BC CANCER
CERVIX SCREENING
Provincial Health Services Authority

At-Home Cervix Screening Pilot

Frequently Asked Questions

Communicating
At-Home Cervix Screening
Information to Patients

www.screeningbc.ca/cervix

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Pilot Overview

The BC Cancer Cervix Screening Program is conducting a pilot to assess and optimize how best to offer and deliver HPV self collection kits to patients to complete cervix screening at home. After a patient collects their sample, it is delivered to the lab where HPV testing will be performed. Patients will be invited to participate in the pilot by mail. Several mailing strategies will be trialed during the pilot. The uptake of at-home cervix screening will be assessed in three cohorts:

1) Never-screened (including those with a Pap test ≥ 10 years ago);
2) Under-screened (Pap test 5-9 years ago); and
3) Routinely screened (Pap test 3-4 years ago).

The program will evaluate attendance at recommended follow-up through the pathway of care (follow-up Pap, colposcopy and/or treatment as needed) after a positive result. While at-home cervix screening holds promise to increase screening coverage, the optimal programmatic approach has yet to be determined. Furthermore, there are many system level changes that need to be established before offering at-home cervix screening to people and obtaining outcome information for the program. A pilot provides the opportunity to establish the infrastructure and test several strategies on a small scale.

At-home cervix screening offers an innovative approach to increase screening capacity within the system and has been shown to reduce barriers to screening.

Who is eligible for this pilot?

- Residents of pilot communities in BC;
- People with a cervix who are due for screening;
- Registered with Medical Services Plan; and,
- Ages 25 to 69 with ages ending in 0 or 5 (e.g. 25, 30, 35, etc.).

Who is ineligible for this pilot?

Participants who are ineligible for the pilot include those that are:

- Pregnant;
- Total hysterectomy;
- History of cervical intraepithelial neoplasia grade 2 or 3 or cervical cancer in the last five years;
- History of adenocarcinoma in situ of the cervix at any time in the past;
- Have had a solid organ transplant;
- HIV positive; or,
- Exhibiting symptoms:
    - Post coital bleeding, persistent intermenstrual bleeding and/or a persistent vaginal discharge that cannot be explained by benign causes such as infection should have a speculum examination by someone with experience in cervical disease. Referral to a colposcopist is appropriate and may be expedited if the clinical suspicion is high. A pap test is not required for referral.

How do people participate?

The pilot targets people living in specific communities in B.C. The pilot will be age-based and will target people who have an age ending in 0 or 5 to help transition the population to HPV-based screening from a three year interval with Pap testing, to a five year interval for those who are HPV negative.

Mailed invitations will be sent to eligible participants in each cohort. Participants may be offered screening in one of the following ways:

- Invitation(s) sent telling them how to request a kit;
- Invitation(s) sent telling them a kit will arrive in the mail for them in a few weeks (various intervals may be trialed during the pilot to determine the optimal interval for kits being sent); or,
- Invitation and kit sent together with instructions on how to collect their sample.

What happens after participants receive their kit?

