# Ontario Cervical Screening Program Guidance for Vaginal Vault Testing

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Ontario Health
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# Contents

# Acronyms and Abbreviations

| | |
|---|---|
| ACC | Adenocarcinoma |
| ACC-E | Endocervical adenocarcinoma |
| AGC | Atypical glandular cells |
| AIS | Adenocarcinoma in situ |
| ASC-H | Atypical squamous cells, cannot exclude HSIL |
| ASCUS | Atypical squamous cells of undetermined significance |
| CIN | Cervical intraepithelial neoplasia |
| HPV | Human papillomavirus |
| HSIL | High-grade squamous intraepithelial lesion |
| IR | Incidence rate |
| LSIL | Low-grade squamous intraepithelial lesion |
| LSIL-H | Low-grade squamous intraepithelial lesion, cannot exclude HSIL |
| OCSP | Ontario Cervical Screening Program |
| SCC | Squamous cell carcinoma |
| VaIN | Vaginal intraepithelial neoplasia |

# Introduction

## Purpose

The purpose of this document is to summarize the Ontario Cervical Screening Program (OCSP) guidance for vaginal vault testing. The guidance includes populations to consider testing, which test to use, when to test, how to manage human papillomavirus (HPV)-negative and HPV-positive results, and populations for whom vaginal vault testing is not appropriate. The supporting evidence and contextual factors used to develop this guidance are also summarized in this document.

## Scope

In scope for this guidance are people who have had a total hysterectomy (i.e., uterus and cervix removed) for benign indications, as well as those with a history of cervical dysplasia and early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) treated with hysterectomy, with or without cone biopsy. Note that these groups are in scope for *consideration* about appropriateness of vaginal vault testing, they are not necessarily appropriate to test. For guidance on who is appropriate to test, refer to the *Whom to test* section below.

Populations that are out of scope for this guidance are (1) those with a history of cervical cancer beyond stage 1A1, (2) those who have been treated with radical trachelectomy, radiation or chemotherapy, and (3) those who are under surveillance in the cancer system. Guidance for managing people in colposcopy is also out of scope at this time.

## Background

People who have had their cervix removed via hysterectomy are no longer at risk of developing cervical cancer, but because both cervical and vaginal cancer are HPV-related, these people may be at risk of developing vaginal cancer. Vaginal vault testing can be done to identify people at risk of vaginal cancer and its precursor, high-grade vaginal intraepithelial neoplasia (VaIN3). Currently in Ontario, some people continue to be tested with vaginal vault cytology after hysterectomy, especially when they have a history of cervical dysplasia.

Vaginal cancer is rare in Ontario with an incidence rate (IR) of 0.6 squamous cell cancers per 100,000 people from 2014-2018 (age-standardized to the age distribution of the 2011 Canadian Standard Population; unpublished data). Given the rarity of vaginal cancer in Ontario, Wilson and Jungner's principle of screening that a disease must be an important health problem is not met (1).

Another of Wilson and Jungner's principles of screening is that the natural history of the condition should be adequately understood (1). It is unclear if vaginal cancer meets this requirement. As with cervical cancer, there is a strong correlation between VaIN and HPV infection (2), and VaIN3 is considered a true pre-cancer (3). Additionally, while we know that vaginal cancer is more prevalent in older people (median age of diagnosis in Ontario is 68 years; unpublished data), the time from HPV infection to the development of VaIN3 and vaginal cancer is unknown.

The ability to adequately treat a disease once identified is another principle of screening (1). At this time, there is limited published evidence regarding the effectiveness of treatment of VaIN. Remission of VaIN often occurs after treatment (e.g., 70% of cases after a single treatment of VaIN1/2/3) (4). However, VaIN recurrence after treatment is also common. One review found 0–34% of cases of VaIN recurred after treatment (5). Furthermore, there is no agreement on the most effective treatment for VaIN (5, 6). Importantly, no evidence was identified that demonstrates the effectiveness of treating VaIN to prevent vaginal cancer. Therefore, it is unknown whether treating VaIN will result in reducing the incidence of vaginal cancer.

Given that several of Wilson and Jungner's principles of screening are not met, organized population-level screening for vaginal cancer is not appropriate. However, hysterectomy is a common procedure in Ontario (> 15,000 performed in 2014/15 [7]) and health care providers must frequently consider the role of vaginal vault testing in patients at risk of vaginal cancer. Currently, there are no evidence-based guidelines in Ontario that incorporate HPV testing to support decision-making on vaginal vault testing. Therefore, the OCSP has developed guidance that (1) identifies people for whom vaginal vault testing may be appropriate, and (2) provides a vaginal vault testing pathway.

