Getting ready for the implementation of human papillomavirus (HPV) testing in the Ontario Cervical Screening Program (OCSP)

Waterloo Wellington Regional Cancer Program

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Land acknowledgement





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Implementation of HPV Testing in the OCSP

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- Neil Naik has received payment from WWRCP whose deliverables are being discussed in this program
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Mitigating potential bias

• This program does not reflect the opinions of the speaker(s) and was designed by Ontario Health (Cancer Care Ontario) using evidence-based content

Inclusive language

- There are many gender identities
- Inclusive language can help screen-eligible people understand whether screening is for them

Agenda topics

- Quiz
- Cervical cancer in Ontario and about the OCSP
- HPV and cervical cancer
- Understanding HPV testing
- Cervical screening terminology
- New cervical screening recommendations
- Colposcopy
- Post-discharge from colposcopy
- Vaginal vault testing
- Case studies
- Changes to your practice





Fill in the blank: Approximately ______ of sexually active people will have at least 1 HPV infection in their lifetime

- a) 50%
- b) 80%
- c) 60%
- d) 20%





True or False: Almost all cervical cancers are caused by persistent infection with oncogenic types of HPV

a) True

b) False





Fill in the blank: It typically takes ______ for persistent infections with oncogenic types of HPV to develop into cervical cancer

- a) Less than 6 months
- b) 1 to 5 years
- c) 5 to 10 years
- d) 15 to 20 years



Cervical cancer in Ontario and about the OCSP

Burden of cervical cancer in Ontario

- About 530 people are diagnosed with cervical cancer every year and 160 die from it
- Most cervical cancers are found in people who have never been screened or have been screened less often than recommended

• From 2017 to 2019, 35.5% of the people diagnosed with invasive cervical cancer had not been screened in the previous 10 years

Source: Subramaniam A, Fauci J, Schneider K, et al. Invasive Cervical Cancer and Screening: What are the Rates of Unscreened and Underscreened Women in the Modern Era? Journal of lower genital tract disease. 2011;15(2):110-113.

The OCSP

- A population-based organized screening program
- Goal is to reduce people's risk of developing or dying from cervical cancer
- Aims to achieve this goal by increasing the percentage of people who get screened regularly and who have timely and appropriate follow-up when necessary

Population-based organized screening

Population benefits maximized and harms minimized



Disease/Condition Principles

- Common and burdensome
- Detectable preclinical phase
- Defined population



Test/Intervention Principles

- Acceptable accuracy
- Safe and easy to implement
- Acceptable to patients



Program/System Principles

- Supportive infrastructure: coordination or integration
- Quality improvement and performance management

HPV and cervical cancer

About HPV

- HPV infections are common and 80% of sexually active people will have at least 1 HPV infection in their lifetime
- There are over 100 types of HPV and 13 types are known to be oncogenic (cancer-causing or high-risk) – HPV types 16, 18 and 45 are of particular concern
- Persistent infection with oncogenic types of HPV is the main cause of cervical cancer

Natural history of cervical cancer

 It takes 15 to 20 years for persistent infection with oncogenic types of HPV to develop into cervical cancer



Source: World Health Organization. Cervical Cancer [Internet]. 2019 [cited 2022 Sep 22]. Available from: https://www.who.int/news-room/fact-sheets/detail/cervical-cancer

Natural history of HPV clearance



Risk of progression to cervical cancer varies by HPV type



Understanding HPV testing

HPV testing vs. cytology

	HPV test	Cytology test
One-time sensitivity* (range) ¹	96.1% (94.2% to 97.4%)	53.0% (48.6% to 57.4%)
One-time specificity** (range) ¹	90.7% (90.4% to 91.1%)	96.3% (96.1% to 96.5%)
Detects	Oncogenic (cancer causing) types of HPV	Abnormal cell changes in the cervix
Interpretation	Objective and reproducible ²	Subjective

*Sensitivity: The effectiveness of a screening test in detecting pre-cancer and cervical cancer in people who have pre-cancer and cervical cancer **Specificity: The effectiveness of a screening test in indicating a normal result in people who do not have pre-cancer and cervical cancer

Key takeaway:

HPV testing has higher sensitivity, but lower specificity than cytology testing

Sources:

1. Cuzick J, Clavel C, Petry KU, Meijer CJ, Hoyer H, Ratnam S, et al. Overview of the European and North American studies on HPV testing in primary cervical cancer screening. Int J Cancer 2006;119:1095-101. 2. Stoler MH, Schiffman M. Interobserver reproducibility of cervical cytologic and histologic interpretations: realistic estimates from the ASCUS-LSIL triage study. JAMA 2001;285:1500-5.