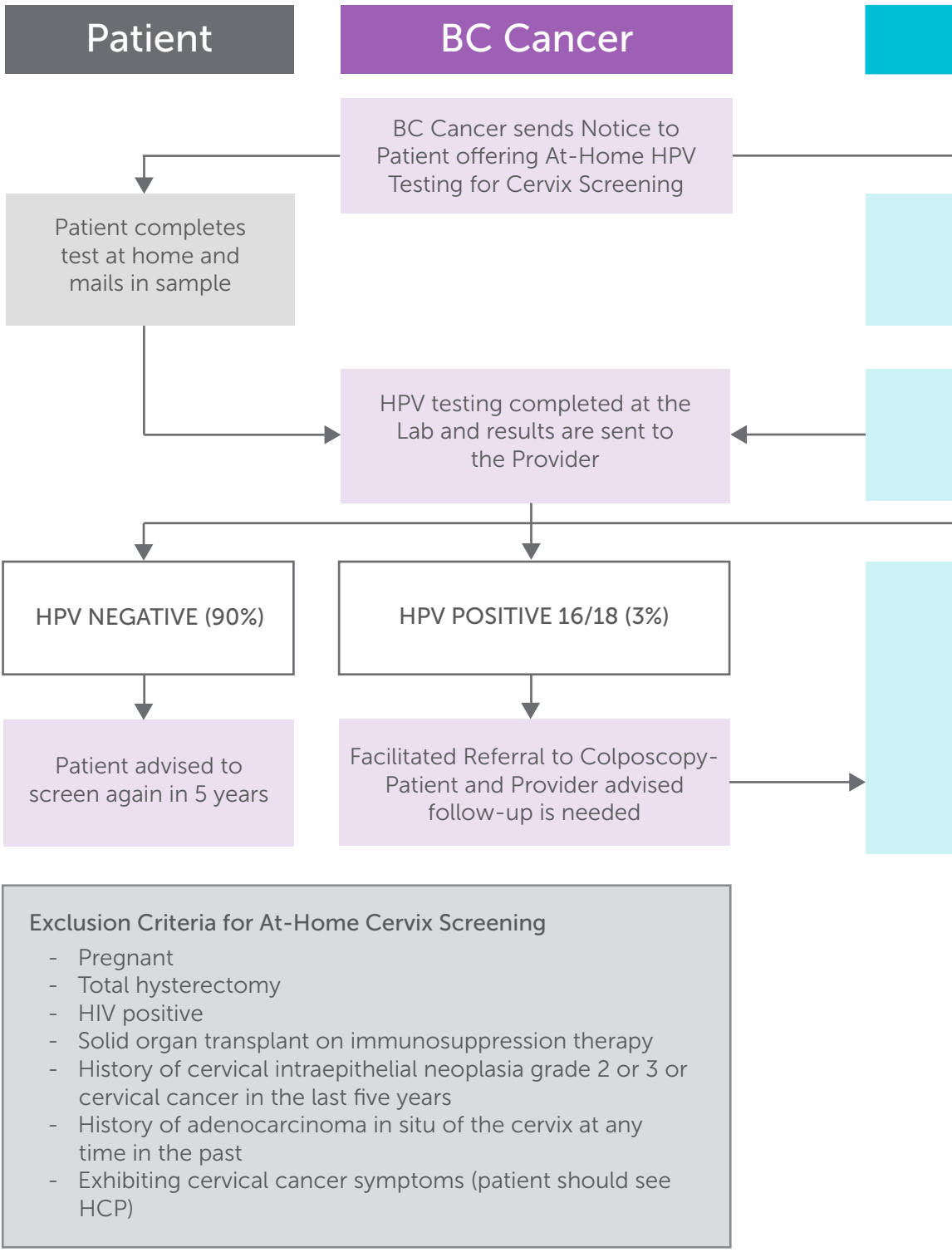
Participants will complete self-sampling following the instructions inside their kit. They will then drop off their completed kit at a Canada Post office or post box free of charge (each kit contains a prepaid return envelope provided by BC Cancer). Results will be sent to both participants and their health care provider (HCP) within 4 to 6 weeks after they drop off their kit. Please refer to the Pilot Flowchart (next page) and the Screening Results section (page 16) for information on the types of HPV results and recommended follow-up.

At-Home Cervix Screening Kit

Additional Questions?

For more information about the pilot, please visit our website at: www.screeningbc.ca/health-professionals or call the Cervix Screening Program at 1-877-702-6566.

Pilot Flowchart



Exclusion Criteria for At-Home Cervix Screening

- Pregnant
- Total hysterectomy
- HIV positive
- Solid organ transplant on immunosuppression therapy
- History of cervical intraepithelial neoplasia grade 2 or 3 or cervical cancer in the last five years
- History of adenocarcinoma in situ of the cervix at any time in the past
- Exhibiting cervical cancer symptoms (patient should see HCP)

Primary Care Provider

Some patients may have questions for their Provider about At-Home Cervix Screening or may request support to take the sample - Provider offers instruction and space to Patient to take their own sample or Provider takes sample

If taken at the Provider's office, the completed sample can be returned along with other Pap tests being submitted to the lab

Some patients may have questions for their Provider about HPV positive results and/or colposcopy

Some patients may need support from their Provider to ensure they attend all recommended follow-up

HPV POSITIVE OTHER (7%)

Patient advised a Pap test is required

Most patients who complete At-Home Cervix Screening will have a Provider and can access a Pap through their Provider

A few patients in the community may need to be connected to a Provider for a Pap test

Provider performs Pap test

Low or High Grade Pap Result (i.e. NOT NILM)

Facilitated Referral to Colposcopy

NILM Pap Result

HPV Test in 1 year

*NILM: Negative for intraepithelial lesion or malignancy

Human Papillomavirus (HPV) and Cervical Cancer

What is the relationship between HPV and cervical cancer?