The OCSP's guidance for vaginal vault testing was developed based on the following inputs: rapid reviews of the primary literature, Ontario data analyses, a jurisdictional scan, the OCSP's guiding principles and expert opinion from a multidisciplinary, international expert panel. In addition, the draft recommendations were shared for input with Ontario, national and international stakeholder groups and subject matter experts for review prior to finalization.

For more details on the methods, please refer to the Methods: Recommendation development section of the OCSP's Recommendations for Cervical Screening and Colposcopy with Human Papillomavirus Testing in Ontario document.

## Health Canada approval

The use of the HPV test is approved by Health Canada for health care provider-collected cervical samples but has not been reviewed or authorized by Health Canada for use in the vaginal vault. HPV test performance has not been specifically evaluated for detecting vaginal precancer/cancer in relevant populations, therefore risks to the patient may include, but are not limited to, a decrease in testing accuracy. The Ontario Cervical Screening Program Guidance for Vaginal Vault Testing has been developed by Ontario Health in consultation with a multidisciplinary, international expert panel. Other Canadian and international jurisdictions also provide guidance on using the HPV test in the vaginal vault. The information provided by Ontario Health is not intended to serve as a substitute for a clinician's professional experience, independent judgment and decision making. Ontario Health assumes no liability whatsoever for any errors or omissions associated with the information provided herein and furthermore assumes no liability for any decision or action taken by the clinician or others in reliance on the information contained in these materials.

# Vaginal vault testing guidance

## Who to consider testing

Based on Ontario data and limited published evidence, the post-hysterectomy population has been divided into two groups: **elevated-risk** and **low-risk** for vaginal intraepithelial neoplasia (VaIN3) and vaginal cancer.

The Ontario Cervical Screening Program (OCSP) advises that vaginal vault testing may be appropriate for the **elevated-risk group**. This group consists of two types of people (including women, Two-Spirit people, transmasculine people and nonbinary people):

- People with evidence of any of the following histologies in their cervix at hysterectomy (i.e., in the hysterectomy specimen), regardless of margin status or known HPV status:
  - low-grade squamous intraepithelial lesion (LSIL)
  - high-grade squamous intraepithelial lesion (HSIL)
  - adenocarcinoma in situ (AIS)
- People with a history of early cervical cancer (microinvasive cervical cancer, stage 1A1 only), regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy (i.e., cancer or pre-cancer may have been excised with a loop electrosurgical excision procedure [LEEP] or cone prior to hysterectomy).

Vaginal vault testing should only be performed on people in the elevated-risk group who are asymptomatic. Anyone with symptoms or signs of vaginal cancer (e.g., bleeding or lesions) should be immediately referred for appropriate evaluation and investigation.

The OCSP advises that vaginal vault testing is **not** appropriate for the **low-risk group.** This group consists of anyone who does not meet the criteria for the elevated-risk group, including:

- People with a history of LSIL, HSIL or AIS histology in the cervix but no evidence of it in the hysterectomy specimen.
- People with an unknown or no screening history, including Two-Spirit people, transmasculine people and nonbinary people who did not get cervical screening before their hysterectomy.
- People who have had an HPV-positive result in their screening history, but do not meet the elevated-risk criteria.

## Which test

Human papillomavirus (HPV) testing (with reflex cytology for people with HPV-positive results) should be used to test the vaginal vault in the **elevated-risk group**.

## When to test

Perform primary HPV test (with reflex cytology for people with HPV-positive results) approximately six to 12 months after hysterectomy (or at the first post-operative visit, if preferred), in the **elevated-risk group**.

## Managing HPV-negative test results

Vaginal vault testing can be stopped after one negative HPV result.

## Managing HPV-positive test results

Anyone with an HPV-positive result should be referred to colposcopy, regardless of HPV type or cytology result.

## Managing invalid HPV test results

An invalid HPV test should be repeated. If the repeat HPV test is invalid, refer to colposcopy.

## Interim guidance for people who had vaginal vault cytology testing post-hysterectomy before the launch of HPV testing in the OCSP

This interim guidance for vaginal vault testing is for people who already had one or more vaginal vault cytology test(s) before the formal guidance for vaginal vault testing was released to support the implementation of HPV testing in the OCSP.

People who had one or more vaginal vault cytology tests with normal results do not need more testing. If someone's most recent cytology was abnormal, they should be managed according to that cytology result (see Table 1).