Negative predictive value of HPV tests

# of years after negative HPV test	Outcome	Negative predictive value ^a	Author
5	HSIL histology and cervical cancer (defined in the study as CIN3+)	0.9968	Elfström et al.
6	HSIL or AIS histology and cervical cancer (defined in the study as CIN3+)	0.997	Dillner et al.

^aThe likelihood that negative results will correctly identify people who do not have a high-grade squamous intraepithelial lesion (HSIL) or adenocarcinoma in situ (AIS) histology and cervical cancer and will not develop these outcomes in the next 5 years

Key takeaway:

A negative HPV test result has long-term protection against high-grade histology and cervical cancer

Sources:

1. Elfström KM, Smelov V, Johansson AL V., Eklund C, Naucler P, Arnheim-Dahlstrom L, et al. Long term duration of protective effect for HPV negative women:

follow-up of primary HPV screening randomised controlled trial. BMJ. 2014 Jan 16;348(jan16 1):g130–g130.

2. Dillner J, Rebolj M, Birembaut P, Petry KU, Szarewski A, Munk C, et al. Long term predictive values of cytology and human papillomavirus testing in cervical cancer screening: joint European cohort study. BMJ. 2008 Oct 13;337(oct):a1754–a1754.

Addressing lower specificity

- HPV testing's lower specificity means it is not as good as cytology at correctly identifying someone who does not have a pre-cancer or cancer
- Specificity can be improved by doing partial genotyping and reflex cytology

Partial genotyping in the OCSP

- Partial genotyping will be done automatically by a lab on all samples that test positive for oncogenic types of HPV
- Partial genotyping will stratify results as:
 - \circ HPV type 16
 - HPV types 18/45
 - Other high-risk oncogenic types of HPV

Reflex cytology in the OCSP

- A reflex cytology test will also be done **automatically** by a lab on samples that test positive for oncogenic types of HPV
- Reflex cytology checks for the presence or absence of cervical cell changes and whether the changes are high-grade or low-grade

Overview of HPV testing in the OCSP

- The HPV test will become the primary test for cervical screening and will also be used for follow up testing of abnormal results in colposcopy
- The HPV test will only detect oncogenic types of HPV
- **Reflex cytology** and **partial genotyping** will be performed automatically on samples testing positive for HPV

HPV screening in Canada, 2024

Status of HPV screening

- No current HPV screening activities
- Planning for implementation
- Partial implementation
- Jurisdiction-wide implementation
- \bigstar Plans include self-collection



Benefits of HPV testing

- Better screening test for pre-cancer and early cervical cancer
- Reduces unnecessary colposcopy referral
- Safer, earlier, more appropriate discharge from colposcopy

Improved quality of screening and colposcopy services in Ontario

Cervical screening terminology

HPV testing results

- HPV-negative: No oncogenic types of HPV detected
- HPV-positive (types 16, 18/45): Oncogenic HPV types 16, 18/45 detected
- HPV-positive (other high-risk types): Other oncogenic types of HPV detected

Note:

HPV testing through the OCSP will not test for non-oncogenic types of HPV, such as those that cause genital warts, so a negative HPV test result could still mean someone has HPV

