Ontario Health
Cancer Care Ontario

Ontario Cervical Screening Program Guidance for Vaginal Vault Testing Frequently Asked Questions (FAQs)

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Overview

Population-based screening for vaginal cancer is not recommended as part of the Ontario Cervical Screening Program (OCSP) because vaginal cancer is rare and the effectiveness of treating its precursor has not been established. However, people who have their cervix removed via hysterectomy are still at risk for human papillomavirus (HPV)-related cancers, including vaginal cancer. Therefore, the OCSP has developed guidance on vaginal vault testing that will be released at the same time as the launch of HPV testing with reflex cytology in cervical screening and in colposcopy for screening-related abnormalities. This guidance is described in the Ontario Cervical Screening Program Guidance for Vaginal Vault Testing document available on the HPV testing implementation resource hub at ontariohealth.ca/hpvhub.

To support this change, FAQs have been developed for providers who may be involved in vaginal vault testing. The FAQs describe which populations to consider testing for, why and how to perform testing, and how to manage test results.

Glossary

Colposcopy: An examination of the cervix or vagina used to rule out the presence of pre-cancer or cancer. If a pre-cancer has been detected, treatment can be performed in colposcopy. Multiple visits in colposcopy may be required over an episode of care, depending on the results of the vaginal vault test or initial colposcopy visit, including whether treatment was required.

Human papillomavirus (HPV): A family of common viruses. There are over 100 types of HPV. Some types are oncogenic (cancer-causing).

Human papillomavirus (HPV) test of the vaginal vault: A test performed on a specimen from the vaginal vault to check for the presence of oncogenic types of HPV.

Reflex test: A test performed by a laboratory when the results of a previous test indicate that additional testing is required. The additional test is performed without requiring another order (requisition) from a health care provider. For the purposes of this document, a reflex test refers to vaginal cytology performed on a specimen that tests positive for HPV.

Vaginal vault cytology test: A test that looks for abnormal cell changes in the vaginal vault.

Eligibility for vaginal vault testing in the Ontario Cervical Screening Program

1. Does everyone need vaginal vault testing post-hysterectomy?

- No. The majority of people will not benefit from vaginal vault testing after a hysterectomy. However, the Ontario Cervical Screening Program has identified some people who are eligible for vaginal vault testing based on the results of their hysterectomy specimen and their history of cervical cancer.

2. Which populations are out of scope for the Ontario Cervical Screening Program Guidance for Vaginal Vault Testing?

- Populations out of scope for the guidance include:
    - People who have been treated for cervical cancer stage 1A2 and beyond;
    - People who have been treated with chemotherapy, radiation, or radical trachelectomy;
    - People who are under surveillance in the cancer system

3. Who is eligible for vaginal vault testing?

- Only people who are at the highest risk of developing vaginal intraepithelial neoplasia and vaginal cancer post-hysterectomy are eligible for vaginal vault testing.
- This group consists of two types of people (including women, transmasculine people and nonbinary people) who have had a hysterectomy:
    - 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., may have been excised with a loop electrosurgical excision procedure (LEEP) or cone prior to hysterectomy).

4. Who is not eligible for vaginal vault testing?

- The group not eligible for vaginal vault testing consists of anyone who does not meet the following eligibility criteria:
    - Evidence of low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL) or adenocarcinoma in situ (AIS) histology in the cervix at hysterectomy (i.e., in the hysterectomy specimen), regardless of margin status; or
    - A history of early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy.

- This includes people 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 transmasculine and nonbinary people who did not get cervical screening before their hysterectomy).
- HPV positivity in someone's screening history is not an indication for vaginal vault testing.

5. Should people who are human papillomavirus (HPV)-positive receive vaginal vault testing?

- HPV-positive status alone is not an indication for vaginal vault testing.
- People who are at highest risk of developing vaginal intraepithelial neoplasia and vaginal cancer post-hysterectomy may benefit from vaginal vault testing. This includes people who have evidence of low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL) or adenocarcinoma in situ (AIS) histology in the cervix at hysterectomy (i.e., in the hysterectomy specimen), regardless of margin status. It also includes people with a history of early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy (i.e., may have been excised with a loop electrosurgical excision procedure (LEEP) or cone prior to hysterectomy).
- For people not in this group, the potential risks of vaginal vault testing (e.g., discomfort, anxiety related to positive test results, over-testing and overtreatment) likely outweigh the potential benefits.
- Vaginal cancer is rare in Ontario. Additionally, the effectiveness of treating its precursor to prevent to vaginal cancer has not been established. These are two of the key reasons the Ontario Cervical Screening Program does not recommend population-level screening.