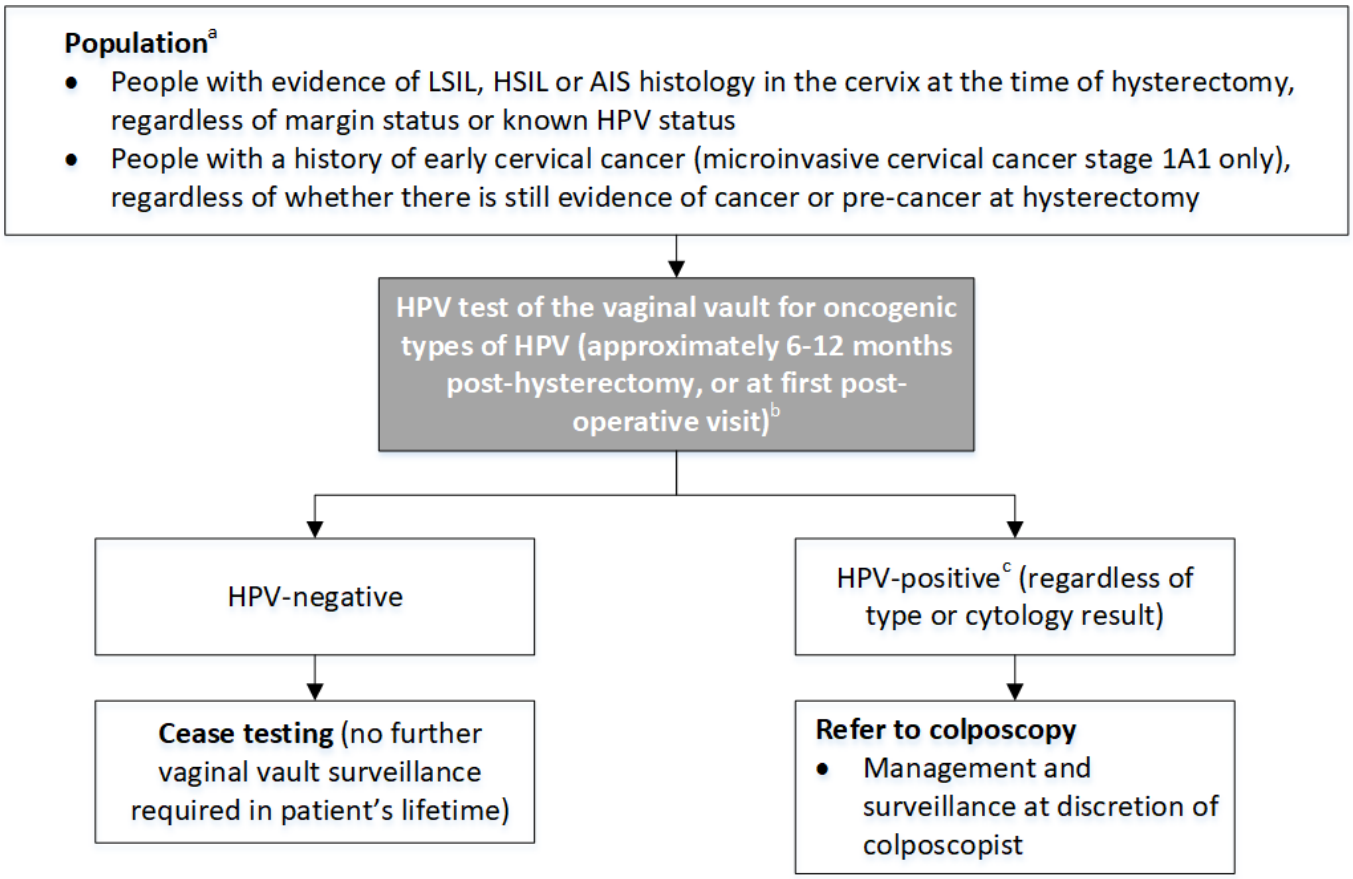
**Table 1:** Guidance for vaginal vault HPV testing for people who had vaginal vault cytology testing post-hysterectomy

| Most recent cytology-based vaginal vault test result (before HPV testing implementation) | Recommended next step (after HPV testing is implemented) |
|---|---|
| Normal | No further vaginal vault testing needed |
| Unsatisfactory | Do an HPV test if criteria for vaginal vault testing are met (i.e., LSIL, HSIL or AIS histology in the cervix at hysterectomy or a history of early cervical cancer [microinvasive cervical cancer stage 1A1 only], regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy)<br>If criteria for vaginal vault testing are not met, no further vaginal vault testing is needed |
| Low-grade (ASCUS, LSIL) | HPV test in 12 months |
| High-grade (ASC-H, LSIL-H, HSIL, AGC[a], AIS) | Refer to colposcopy |
| High-grade (SCC, ACC, ACC-E, PDC) | Refer to colposcopy or consider referral to gynecologic oncology centre if an obvious lesion is seen |