Reflex cytology results

High-grade result types	Low-grade result	Normal result type
 HSIL = high-grade squamous intraepithelial lesion ASC-H = atypical squamous cells, cannot exclude HSIL LSIL-H = low-grade squamous intraepithelial lesion, cannot exclude HSIL AGC-N = atypical glandular cells – favours neoplastic AGC-NOS = atypical glandular cells – not otherwise specified AEC-N = atypical endocervical cells – favours neoplastic AEC-NOS = atypical endocervical cells – not otherwise specified AIS = adenocarcinoma in situ SCC = squamous cell carcinoma ACC-E = endocervical adenocarcinoma PDC = poorly differentiated carcinoma 	 types ASCUS = atypical squamous cells of undetermined significance LSIL = low-grade squamous intraepithelial lesion 	 NILM = negative for intraepithelial lesion or malignancy

Cervical pre-cancer

- Abnormal cell growth in the cervix that is considered moderate or severe
- Cervical pre-cancer includes the following **histology** result types:
 - HSIL = High-grade squamous intraepithelial lesion
 - AIS = Adenocarcinoma in situ

New cervical screening recommendations

Cervical screening eligibility

Eligibility for cervical screening

- Have a cervix
- Are age ≥**25**
- Have ever been sexually active
- Have Ontario Health Insurance Plan (OHIP) coverage
- Have no symptoms suggestive of cervical cancer
Age of initiation

Age of initiation recommendations

- Start at age 25 for people with a cervix who have ever been sexually active
- Start age is the same for people who are immunocompetent, immunocompromised and vaccinated for HPV
- Do not screen:
 - People younger than age 25 who are sexually active
 - People who have never been sexually active

Evidence supporting age of initiation

- Cervical cancer is extremely rare in people under age 25
- From 2016 to 2020:
 - 29 new cases of cervical cancer were diagnosed in people under age 25 in Ontario
 - $\circ~$ 3,058 new cases were diagnosed for all ages
 - \circ **11** of these new cases were diagnosed in people ages 21 to 24
- Screening people under age 25 may result in follow-up tests and treatments that do not benefit them
- There is insufficient evidence on the benefit of cervical screening in immunocompromised people before age 25

Cervical screening categories and pathway

Background

- Not all people with HPV-positive results will be referred to colposcopy
- The OCSP assessed published literature and Ontario data to determine who should be referred to colposcopy based on their risk of cervical precancer and cancer - known as the "colposcopy referral threshold"
- Aligns with the principle of "equal management for equal risk"

Key takeaway:

The OCSP's colposcopy referral threshold is ≥6%, which has informed the cervical screening pathway

Risk-based screening recommendations

- The OCSP has 4 risk-based screening categories
- Recommendations for each category are based on the risk of cervical pre-cancer and cancer
 - Risk is determined by someone's most recent cervical screening result and immune status

Risk-based screening categories

Screening risk category	Screening results	Risk of cervical pre-cancer and cancer	Clinical next step
Average risk	HPV-negative	0.12% to 0.41% (5-year risk) ¹	Screen in 5 years
Immunocompromised	• N/A	Unknown or variable	Screen in 3 years
Moderate risk	 HPV-positive (other high-risk types) with normal or low-grade cytology 	1.3% to 3.7% (immediate risk) ²	Re-screen in 2 years
Elevated risk	 HPV-positive (types 16, 18/45) with high-grade cytology HPV-positive (types 16, 18/45) with normal or low-grade cytology HPV-positive (other high-risk types) with high-grade cytology 	≥6% (immediate risk) ³	Refer to colposcopy

Sources:

1. Dillner J, Rebolj M, Birembaut P, Petry KU, Szarewski A, Munk C, et al. Long term predictive values of cytology and human papillomavirus testing in cervical cancer screening: joint European cohort study. BMJ. 2008 Oct 13;337(oct):a1754–a1754.

2. Demarco M, Egemen D, Raine-Bennett TR, Cheung LC, Befano B, Poitras NE, et al. A Study of Partial Human Papillomavirus Genotyping in Support of the 2019 ASCCP Risk-Based Management Consensus Guidelines. J Low Genit Tract Dis. 2020;24(2):144–7.

3. This risk threshold was selected based on OCSP's cytology-based screening recommendations, jurisdictional scan data, input from expert panel members.