Performing vaginal vault testing

6. What is the suggested approach for collecting an adequate vaginal vault sample?

- When collecting a sample from the vaginal vault, use either of the following collection devices:
    - The broom-like device, or
    - The plastic spatula only (i.e., do not use the endocervical brush)
- Samples should be collected from the top of the vaginal vault in a back and forth, horizontal sweeping motion five times. The broom or spatula should make full contact with the vaginal mucosa at the top of the vault during collection.
- For more information, refer to the Ontario Cervical Screening Program (OCSP): How to Collect a Cervical Sample resource available on the human papillomavirus (HPV) testing implementation resource hub at ontariohealth.ca/hpvhub.

7. Who should perform the vaginal vault test?

- Multiple types of providers can perform the test, including:
    - Primary care providers;

- Colposcopists; and
- Gynecologists or surgeons who perform hysterectomy.

- A primary care provider may wish to seek guidance from the gynecologist who performed the hysterectomy and who has the relevant pathology results to determine whether a vaginal vault test is warranted. Pathology reports may also be accessible on provincial databases, such as Connecting Ontario, the Ontario Laboratory Information System (OLIS) or electronic medical records.

8. When should the vaginal vault test be performed?

- For those who are eligible, vaginal vault HPV testing (with reflex cytology) should be performed approximately six to 12 months after hysterectomy, or at the first post-operative visit, if preferred. Because the risk of vaginal intraepithelial neoplasia (VaIN) 2/3 or vaginal cancer is greatest in the two years immediately following hysterectomy, it is not necessary to do an exhaustive search for old hysterectomy specimen results that could have low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL) or adenocarcinoma in situ (AIS) histology. Ontario data indicate that 55 per cent of people who were diagnosed with VaIN2/3 or vaginal cancer after having HSIL of the cervix (defined in the study as cervical intraepithelial neoplasia [CIN]3+) and a hysterectomy received their VaIN2/3 or vaginal cancer diagnosis within two years of their hysterectomy[1].
- If a patient's hysterectomy specimen results are unknown and they do not have a history of early cervical cancer (microinvasive cervical cancer, stage 1A1 only), vaginal vault testing should not be performed.
- The guidance to performance the vaginal vault test six to 12 months post-hysterectomy is based on expert opinion. This 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 follow-up scenarios. In addition, this time frame is supported by Ontario data, which suggest that the time from hysterectomy to VaIN2/3 or vaginal cancer diagnosis is often two years or less.

9. Should I perform vaginal vault testing if someone's hysterectomy was more than 12 months ago?

- Providers can perform a vaginal vault test, regardless of when the hysterectomy occurred if the eligibility criteria are met:
    - People (including women, transmasculine people and nonbinary people) who have had a hysterectomy and have
        - 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)

- 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., may have been excised with a loop electrosurgical excision procedure [LEEP] or cone before hysterectomy)

- If someone's hysterectomy specimen results are unknown and they do not have a history of early cervical cancer (microinvasive cervical cancer, stage 1A1 only), vaginal vault testing should not be performed.

10. What if I do not have access to the results of a patient's hysterectomy specimen?

- If a patient's hysterectomy specimen results are unknown and they do not have a history of early cervical cancer (microinvasive cervical cancer, stage 1A1 only), vaginal vault testing should not be performed.
- Because the risk of vaginal intraepithelial neoplasia (VaIN) 2/3 or vaginal cancer is greatest in the two years immediately following hysterectomy, it is not necessary to do an exhaustive search for old hysterectomy specimen results that could have low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma in situ (AIS) or early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) histology. Ontario data indicate that 55 per cent of people who were diagnosed with VaIN2/3 or vaginal cancer after having HSIL of the cervix (defined in the study as cervical intraepithelial neoplasia [CIN]3+) and a hysterectomy received their VaIN2/3 or vaginal cancer diagnosis within two years of their hysterectomy[2].
- Only people who are at highest risk of developing vaginal intraepithelial neoplasia and vaginal cancer post-hysterectomy should be tested approximately six to 12 months after hysterectomy, or at the first post-operative visit, if preferred. This includes people with evidence of LSIL, HSIL or AIS histology in the cervix at hysterectomy (i.e., in the hysterectomy specimen), regardless of margin status. It also includes people with a history of early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy (i.e., may have been excised with a loop electrosurgical excision procedure (LEEP) or cone prior to hysterectomy).