ACC: adenocarcinoma; ACC-E: endocervical adenocarcinoma; AGC: atypical glandular cells; AIS: adenocarcinoma in situ; ASC-H: atypical squamous cells, cannot exclude HSIL; ASCUS: atypical squamous cells of undetermined significance; HSIL: high-grade squamous intraepithelial lesion; LSIL: low-grade squamous intraepithelial lesion; PDC: poorly differentiated carcinoma; SCC: squamous cell carcinoma

[a]Includes AGC-N/NOS, AEC-N/NOS (AGC-N: atypical glandular cells – favour neoplastic; AGC-NOS: AGC– not otherwise specified; AEC-N: atypical endocervical cells – favour neoplastic; AEC-NOS: AEC– not otherwise specified)

**Figure 1:** Vaginal vault testing pathway for elevated-risk group




Legend:

Grey Screening test

AIS: adenocarcinoma in situ; HPV: human papillomavirus; HSIL: high-grade squamous intraepithelial lesion; LSIL: low-grade squamous intraepithelial lesion

[a]Out of scope for this guidance: (1) people with a history of cervical cancer beyond stage 1A1, (2) people treated with radical trachelectomy, radiation or chemotherapy, and (3) people under surveillance in the cancer system. People with a history of cervical cancer stage 1A2 and beyond who have had a negative HPV test during cancer surveillance do not require further vaginal vault HPV testing once discharged to primary care.

[b]If HPV test is invalid, repeat sample collection at the participant's earliest convenience (preferably within 3 months). If repeat test is invalid, refer to colposcopy

[c]Reflex cytology performed automatically by the lab on all positive specimens; results will support management in colposcopy

# Key evidence

## Who to consider testing

### Jurisdictional scan

Some jurisdictions such as Australia and the UK as well as the US-based American Society for Colposcopy and Cervical Pathology (ASCCP) provide guidance on vaginal vault testing for a variety of post-hysterectomy populations. Many aspects of this guidance vary across jurisdictions such as which populations to test and which test to use. This is likely because expert opinion was the primary input for the guidance due to a lack of high-quality published evidence. Given the lack of high-quality evidence and the variation in guidance across jurisdictions, the findings from this scan were not a major input to the Ontario Cervical Screening Program's (OCSP's) final guidance.

### Published literature

A rapid review was conducted to identify the risk of vaginal intraepithelial neoplasia (VaIN3) and vaginal cancer post-hysterectomy in two groups: (1) people with a history of high-grade squamous intraepithelial lesion/ adenocarcinoma in situ (HSIL/AIS) (defined in the review as cervical intraepithelial neoplasia [CIN] 3/AIS of the cervix), (2) people with a history of early cervical cancer.

One systematic review and seven cohort studies were identified that addressed risk in the first group (people with a hysterectomy and a history of HSIL/AIS (defined in the review as CIN3/AIS of the cervix). These studies were of generally low methodological quality and found a pooled five-year risk estimate of 0.50% for VaIN3 and 0.60% for vaginal cancer.

One of the studies included in the rapid review that addressed risk in the first group was a large Swedish cohort study of almost 5 million people that utilized registry data from 1987–2011 (8). This study was of higher quality than the others identified in the review and had the largest sample. The authors compared risk of vaginal cancer in four groups: 1) those with an intact cervix (had not had a hysterectomy), 2) those who had a hysterectomy without history of HSIL (defined in the study as CIN3 or AIS of the cervix [i.e., people with a benign cervical history]), 3) those who had a hysterectomy and had a history of HSIL or AIS of the cervix and 4) those who had prevalent low-grade squamous intraepithelial lesion (LSIL), HSIL (defined in the study as CIN or AIS of the cervix at hysterectomy). The study found that the risk of vaginal cancer is elevated in both those with a history of HSIL or AIS of the cervix (incidence rate [IR]: 17.1 per 100,000 person-years) and those with prevalent LSIL, HSIL or AIS of the cervix at hysterectomy and that risk was highest in the latter group (IR: 51.3 per 100,000 person-years).