Rationale for 5-year screening interval for people at average risk

3-year risk of HSIL or AIS histology and cervical cancer after a <u>normal</u> <u>cytology tes</u> t (defined in the study as CIN3+) (95% CI)	5-year risk of HSIL or AIS histology and cervical cancer after a <u>negative HPV test</u> (defined in the study as CIN3+) (95% CI)	Author
0.19% (not reported)	0.14% (not reported)	Gage et al.
0.51% (0.23% to 0.77%)	0.25% (0.12% to 0.41%)	Dilner et al.

HSIL = high-grade squamous intraepithelial lesion AIS = adenocarcinoma in situ

Key takeaway:

A negative HPV test result every 5 years provides at least as much protection against cervical pre-cancer and cancer as a normal cytology test result every 3 years

Sources:

1. Dillner J, Rebolj M, Birembaut P, Petry KU, Szarewski A, Munk C, et al. Long term predictive values of cytology and human papillomavirus testing in cervical cancer screening: joint European cohort study. BMJ. 2008 Oct 13;337(oct):a1754–a1754.

2. Gage JC, Schiffman M, Katki HA, Castle PE, Fetterman B, Wentzensen N, et al. Reassurance against future risk of precancer and cancer conferred by a negative human papillomavirus test. J Natl Cancer Inst. 2014 Jul 18;106(8).

Rationale for 3-year screening interval for people who are immunocompromised

 People who are immunocompromised may be at higher risk of having or developing cervical pre-cancer and cancer

• Immunosuppression may impair someone's ability to clear an HPV infection

 A 3-year screening interval was selected based on input from an expert panel, jurisdictional scan data and the precautionary principle (when there are potential harms, scientific uncertainty must be resolved in favour of prevention)

Immunocompromised populations

Populations defined as immunocompromised by the OCSP

- People with HIV/AIDS, regardless of CD4 cell count
- People on long-term immunosuppressive medication (either continuously or at frequent intervals)
- People with organ transplants (solid organ transplant or allogeneic stem cell transplants)
- People with systemic lupus erythematosus, regardless of treatment
- People with congenital (primary) immunodeficiency
- People on dialysis with renal failure

Populations <u>not</u> defined as immunocompromised by the OCSP

- X People with a past history of cytotoxic treatments for cancer
- X People with Crohn's disease or multiple sclerosis who are not receiving immunosuppressant treatment
- X The offspring of people with a cervix exposed in utero to diethylstilbestrol (DES) (i.e., grandchildren of people who were prescribed DES)
- X People with diabetes (excluding those with renal failure)



Rationale for screening in 2 years



Demarco M, Hyun N, Carter-Pokras O, et al. A study of type-specific HPV natural history and implications for contemporary cervical cancer screening programs. EClinicalMedicine. 2020;22:100293.







Management of invalid HPV tests or unsatisfactory cytology results

When to repeat testing or refer to colposcopy

- Specimens should be repeated within 3 months
- A repeat specimen is not required and refer to colposcopy if:
 - The HPV test is positive for types 16, 18/45 with unsatisfactory cytology
 - There are 2 consecutive unsatisfactory cytology or invalid HPV test results

When to use intravaginal estrogen therapy

Intravaginal estrogen therapy may be considered after 1 unsatisfactory cytology result in people who are using androgen therapy (e.g., for gender transition) and in post-menopausal people

Cessation criteria

People ages 65 to 69

Test result	Clinical next step	Considerations and exceptions
Not screened	Continue screening	If a person did not have a cervical screening test from age 65 to 69, they should be screened until age 74
HPV-negative	Stop screening	 Someone can stop cervical screening if they have had 1 negative HPV test result, with the following exceptions: Immunocompromised people should screen until age 74 People ages 65 to 69 who have been discharged from colposcopy and have been advised to screen in 2 years should screen until age 74
HPV-positive	Follow screening pathway and refer to colposcopy if appropriate	Can stop screening when they have a negative HPV test result or when they are age 74, whichever occurs first

People ages 70 to 74

- People with an HPV-positive result, regardless of HPV type or reflex cytology, should be referred to colposcopy
- A colposcopy is needed to exclude a high-grade lesion