11. Should I stop testing people who have been receiving regular vaginal vault cytology tests after hysterectomy prior to the launch of human papillomavirus (HPV) testing in the Ontario Cervical Screening Program (OCSP)?

- No further testing is required for people who have been receiving vaginal vault cytology tests after a hysterectomy and have had normal results.
- If someone's most recent vaginal vault cytology result was abnormal, manage them according to the cytology result (for details, refer to the Ontario Cervical Screening Program Guidance for Vaginal Vault Testing document available on the HPV testing implementation resource hub at ontariohealth.ca/hpvhub).

- Only people who are at the highest risk of developing vaginal intraepithelial neoplasia and vaginal cancer post-hysterectomy should receive vaginal vault testing. This includes people with evidence of low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL) or adenocarcinoma in situ (AIS) histology in the cervix at hysterectomy (i.e., in the hysterectomy specimen), regardless of margin status. It also includes people with a history of early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy (i.e., may have been excised with a loop electrosurgical excision procedure (LEEP) or cone prior to hysterectomy).

12. Should vaginal vault testing be done annually for people who are eligible?

- No. If the first vaginal vault human papillomavirus (HPV) test is negative, testing should stop. Research shows that people who have had a hysterectomy and one negative HPV test have a very low risk of vaginal disease (i.e., vaginal intraepithelial neoplasia or squamous cell carcinoma)[3].
- If someone's HPV test if positive, refer them directly to colposcopy, regardless of HPV type or cytology result.
- If someone is discharged from colposcopy back to primary care, the colposcopist should provide primary care providers with clear instructions for next steps (e.g., no further vaginal vault testing required). If this has not been done, primary care providers may contact the colposcopist for this information.
- In most cases, people who have been discharged from colposcopy will be able to stop vaginal vault testing.

13. Why do a reflex cytology test when anyone who is human papillomavirus (HPV)-positive should be referred to colposcopy?

- Cytology results can help determine management in colposcopy and supports fewer colposcopy visits because the cytology will be known at first visit.

Understanding the Ontario Cervical Screening Program's vaginal vault testing guidance

14. Is the vaginal vault testing guidance different for people who have squamous (low-grade squamous intraepithelial lesion (LSIL) or high-grade squamous intraepithelial (HSIL) lesion) versus glandular (adenocarcinoma in situ [AIS]) histology on their hysterectomy specimen?

- No. The guidance is the same whether someone has squamous or glandular histology on their hysterectomy specimen.

- The guidance is to perform a human papillomavirus (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. Vaginal vault testing can be stopped after one negative HPV test result. Anyone with an HPV-positive test result should be referred directly to colposcopy, regardless of HPV type or cytology result.

15. Is it appropriate to stop vaginal vault testing after one negative human papillomavirus (HPV) test?

- Yes. Research shows that people who have had a hysterectomy and one negative HPV test have a very low risk of vaginal disease (i.e., vaginal intraepithelial neoplasia or squamous cell carcinoma)[4].
- Given the low risk of disease for people who have a negative HPV test result, risks of ongoing testing (e.g., discomfort, anxiety related to positive test results, over-testing and overtreatment) likely outweigh the benefits.

16. What is the guidance from the Ontario Cervical Screening Program (OCSP) based on?

- The OCSP's vaginal vault testing guidance is based on:
    - The limited available published evidence*;
    - Ontario registry data that suggests that the risk for vaginal intraepithelial neoplasia and vaginal cancer post-hysterectomy is very low, including among people with a history of cervical dysplasia; and
    - Expert opinion gathered via expert panel.

* If new evidence becomes available, the OCSP will consider updating its guidance.

17. If someone has a history of high-grade squamous intraepithelial lesion (HSIL) histology or is human papillomavirus (HPV)-positive, and has no evidence of low-grade squamous intraepithelial lesion (LSIL), HSIL or adenocarcinoma in situ (AIS) histology in the cervix at hysterectomy, is it appropriate not to test them?