Human papillomavirus (HPV) is a group of more than 100 different types of viruses - approximately 15 of which may cause anogenital cancers. HPV infection is very common, and will affect almost all individuals who have not received HPV vaccination at some point in their lives. Although most HPV infections will clear on their own, long-term infection with high-risk HPV (hr-HPV) can cause pre-cancerous changes to cells of the cervix, which can lead to cervical cancer if left undetected and untreated.

What the Evidence Says

- Approximately 99.7% of cervical cancers are associated with a persistent HPV infection preceding the invasive cervical tumour[1].
- Of the more than 100 known types of HPV, approximately 15 hr-HPV are known to cause cervical cancer[2]. The two most prevalent hr-HPV types (associated with ~70% of cervical cancers) are HPV-16 and 18[3-5].
- Low-risk HPV (lr-HPV) types cause anogenital warts (AGW) and are NOT associated with cervical cancer or its precursors. The two most common lr-HPV types are HPV-6 and 11.
- HPV is transmitted sexually, through skin to skin contact, which can include intimate touching, and oral, vaginal and anal sex[3].
- HPV is the most common sexually transmitted infection, infecting over 70% of all sexually active non-vaccinated Canadians at some point in their lives.
- The majority of HPV infections are cleared by the body's immune system within 2 years. This is particularly the case in adolescents and people under the age of 40[6-8].
- Research has found that long-term infection with hr-HPV types may lead to cervical pre-cancer which can progress to cervical cancer if left undetected and untreated[9-10].
- It typically takes 10 to 15 years from the time of an initial hr-HPV infection to the development of cervical cancer[11].
- It is not possible to predict which pre-cancerous lesions will become a cancer and which will regress. As a result, the threshold for treatment in British Columbia is cervical squamous intraepithelial neoplasia grade 2 (CIN 2).

Did You Know?

- HPV is very common - over 70% of all sexually active Canadians who have not received the HPV vaccine will get HPV at some point in their lives.
- Long term infection (usually lasting 10 years or more) with a high-risk type of HPV may lead to cervical cancer if left undetected and untreated.

What Your Patient Should Know

- HPV is sexually transmitted through skin to skin contact which includes intimate touching, and oral, vaginal and anal sex.
- There are two groups of HPV - low-risk and high-risk types. Long term infection (usually lasting 10 years or more) with a high-risk type of HPV may lead to cervical cancer if left undetected and untreated.
- HPV is a very common virus - most people will have an HPV infection at some point in their lives without them even knowing. HPV is usually harmless and clears on its own within about 2 years.
- In a small portion of people, HPV does not clear on its own, and can over time, cause changes to the cells on the cervix that cannot be seen or felt. These abnormal cells may turn into cervical cancer if not found and treated early.
- By looking for HPV and identifying abnormalities early, abnormal cell changes can be treated and cervical cancer can be prevented.

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HPV Testing

What is HPV Testing?

HPV testing involves collecting a sample from either the vagina or the cervix. The sample is checked for high-risk HPV DNA on a molecular diagnostic machine. HPV testing detects the presence of HPV, the virus that causes cell changes to the cervix, providing the ability to identify individuals at risk for having cell changes, often before they develop. HPV-based screening has been shown to detect pre-cancerous lesions earlier and better than cytology[1,2]. HPV testing has higher sensitivity and higher negative predictive value than cytology screening; as a result, the interval between negative screens can be safely extended. Those who test positive for HPV may be considered higher risk for cervical pre-cancer, and therefore, will require follow-up.

What the Evidence Says

- Cervical pre-cancer and cancer are caused by hr-HPV types. Testing for hr-HPV can identify people at higher risk of having pre-cancerous changes of the cervix.
- There has been extensive research on the use of polymerase chain reaction (PCR) HPV DNA testing for primary cervix screening, which has led to the implementation of HPV DNA testing in a variety of jurisdictions globally[1].
- Research from BC has shown when cytology is combined with HPV testing, or when HPV testing is used alone, there is earlier and enhanced detection of pre-cancerous lesions and a reduction in subsequent cancerous lesions[2-4].