People ages 75 and older

- The OCSP does not recommend screening people ages 75 and older
- Any visible cervical abnormalities or abnormal symptoms should be referred for appropriate investigation by gynecology oncology

Summary of screening recommendations

Screening: Key changes

	Cytology testing	Following the implementation of HPV testing
Screening test	Cytology	HPV test with reflex cytology
Initial triage test	N/A	Partial genotyping, reflex cytology
Interval after negative test	Average risk: 3 years Immunocompromised: 1 year	Average risk: 5 years Immunocompromised: 3 years
Repeat test	Repeat cytology in 1 year	Repeat HPV test in 2 years
Start age	Age 21 ¹	Age 25
Cessation age	70 years if cessation criteria are met	Most people ages 65 to 69 with a negative HPV test

¹In January 2021, the OCSP began encouraging providers to initiate cervical screening at age 25 for immunocompetent people

Management of people under age 25

Testing no longer offered after HPV implementation

- The following will not be available through the OCSP once HPV testing is implemented:
 - Stand-alone cytology as a primary screening test (every 3 years)
 - Screening for people under age 25

HPV testing for people ages 21 to 24

- For people ages 21 to 24 who started screening before HPV testing was implemented in the OCSP, start HPV testing when someone is next due for a cytology test
- Apply the new recommended intervals after their first screening result

People ages 21 to 24 who started screening before launch of HPV testing

Pre-launch cytology result	Post-launch recommendations for people who are immunocompetent	Post-launch recommendations for people who are immunocompromised	
Normal	Delay next screening test to age 25 or in 3 years, whichever comes later	Delay next screening test to age 25 or 12 months, whichever comes later	
Unsatisfactory cytology	Delay next screening test to age 25 or, if requested, repeat the test at patient's earliest convenience	Delay next screening test to age 25 or, if requested, repeat the test at patient's earliest convenience	
Low-grade (ASCUS, LSIL) x1	Delay next screening test to age 25 (repeat screening optional*)	Repeat screening in 12 months	
Low-grade (ASCUS, LSIL) x2	Refer to colposcopy		
High-grade (ASC-H, LSIL-H, HSIL, AGC, AGC-N, AGC-NOS, AEC, AEC-N, AEC-NOS, AIS)	n-grade (ASC-H, LSIL-H, HSIL, AGC, C-N, AGC-NOS, AEC, AEC-N, AEC-NOS, 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 in the cervix		

*People who choose not to delay after a discussion about the limited benefits and potential risks of screening before the age of 25, can screen with an HPV test in 12 months

Considerations for cervical screening in pregnancy

Cervical screening in pregnancy

- Pregnancy does not affect someone's risk of developing cervical pre-cancer or cancer
- Screen when due or overdue for cervical screening
- Defer to postpartum period for people in the third trimester, when there are risk factors for preterm labour or bleeding, or based on patient preference
- The screening recommendations and indications for referral to colposcopy are the same for all average-risk people, regardless of pregnancy status
- Collection devices should not enter the cervical canal, which means the endocervical brush should not be used
- For patient comfort, cervical screening is usually avoided after 24 weeks and can be resumed as early as 6 weeks postpartum

Considerations for people with a double cervix

How to collect and label samples

• Collect 1 sample from each cervix

• A new collection device should be used for each cervical sample

- Place in separate vials that identify which cervix the sample is from (i.e., right or left)
- Use a single requisition form for both samples

How to interpret results

- People with a double cervix will have a result for each cervix
 - Will get 2 result letters from the OCSP
 - Will only get a single recall letter based on their most severe result
- Providers should manage both cervixes based on the most severe result (following only the screening pathway for the most severe result)



Colposcopy

Colposcopy pathways

- 7 colposcopy pathways
- Summarize episodes of care in colposcopy
- Most people will require 1 to 4 colposcopy visits in an episode of care unless persistent disease is found
- Goals are to discharge patients from colposcopy as appropriate, minimize over-testing and avoid over-treatment
High-level overview: Episode of care



