake by expanding the accessibility and availability of screening to women who prefer self-sampling over clinician-sampling due to various reasons, and to areas with limited clinician access (5, 6).

HPV testing of self-collected vaginal samples has been studied extensively with systematic reviews and meta-analyses showing high sensitivity and agreement for precancer detection between self-collected vaginal and clinician-collected cervical samples when HPV PCR assays were used (6-8). Self-collected vaginal samples have been recommended by the World Health Organization (WHO) as a method of screening (9). Furthermore, self-sampling is gaining significant acceptance in many counties with incorporation of self-sampling as a screening option into the national screening programs, such as in Australia and the Netherlands (10, 11). Data from these screening strategies suggest that it can increase the screening participation. In Hong Kong, several local studies have shown that self-sampling is a well-accepted method for cervical cancer screening in terms of convenience, ease of use and privacy (12-14).

2 RECOMMENDATIONS

Clinician-collected cervical samples for HPV testing or co-testing are preferred, and self-collected vaginal samples for HPV testing are acceptable alternatives for cervical cancer screening.

Clinician-collected cervical sample is the standard of care for cervical screening and has the advantage of enabling HPV testing and reflex cytology or p16/Ki-67 dual-stain to be performed on the same sample because cervical cells are collected. Conversely, cytology or dual-stain cannot be performed on self-collected vaginal sample because it is not taken directly from the cervix. Hence, women who screen positive for HPV on the initial self-sample will need to attend for cervical sampling by clinician to further triage these women with cytology or dual-stain. Self-sampling has the potential to increase screening uptake by overcoming the barriers of clinician-collected sample, including factors related to the patient, clinician and health system (5).

The target population for HPV self-sampling is average-risk, asymptomatic women with a cervix aged 30 to 64 years (or ≥25 years if had HPV vaccination).

Women aged ≥65 years who never had cervical screening and with history of being sexually active can be offered HPV self-sampling.

HPV self-sampling is currently **NOT** recommended in the following scenarios:

- Symptomatic women, especially those with abnormal bleeding or vaginal discharge.
- History of hysterectomy with removal of cervix for benign disease or cervical dysplasia.
- Immunocompromised women (e.g. women with human immunodeficiency virus).
- Surveillance for previous abnormal results, after colposcopy or treatment.

Screening at 3-yearly intervals is recommended after an HPV-negative results on self-collected vaginal samples in the screening setting.

Evidence from systematic reviews supports the safety of 3-year screening interval (7, 15). Currently, there is insufficient long-term prospective data comparing self-collected and clinician-collected samples to decide on longer screening interval of 5 years as recommended for clinician-collected HPV testing.

When the self-collected vaginal samples are positive for HPV 16 and/or HPV 18, direct referral to colposcopy for concurrent collection of cervical cytology is recommended.

Women with HPV 16 and/or 18 have increased risk of CIN3+, and therefore colposcopy is indicated (See 2024 guidelines section 3.4.2.2 and Fig. 4) (1). As for the clinician-collected sample, this recommendation also applies to self-collected vaginal sample. During colposcopy visit, collection of cervical cytology should be done to inform on subsequent management.

When the self-collected vaginal samples are: (a) positive for high-risk HPV (untyped/ genotypes not available) or (b) positive for other types of high-risk HPV (non-16/18), clinician-collected cervical samples using a speculum for triage test (cytology or dual-stain) are recommended.

Studies have found good agreement for HPV genotyping between self-collected and clinician-collected samples (16-18). Therefore, subsequent management would be the same as clinician-collected samples (see 2024 guidelines section 3.4.2.2 and Fig. 4) (1). In summary, women with positive cytology (ASCUS or above) or dual-stain should be referred for colposcopy. If the cytology is normal or the dual-stain is negative, repeat HPV testing in 1 year is recommended. Women with initial results of normal cytology or dual-stain negative who have repeat HPV testing or co-testing at 1 year should be referred for colposcopy if the repeat test is HPV positive (regardless of type).

When the self-collected vaginal samples are inadequate or inconclusive, a repeat sample is recommended which can be done at any time.

When the first self-collected vaginal sample is inadequate or inconclusive, either a repeat self-collected vaginal sample or a clinician-collected cervical sample can be done at any time (no need to wait). However, after two consecutive inadequate or inconclusive self-collected vaginal samples, a clinician-collected cervical sample is recommended.

Clinician-collected cervical samples are preferred in surveillance setting (after previous abnormal results, colposcopy or treatment). Self-collected vaginal samples are acceptable after joint decision-making if clinician-collected samples cannot be performed.

Although the sensitivity of HPV test is comparable between self-collected and clinician-collected samples in different settings (e.g. screening and colposcopy), there is insufficient data to support the use of self-sampling in the surveillance setting (e.g. for test of cure after treatment of high-grade squamous or glandular abnormality). Moreover, women in surveillance setting have a higher risk of being HPV-positive, leading to more women needing clinician-collected sample for triage testing. Thus, clinician-collected cervical samples are preferred. However, if clinician-collected samples cannot be performed, self-collected vaginal samples are acceptable after joint decision-making with the women because it is better than no testing. If self-collected vaginal sample is utilised for surveillance, subsequent management should be according to the 2024 guidelines.

Self-sampling devices and HPV assays that have regulatory approval for primary HPV screening using self-collected vaginal samples should be used.

When considering recommendations for self-collected vaginal samples for primary HPV screening, only tests including the sampling kits and HPV assays with regulatory approval should be used. Currently, the combination of the BD Onclarity HPV assay with Copan 522C.80 swab and the Roche cobas assay with Copan 522C.80 swab or Evalyn brush have received US Food and Drug Administration (FDA) approval for primary HPV screening in self-collected vaginal sample (19).

Table 1: Management of self-collected vaginal samples results

HPV test results	Suggested actions
Negative for high-risk HPV	Repeat in 3 years
Inadequate/ inconclusive	Repeat at any time (no need to wait) • First inadequate/ inconclusive result, repeat with either self-collected vaginal sample or clinician-collected cervical sample • Two consecutive inadequate/ inconclusive results, refer for clinician-collected cervical sample
HPV 16 and/or 18 positive	Refer for colposcopy
Other high-risk HPV positive (non-16/18) or untyped HPV positive	Refer for clinician-collected cervical sample for cytology or p16/Ki-67 dual-stain. Manage according to the 2024 guidelines for HPV primary testing in Fig. 4

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