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What Your Patient Should Know

- HPV has always caused cervical cancer, but when screening was first introduced, this was not known and the ability to test individuals for HPV was not available. We now have the technology available to screen with testing that identifies the presence of cancer causing HPV types.
- HPV testing is well established to be safe and accurate for cervix screening. The test looks for high-risk types of HPV known to cause cervical cancer.
- Having a positive HPV test result does not mean you have or will develop cervical cancer. A positive result helps to identify those who may be at risk of developing cervical abnormalities. Cervical abnormalities can be treated before they become cancer. Therefore, it is important to attend all follow-up appointments.
- If no HPV is found, the chances of having abnormal cervix cell changes are very low for many years. Because of the improved detection in HPV testing, people can go longer between screening visits when no HPV is detected.

HPV Self-Sampling Process

How does the HPV self-sampling process work?

Unlike a Pap test, which requires that a health care provider collects cells from a patient's cervix, samples tested for HPV can be taken from either the cervix or the vagina. This presents the opportunity for people to safely and easily collect their own samples for cervix screening. The sample is then tested at the laboratory for the presence of hr-HPV.

Health care providers play a critical role in supporting patients to feel comfortable with using at-home cervix screening instead of seeing a provider for a Pap test. Health care providers also play a vital role when it comes to educating patients about their HPV result, implications for testing, and what type of follow-up to expect. Your patients may have questions about this new approach to screening. Some patients may want to know that you support them in completing at-home cervix screening, and others may bring their kit into your office to collect their sample themselves or to have you take their sample for them.

What the Evidence Says

- Self-collected HPV samples are as accurate in detecting pre-cancerous lesions or cancer as health care provider-collected HPV samples[1].
- Several countries including the Netherlands, Australia, and the UK have implemented HPV testing as the primary screening method for cervical cancer. Both Australia and the Netherlands currently offer self-sampling to under-screened patients through their national programs[2].
- HPV self-sampling has been proven to address many of the barriers associated with irregular or non-attendance at cervix screening, including inability to attend clinics, cultural barriers, trauma, and indirect costs (e.g. childcare, time-off work)[3-4].
- HPV self-sampling has been found to be highly acceptable among people; in one systematic review and meta-analysis, participants reported that they prefer self-sampling over HPV testing by their health care provider, citing factors such as ease and privacy[5].
- Offering self-collected HPV testing has been shown to increase participation in cervix screening, particularly among non-attenders[6-9].
- The acceptability and feasibility of using mailed HPV self-sampling kits to reach under-served people for screening have been well demonstrated in Canada among street-involved or otherwise marginalized women[4], rural communities[10], and Indigenous communities[11].

What Your Patient Should Know

- Self-sampling for cervix screening is easy, safe and should not be painful.
- Studies show self-collected samples are just as accurate as samples collected by a health care provider.
- Self-sampling provides patients with flexibility to take the sample at a time and place convenient to them.
- Patients are capable of collecting their own sample. If no sample was collected or if there was insufficient sample, the test will come back with an invalid result.

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HPV Testing Interval

Why is the recommended screening interval for HPV testing every 5 years when the Pap test is every 3 years?

Reasons for the increased screening interval include:

1) HPV testing is much more sensitive and effective at identifying people at greater risk of developing pre-cancerous cervical lesions than cytology screening (Pap test);
2) An HPV infection needs to persist for many years, usually 10 or more, for it to lead to cervical cancer;
3) HPV is very common and will often go away on its own without a person even knowing they had it;
4) There are harms to over-screening including unnecessary follow-up and treatments, some of which may have long-term consequences for pregnancy or cause undue anxiety and distress.

What the Evidence Says

HPV testing is more sensitive and effective at identifying people at greater risk of developing pre-cancerous cervical lesions than cytology screening (Pap test)[1-4].

- The recommended screening interval for cytology screening (Pap test) is 3 years to enhance the performance/sensitivity of the test, not because cell changes occur that quickly. Since HPV testing has much higher negative predictive value, the interval between negative screens can be safely extended to 5 years[5-8].
- It is now well established that a negative HPV test is associated with significantly lower risk of cervical pre-cancer and cervical cancer compared to a negative Pap test, allowing people to go longer between negative HPV tests than they can between negative Pap tests[2,9-13]. HPV testing every 5 years is as safe as Pap testing every 3 years.

Cervical cancer develops very slowly.

- Cervical cancers develop starting with cellular atypia due to infection with hr-HPV types, then cervical pre-cancer, and finally invasive cervical cancer. It typically takes 10 to 15 years from the time of an initial hr-HPV infection to cancer.

HPV is very common and will often go away without a person even knowing they had the virus[14].

- The majority of HPV infections are cleared by the body's immune system, especially among adolescents and younger people[15-17].