Post-discharge from colposcopy

Discharge from colposcopy to primary care

- HPV and cytology co-testing and histology supports timely discharge from colposcopy
- Discharge is important given the harms of over-management in colposcopy
- Colposcopists are encouraged to provide clear recommendations on the post-discharge screening interval

When to resume screening

- People discharged from colposcopy will return to:
 - Average risk screening in 5 years or immunocompromised screening in 3 years
 - Moderate risk screening in 2 years
- People at elevated risk will remain in colposcopy

Post-discharge: People not treated*

LEGEND
Average risk
Moderate risk
Elevated risk

F	First post-discharge inte	Second post-discharge interval			
Referral cytology	HPV status at discharge	Action	HPV result	Action	
Normal or low-	N/A (HPV test not	Sereen in 2 years	HPV-negative	Return to average risk or immunocompromised screening	
grade	repeated in colposcopy)	Screen in 2 years	HPV-negative HPV-positive (regardless of type or cytology) N/A	Re-refer to colposcopy	
	HPV-negative	Return to average risk or immunocompromised screening	N/A		
High-grade	HPV-positive (regardless	Sereen in 2 years	HPV-negative	Return to average risk or immunocompromised screening	
	of subtype or cytology)	Screen in 2 years	HPV-positive (regardless of type or cytology)	Re-refer to colposcopy	

Post-discharge: People treated for HSIL histology

LEGEND Average risk Moderate risk Elevated risk

First post-discharge interval			Second post	ond post-discharge interval Third post-discharge inte		discharge interval
HPV result at first post- treatment visit	HPV status at discharge	Action	HPV result	Action	HPV result	Action
HPV-negative	HPV-negative	Return to average risk or immunocompromis ed screening	N/A			
	HPV-positive	s Screen in 2 years	HPV- negative	Sereen in 2 years	HPV-negative	Return to average risk or immunocompromised screening
HPV-negative				Screen in 2 years	HPV-positive (regardless of type or cytology)	Re-refer to colposcopy
			HPV-positive (regardless of type or cytology)	Re-refer to colposcopy	N/A	

Post-discharge: People treated for HSIL histology continued

LEGEND Average risk Moderate risk Elevated risk

First post-discharge interval			Second post	t-discharge interval	Third post-discharge interval	
HPV result at first post- treatment visit	HPV status at discharge	Action	HPV result	Action	HPV result	Action
			HPV-negative Screen in 2 years		HPV-negative	Return to average risk or immunocompromised screening
HPV-positive	HPV-positive	Screen in 2 years		HPV-positive (regardless of type or cytology)	Re-refer to colposcopy	
			HPV-positive (regardless of type or cytology)	Re-refer to colposcopy	N/A	
HPV-positive	HPV-negative	Screen in 2 years	HPV-negative	Return to average risk or immunocompromised screening	N/A	
			HPV-positive	Re-refer to colposcopy		

Post-discharge: People treated for AIS histology

First post-discharge interval		Second post-discharge interval		Third post-discharge interval		Fourth post-discharge interval		
HPV result at first post- treatment visit	HPV status at discharge	Action	HPV result	Action	HPV result	Action	HPV result	Action
		PV-negative Screen in 2 years	en in ars	Re-screen in 2 years	HPV-negative	Re-screen in 2 years	HPV-negative	Return to average risk or immunocompromised screening
Regardless of							HPV-positive (regardless of type or cytology)	Re-refer to colposcopy
first post- treatment HPV result	HPV-negative				HPV-positive (regardless of type or cytology)	Re-refer to colposcopy		N/A
			HPV- positive (regardless of type or cytology)	Re-refer to colposcopy	N/A			

LEGEND Average risk

Moderate risk

Elevated risk

Overview: Post-discharge screening



Post-discharge key takeaways

- Some people can be discharged to primary care after only 1 visit in colposcopy
- Some people may be HPV-positive when they are discharged to primary care
- People who are HPV-positive (regardless of HPV type and reflex cytology) at their 2-year post-discharge screening test should be referred back to colposcopy

Discharge letter

- You may receive the following information from the colposcopist in the form of a discharge letter:
 - Next screening interval in primary care
 - ✓ Whether or not patient was treated in colposcopy
 - ✓ When to refer patient back to colposcopy based on post-discharge screening results