A retrospective cohort study published after the rapid review was conducted was identified by an Expert Panel member. This study measured the risk of VaIN and vaginal cancer after a hysterectomy in those with and without a history of LSIL or HSIL of the cervix (defined in the study as CIN) (9). This study found that the incidence rate of VaIN 1/2/3 or squamous cell carcinoma was significantly higher among those with a history of LSIL or HSIL compared with those without this history (IR = 7.3% vs. 0.3%).

Based on this limited evidence, it appears that those with a history of HSIL or AIS of the cervix are at elevated risk and those with prevalent LSIL, HSIL or AIS in the cervix at hysterectomy are at the highest risk of developing VaIN and vaginal cancer. However, the disease is still very rare even in this group.

Only one study of weak methodological quality was identified that addressed risk in the second group (people with a hysterectomy and history of early cervical cancer). Therefore, there was insufficient evidence to make conclusions regarding risk in this population.

### Ontario data

Ontario data was analyzed to assess the risk of VaIN 2/3 and vaginal cancer post-hysterectomy (10). A retrospective cohort study was carried out on people who had a hysterectomy after a diagnosis of HSIL or AIS of the cervix

(defined in the study as CIN3+) and early cervical cancer between 2005–15 to determine subsequent risk of VaIN2/3 and vaginal cancer from 2010–2021. This analysis found that 1.9% (119/6,230) of people with a history of HSIL, AIS or early cervical cancer went on to be diagnosed with VaIN 2/3 and 0.3% (18/6,230) went on to be diagnosed with vaginal cancer. The analysis also found that the incidence of VaIN 2/3+ is higher in those with residual HSIL, AIS or early cervical cancer in the cervix at hysterectomy than in those without (5.8% vs. 2.1%).

The Ontario data indicates that risk of VaIN 2/3 and vaginal cancer is low, but higher for those with residual HSIL, AIS or early cervical cancer in the cervix at hysterectomy, which may support the evidence from the literature described above.

## Benefits and risks of testing

The expert panel considered the potential benefits and risks of vaginal vault testing when developing this guidance. One of the benefits of vaginal vault testing is that it may result in detection of VaIN3 in patients which can then be treated, potentially preventing some cases of vaginal cancer. However, as described earlier, there is no evidence on effectiveness of treatment to prevent invasive disease and therefore the impact of this potential benefit, if any, is unknown.

As with any medical test or procedure, the benefits of vaginal vault testing must be weighed against potential risks. Given the rarity of VaIN and vaginal cancer, a large number of people need to be tested to find one VaIN/cancer. Ontario cervical screening data estimate that 5,577 people need to be screened within three years to prevent one invasive cervical cancer. Extrapolating to squamous cell vaginal cancer, which has a much lower incidence rate (0.6/100,000 vs. 8.4/100,000 for cervical cancer [11]), the number needed to screen may be up to 14 times greater. This suggests that approximately 78,078 people need to be tested and may be exposed to the potential harms of testing (e.g., discomfort, anxiety related to positive test results, over testing and over treatment, etc.), to prevent one invasive vaginal cancer. An additional important risk to consider is the difficulty of performing an accurate exam due to anatomical challenges associated with colposcopy of the vaginal vault (5). This results in many interventions in colposcopy that do not yield any significant findings (9). The procedure can also cause significant discomfort, particularly for older patients (12).

## Summary

Based on the limited published evidence and Ontario data, the overall risk of vaginal cancer is low; however, some groups may be at elevated risk. As a result, two patient populations were identified:

- **Elevated-risk group**:
    - People with evidence of any of the following histologies in their cervix at hysterectomy (i.e., in the hysterectomy specimen), regardless of margin status or known human papillomavirus (HPV) status:
        - low-grade squamous intraepithelial lesion (LSIL)
        - high-grade squamous intraepithelial lesion (HSIL)
        - adenocarcinoma in situ (AIS)
    - People with a history of early cervical cancer (microinvasive cervical cancer stage 1A1 only), regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy (i.e., cancer or pre-cancer may have been excised with a LEEP or cone prior to hysterectomy)
- **Low-risk group**:
    - Anyone who does not meet the criteria for the elevated-risk group, including those with a history of LSIL, HSIL or AIS histology in the cervix but no evidence of it in the hysterectomy specimen and people with an unknown or no screening history (including Two-Spirit people, transmasculine people and nonbinary people who did not get cervical screening before their hysterectomy). Note that HPV positivity in someone's screening history is not an indication for vaginal vault testing.