There are risks associated with unnecessary follow-up and treatments.

- Over-diagnosis and treatment of transient lesions are associated with potential harms, most importantly an increased risk of pre-term and low-birth weight babies (especially for people treated with excisional approaches), but also adverse psychosocial consequences[18-20].

What Your Patient Should Know

- Due to the accuracy of HPV testing, it is safe for people to go longer between screenings than they are used to with Pap testing.
- The Pap test can sometimes miss finding abnormal cells. Screening every three years using a Pap test has more to do with ensuring the accuracy of the Pap test, and less to do with how quickly cervical cancer could develop between screenings. It can take more than a decade for HPV to cause cervical cancer.
- HPV testing every 5 years is as safe as Pap testing every 3 years.
- HPV is very common in the population and will often go away on its own within about 2 years, without a person even knowing they had it.
- Over-screening increases the likelihood of causing harm, including unnecessary follow-up and treatments, some of which may have long-term consequences for pregnancy or cause undue anxiety and distress.

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HPV Vaccine and Cervical Cancer

Do individuals who have received the HPV vaccine still need to be screened?

People who have received the HPV vaccine still require screening because the vaccine does not protect against all types of HPV that can cause cervical cancer, nor does it protect against HPV types a person may have been exposed to prior to vaccination.

What the Evidence Says

- There are two HPV vaccines available in Canada: Cervarix® (HPV2) and Gardasil®9 (HPV9). The HPV9 vaccine is approved for use in both males and females and is offered through school-based immunization programs in BC. The HPV2 vaccine is only approved for use in females aged 9 to 45[1].
- Both vaccines protect against 2 types of HPV that cause about 70% of cervical cancer cases and 80% of anal cancer cases. The HPV9 vaccine protects against 5 additional types of HPV that cause 15% to 20% of cervical cancers, and 11% of anal cancers in women and 4% in men. The HPV9 vaccine also protects against 2 types of HPV that cause about 90% of cases of genital warts[1]. For more information on the HPV vaccine, visit www.immunizebc.ca/hpv.
- The same screening approach must be applied to both vaccinated and unvaccinated individuals because the HPV types that are not prevented by the vaccine can also cause cervical lesions.
- Use of the HPV vaccine will reduce the number of individuals with positive cervix screening results and cervical pre-cancers.

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What Your Patient Should Know

- The HPV vaccine protects against the main types of HPV that can cause changes in the cells of the cervix, but not all. People who received the HPV vaccine should still screen regularly.
- Millions of doses of the HPV vaccine have been administered worldwide and has been proven to be very safe and effective.
- People who received the HPV vaccine should still screen regularly.
- For more information on the HPV vaccine, please visit Immunize BC at: www.immunizebc.ca/hpv.

Screening Results

What types of results are there and what does it mean?

HPV test results are reported by the laboratory to the provider.

- HPV Negative: this means the patient is negative for HPV 16, HPV 18 and Other High-Risk HPV Types.

  Average risk patients are recommended to screen again in five years.

- HPV 16 and/or 18 Positive (Positive Result): this means HPV 16 and/or 18 was found in the patient's sample. Colposcopy is recommended.

  Patients will be automatically referred to colposcopy by the Cervix Screening Program on behalf of their health care provider. Patients will be sent a letter advising them that the result of their screening test indicates further follow-up is needed and that they will be contacted by a colposcopy clinic to arrange for follow-up.

- Other HPV High Risk Types (Positive Result): this means a high-risk type (other than HPV 16 and/or 18) was found in the sample the patient provided. A Pap test is recommended.
  - Cytology (Pap) negative for intraepithelial lesion or malignancy (NILM): Patients will be sent a letter advising them that a Pap test is recommended and to book an appointment with their health care provider.

    Results will also be sent to the patient's health care provider. Participants who are HPV positive for other subtypes with a NILM cytology result will be recommended to have another HPV test in 12 months.
  - Cytology (Pap) result other than NILM (ASC-US, LSIL, ASC-H, HSIL, AGC or invasive carcinoma): Colposcopy is recommended. Results will be sent to the patient's provider.

    Patients will be sent a letter advising them that the result of their screening test indicates further follow-up is needed and that they will be contacted by a colposcopy clinic to arrange for follow-up. Patients who are positive for other HPV types with cytology results other than NILM will be automatically referred to colposcopy by the Cervix Screening Program on behalf of the ordering provider.