Contact the colposcopist if you do not receive this information or require clarification

						Page 2 of 2		
					Treated for	HPV-negative and HPV-	If result	is HPV-positive (regardless of HPV
								PV-negative, re-screen in 2 years
				Page 1 of 2				itive (regardless of HPV type),
Final Dischar	ge Reco	ommenda	ations					ck to colposcopy gative, re-screen in 2 years and if
Colposcopy s	services							UDV and the (anomalian of UDV)
Colposcopist's name:								type), refer back to colposcopy
Contact informa	tion:							HPV-negative, return to average risk screening in 5 years or
Patient informat	tion:							immunocompromised screening
Date:								3 years
Screen patie	their colpo ent in 5 ye ent in 3 ye	ears (averag	e risk so nocomp	no should resume cervi next screening interval creening) <u>or</u> romised screening)	in primary ca	g in primary care. See below for are:		
Cytology at refer	rral	Treatment status	t	HPV result at first post- visit and HPV result at o	-treatment discharge	How to manage screening resu	lts	
Normal (NILM) or No			N/A and HPV-negative		Manage results according to routine			
low-grade (ASCUS, treatment LSIL) needed				cervical screening recommenda				
		Treate	d for	HPV-negative and H	HPV-	1		
□ High-grade (ASC-H,	HSIL		negative				
LSIL-H, AGC, AEC)*	ASC-H, HSIL,	HSIL histolo	PEV	negative				
LSIL-H, AGC, AEC)*	ASC-H, HSIL, ent in 2 ye	HSIL histolo	ogy ate risk	negative screening)				
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Vaginal vault testing

Background

- People who have had their cervix removed via hysterectomy are not at risk of developing cervical cancer, but may be at risk of developing vaginal cancer
- Vaginal vault testing can be done to identify people at risk of vaginal cancer
- Although vaginal cancer is also HPV-related, the risk of vaginal cancer is very low in Ontario
 - Ontario had an incidence rate of 0.6 squamous cell vaginal cancers per 100,000 people from 2014 to 2018

Post-hysterectomy population

• The post-hysterectomy population is organized by risk for vaginal cancer and consists of elevated and low risk groups

	Elevated-risk group	Low-risk group
•	People with LSIL, HSIL or AIS histology	 Anyone who does not meet the criteria
	in the cervix <i>at the time</i> of	for the elevated-risk group, including:
	hysterectomy (i.e., in the	\circ People with a history of LSIL, HSIL or AIS
	hysterectomy specimen), regardless of	histology in the cervix, but no evidence
	margin status or HPV status	of it in the hysterectomy specimen
•	People with a history of early cervical	\circ People with an unknown or no cervical
	cancer (microinvasive cervical cancer,	screening history (including Two-Spirit
	stage 1A1 only), regardless of whether	people, transmasculine people and
	there is evidence of cancer or pre-	nonbinary people who did not receive
	cancer at hysterectomy	cervical screening before their
		hysterectomy)

Out of scope populations

- People with a history of cervical cancer beyond stage 1A1
- People treated with radical trachelectomy, radiation or chemotherapy
- People under surveillance in the cancer system

Who and when to test

Z Elevated risk group

- Perform a 1-time HPV test of the vaginal vault 6 to 12 months after hysterectomy
- Reflex cytology done automatically by the lab for HPV-positive results



• Do **not** perform an HPV test

Note:

You may receive a discharge letter from a colposcopist or the provider who performed the hysterectomy if an HPV test of the vaginal vault is needed

Management of HPV test results

- HPV-positive, regardless of HPV type or cytology result → Refer to colposcopy
- **HPV-negative** \rightarrow No further HPV testing is needed
- Invalid HPV result → Repeat HPV test at participant's earliest convenience (preferably within 3 months) and if repeat HPV test is also invalid, refer to colposcopy