## Which test

**Guidance**: HPV testing (with reflex cytology for people with HPV positive results) should be used for vaginal vault testing in the **elevated-risk group**.

HPV is highly associated with VaIN and vaginal cancer with 90-100% of people with VaIN1/2/3 testing positive for HPV, and 65–75% of people with vaginal cancer testing positive for HPV (13-16).

A rapid review did not find any evidence to determine the clinical performance of vaginal vault tests (HPV and/or cytology) for detecting VaIN3 and vaginal cancer for people with a history of HSIL or AIS (defined as CIN3/AIS/HSIL in the review methodology) and early cervical cancer treated with surgery alone. There is, however, some evidence of clinical test performance in populations previously diagnosed with VaIN. A prospective study evaluating test performance in 830 people post-hysterectomy and previously treated for VaIN (n=44) found that HPV testing has a sensitivity of 90%, specificity of 78%, positive predictive value of 56% and negative predictive value of 92% (17). In addition, a retrospective study compared test performance of cytology and the HPV test for detection of VaIN2/3 (n=529). This study calculated that the sensitivity of HPV testing was superior to that of cytology (92.3–93.5% vs. 58.8–80.8%) (18).

Although the available evidence is insufficient to make precise estimates of the performance of cytology or HPV testing in the vaginal vault (2), we can generalize from the evidence in populations previously diagnosed with VaIN which suggests that test performance is generally aligned to that observed for cervical screening. As a result, HPV testing with reflex cytology for positive HPV results will maximize test performance and minimize unnecessary referrals to colposcopy. (For more detail on the performance of primary HPV testing with reflex cytology in the cervix, refer to the Screening Test section of the Recommendations for Cervical Screening and Colposcopy with Human Papillomavirus Testing in Ontario document.) Also, providing guidance that is consistent with the OSCP's cervical screening recommendations supports ease of adoption for health care providers.

## When to test

**Guidance**: Perform primary HPV test (with reflex cytology for people with HPV positive results) approximately six to 12 months after hysterectomy, or at the first post-operative visit, if preferred.

This guidance is based on expert opinion. The time frame allows for sufficient healing after surgery and resolution of any inflammatory post-surgical changes that may mask the vault testing result. It also allows for physician discretion and consideration of various patient follow-up scenarios.

## Management of HPV-negative results

**Guidance**: Vaginal vault testing can be ceased after one negative HPV result.

People who have had a hysterectomy, including those with a history of LSIL or HSIL of the cervix, and who have one negative HPV test have very low risk of vaginal disease (i.e., VaIN or squamous cell carcinoma). After a negative HPV test, the incidence rate of VaIN 1/2/3 or squamous cell carcinoma is 0.1% in those with no LSIL or HSIL history and 0.7% in those with a LSIL or HSIL history. Comparatively, after a positive HPV test, the incidence rate of VaIN 1/2/3 or squamous cell carcinoma is 3.1% in those with no LSIL or HSIL history and 35.7% in those with a LSIL or HSIL history (9). While we do not have similar data on people with a history of AIS of the cervix, we think it is reasonable to generalize from the data on history of LSIL or HSIL and assume that people with a history of AIS will have a similarly low risk of VaIN or squamous cell carcinoma.

Given the low risk of disease in this group, risks of further testing (e.g., discomfort, anxiety related to positive test results, over testing and over treatment, etc.) likely outweigh the benefits.

## Management of HPV-positive results

**Guidance**: Any HPV-positive result should be referred to colposcopy, regardless of HPV type or cytology result.

For individuals who had LSIL, HSIL or AIS histology in the cervix at the time of their hysterectomy, a post-hysterectomy HPV-positive result may reflect evidence of persistent disease in the vaginal vault (9).

Additionally, Ontario data indicate that among people who had a hysterectomy after a diagnosis of HSIL of the cervix (defined in the study as CIN3+) and went on the be diagnosed with VaIN2/3 or vaginal cancer, 55.5% of the VaIN and cancer diagnoses occurred within two years of the hysterectomy (10). These data suggest that timely follow-up is important and referral to colposcopy after an HPV positive result should not be delayed.

Finally, while the evidence indicates that HPV 16 is the most common type of HPV infection associated with VaIN (VaIN1 = 23.4%, VaIN2/3 = 57.6%) and vaginal cancer (53.7%), there remain a significant portion of VaIN and cancers associated with other types of HPV (11). Therefore, referral to colposcopy is appropriate for any HPV-positive result and should not be limited to certain types.

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