- Yes. The limited available evidence[5,6,7] suggests that it is appropriate to omit HPV testing in the vaginal vault after hysterectomy for people without evidence of LSIL, HSIL or AIS histology on their hysterectomy specimen, even if they have a history of HSIL histology or are HPV-positive.
- The benefits of vaginal vault testing must be weighed against potential risks. Given the rarity of vaginal intraepithelial neoplasia and vaginal cancer, a large number of people need to be tested to prevent one invasive vaginal cancer.
- People with a history of early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) regardless of whether there is still evidence of cancer or pre-cancer at hysterectomy (i.e., may have been excised with a loop electrosurgical excision procedure (LEEP) or cone prior to hysterectomy) are at higher risk and may be considered for vaginal vault testing.

18. If someone has no screening history, and has no evidence of low-grade squamous intraepithelial lesion (LSIL), high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma in situ (AIS) or early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) histology in the cervix at the time of hysterectomy, is it appropriate not to test them?

- Yes. The limited available evidence suggests that it is appropriate to omit human papillomavirus (HPV) testing in the vaginal vault after hysterectomy for people without evidence of LSIL, HSIL, AIS or early cervical cancer (i.e., microinvasive cervical cancer, stage 1A1 only) histology on their hysterectomy specimen, even if they have not had cervical screening prior to the hysterectomy (e.g., people who have undergone gender affirming hysterectomy before onset of screening).
- The benefits of vaginal vault testing must be weighed against potential risks. Given the rarity of vaginal intraepithelial neoplasia and vaginal cancer, a large number of people need to be tested to prevent one invasive vaginal cancer.

19. How should primary care providers manage people who have been discharged back to primary care after having a hysterectomy as part of their cervical cancer treatment for stages beyond 1A1?

- People who have had a negative human papillomavirus (HPV) test of the vaginal vault during cancer surveillance do not need more vaginal vault testing in primary care.
- If someone has not had an HPV test during cancer surveillance, their primary care provider should follow the guidance of their specialist at the time of discharge. If a primary care provider does not have clear instructions, they should contact the specialist for more information.

Vaginal vault testing and colposcopy

20. Does the Ontario Cervical Screening Program (OCSP) provide any guidance for managing people with abnormal vaginal vault tests in colposcopy?

- People with a positive human papillomavirus vaginal vault test should be referred to colposcopy as per the Ontario Cervical Screening Program Guidance for Vaginal Vault Testing available on the HPV testing implementation resource hub at ontariohealth.ca/hpvhub.
- The OCSP does not have guidance on management in colposcopy. Care is provided at the colposcopist's discretion.
- When discharging people back to primary care, colposcopists should provide primary care providers with clear instructions for next steps.

21. How should primary care providers manage people who are discharged from colposcopy after referral for a positive vaginal vault human papillomavirus test result?

- When discharging people back to primary care, colposcopists should provide primary care providers with clear instructions for next steps (e.g., no further vaginal vault testing required). If this has not been done, primary care providers may contact the colposcopist for this information.
- In most cases, people who have been discharged from colposcopy will be able to stop vaginal vault testing.

Administrative information

22. Will the Ontario Cervical Screening Program (OCSP) laboratory reports advise providers to stop testing following a negative vaginal vault human papillomavirus (HPV) test?

- Yes. As with the cervical screening laboratory reports, the vaginal vault laboratory reports will include test results and recommended next steps.
- There will be a separate vaginal vault test indication on the new OCSP screening requisition, which will enable the laboratories to identify vaginal vault tests and tailor the result messaging and next steps to the vaginal vault testing guidance.

23. Will people who are eligible for vaginal vault testing receive correspondence from the Ontario Cervical Screening Program (OCSP) like they do with routine cervical screening?

- No. People without a cervix will not receive correspondence from the OCSP, even if they are eligible for vaginal vault testing.
- Providers will need to advise eligible people that vaginal vault testing is appropriate for them and notify them of their results.

24. Is there an Ontario Health Insurance Plan (OHIP) billing code for vaginal vault testing in eligible people?

- For information on OHIP billing, please refer to the Ministry of Health's Resources for Physicians web page at ontario.ca/document/resources-for-physicians.
- You can also contact the Ministry of Health's Service Support Contact Centre by phone at 1-800-262-6524 or by email at SSContactCentre.MOH@ontario.ca.

25. Is human papillomavirus (HPV) testing of the vaginal vault approved by Health Canada?

- The use of the human papillomavirus (HPV) test is approved by Health Canada for health care provider-collected cervical samples, but it 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 pre-cancer or 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.

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