- HPV invalid results or unsuitable for testing: This will be reported when the specimen could not be tested (e.g. broken container) or when the test was completed but determined to be invalid (i.e. when no DNA was found in the sample). Repeat HPV testing is recommended, a new kit will be mailed to patients.

Acronyms:

NILM:	Negative for intraepithelial lesion or malignancy
ASC-US:	Atypical squamous cells of undetermined significance
LSIL:	Low-grade squamous intraepithelial lesions
ASC-H:	Atypical squamous cells, cannot exclude a HSIL
HSIL:	High-grade squamous intraepithelial lesions
AGC:	Atypical glandular cells

What Your Patient Should Know

- If your patient is HPV negative (no high-risk HPV was found), they will be advised to screen again in five years. HPV testing every 5 years is as safe as Pap testing every 3 years.
- If they have a positive HPV test result (HPV 16 and/or 18 positive), they will be automatically referred to colposcopy on your behalf and will be contacted by a colposcopy clinic to arrange for follow-up.
- If they have a positive test result (other high-risk HPV type positive), they will be recommended for cytology (Pap testing).
- Patients may experience a range of feelings when learning about their positive HPV test result. First and foremost, it is important to remind them that having a positive result does not mean they have or will develop cancer. However, it is important that they attend all recommended follow-up and treatments.

Discussing HPV Test Results

What does a positive HPV result mean?

A positive HPV test result means that a high-risk HPV type was found in the sample the patient submitted. A positive HPV test result can lead to your patient to have a variety of feelings and questions. First and foremost, it is important to reassure them that positive results are very common and does not mean they have or will develop cervical cancer.

What the Evidence Says

- It is important to reassure patients about their positive HPV test result and to ensure they receive the recommended follow-up and treatment.
- HPV testing is only effective if the recommended follow-up and treatment is provided to patients. In fact, appropriate follow-up care and treatment have a greater impact on mortality reduction than high screening coverage. It has been estimated that follow-up and treatment of 50% of patients detected with pre-cancerous lesions in a setting with 100% screening coverage reduces mortality by 50%; while 100% follow-up and treatment in a context of 50% screening coverage reduces mortality by 70%[1].
- When patients receive a positive HPV test result, they may feel a variety of emotions including fear, shame, and guilt. These feelings may impact a patient's adherence to recommended follow-up and treatment. Therefore, it is important to offer support and counseling to patients when discussing their positive HPV test result[2].
- Counseling can involve encouraging patients to share what knowledge they have about HPV and cervical cancer, their experience with gynecological examinations and the goals they have for their care. Providers are encouraged to listen for any fears and concerns their patients have and to probe for any doubts or questions about what the HPV test result means for them[2]. This will help providers to better support their patients and promote adherence to follow-up.
- Providers are also encouraged to share information on the follow-up procedure with their patients, including what to expect, how the procedure is performed and what the intended outcomes of the procedure are[2].
- Patients may wish to discuss their results and concerns over a few appointments and providers are encouraged to have patients take the lead in the pace and content of these discussions.

References

[1] Murillo R, Almonte M, Pereira A, Ferrer E, Gamboa OA, Jeronimo J, Lazcano-Ponce E. Cervical cancer screening programs in Latin America and the Caribbean. Vaccine. 2008:26 Suppl 11:L37-L48.

[2] Cinical Prevention Services. HPV: A Patient's Guide. Vancouver: BC Centre for Disease Control; 2019. Available from: https://smartsexresource.com/sites/default/files/handouts/bccdc-hpv-patient-guidebook-V07.pdf

What Your Patient Should Know

- Having a positive HPV test result does NOT mean you have or will develop cervical cancer. However, it is important that you attend all recommended follow-up and treatment.
- HPV is very common in the population. Most sexually active people who have not received HPV vaccination will have an infection at some point in their lives.
- We can assume that most people at some point in their lives will be in contact with HPV. It's not possible to determine when or from whom they acquired HPV. HPV can persist for many years before it is detected.
- Having HPV will not affect your ability to get pregnant.

What Your Patient May Ask You

Should I tell my partner my results?

It is your choice whether or not you tell them. HPV is very common and most people who are sexually active will get HPV at some point in their lives. In fact, over 70% of all sexually active Canadians will have at least one HPV infection in their lifetime.

Should my partner get screened?

Anyone with a cervix and between the ages of 25 and 69 should receive routine cervix screening.

If your partner does not have a cervix, there is no screening test available at this time.

Notes

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