Management when HPV status is unknown before HPV launch

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 required
Unsatisfactory	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), do an HPV test If criteria for vaginal vault testing are not met, no further vaginal vault testing is required
Low-grade (ASCUS, LSIL)	HPV test in 12 months
High-grade (ASC-H, LSIL-H, HSIL, AGC, AGC-N, AGC-NOS, AEC, AEC-N, AEC-NOS, 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

Health Canada approval

- Guidance for vaginal vault testing has been developed by Ontario Health (Cancer Care Ontario) in consultation with a multidisciplinary, international expert panel
- 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 due to rarity
- As such, a disclosure will be included in OCSP resources and lab reports

Disclosure statement

- 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
- Vaginal vault testing is relatively rare, which makes vaginal vault specimens difficult to obtain. This means it is very
 challenging to obtain sufficient specimens to perform the validation studies that are required to obtain regulatory
 approval
- HPV test performance has not been specifically evaluated for detecting vaginal pre-cancer and cancer in relevant populations, so risks may include a decrease in testing accuracy
- Guidance for vaginal vault testing has been developed by Ontario Health (Cancer Care Ontario) in consultation with a multidisciplinary, international expert panel and other Canadian and international jurisdictions also provide guidance on using the HPV test in the vaginal vault
- The information provided by Ontario Health (Cancer Care Ontario) is not intended to serve as a substitute for a clinician's professional experience, independent judgment and decision-making
- Ontario Health (Cancer Care Ontario) assumes no liability whatsoever for any errors or omissions associated with the information provided and assumes no liability for any decision or action taken by the clinician or others in reliance on the information contained in materials

Case studies

Case study 1 – due for cervical screening

Alex is 28 years old and is due for cervical screening. Her screening test result is HPV-positive (other high-risk types) with ASCUS reflex cytology. What is the recommended next step?

- a) Alex is at moderate risk \rightarrow Repeat HPV test in 2 years
- b) Alex is at moderate risk \rightarrow Repeat HPV test in 1 year
- c) Alex is at elevated risk \rightarrow Refer to colposcopy
- d) Alex is at average risk \rightarrow Return to screening in 5 years

Case study 1 – repeat HPV test

In 2 years, Alex receives a letter from Ontario Health (Cancer Care Ontario) reminding her to get tested again. Her HPV test result is HPV-positive (other high-risk types) with LSIL reflex cytology. What is the recommended next step?

- a) Alex remains at moderate risk \rightarrow Repeat HPV test again in 2 years
- b) Alex is now at elevated risk \rightarrow Refer to colposcopy
- c) Alex is now at average risk \rightarrow Return to screening in 5 years

Case study 1 - colposcopy

- Alex is seen in colposcopy
- Her cervix is assessed and high-grade histology is not detected at her first colposcopy visit
- Treatment is not needed

Case study 1 – post-discharge screening test

2 years later, Alex's screening test result is HPV-positive (other high-risk types) with normal reflex cytology. What is the recommended next step?

- a) Refer back to colposcopy
- b) Repeat another HPV test in 2 years
- c) Return to screening in 3 years
- d) Return to screening in 5 years

Case study 2 – first scenario

Sarah is 68 years old and has received routine cervical screening with the HPV test. Sarah is due for screening and the result is HPV-positive (other high-risk types) with normal reflex cytology. What is the recommended next step?

- a) Stop screening immediately
- b) Refer to colposcopy
- c) Repeat HPV test in 2 years → Refer to colposcopy if repeat result is HPV-positive, regardless of HPV type or cytology result
- d) Repeat HPV test in 2 years → Stop screening if repeat result is HPVnegative

Case study 2 – second scenario

Zara is 70 years old and has not received cervical screening in a long time. She decides to make an appointment with her primary care provider to get a screening test. Her test result is HPV-positive (other high-risk types) with ASCUS reflex cytology. What is the recommended next step?

- a) Refer to colposcopy
- b) Stop screening immediately
- c) Repeat HPV test in 2 years

Case study 3

Rickie (he/him) is 22 years old and is a transmasculine person who got screened just before primary HPV testing was implemented in the OCSP. His cytology result was a first time LSIL. HPV testing is now implemented. How and when should he be screened next?

- a) Delay re-screening with the HPV test to age 25
- b) Re-screen with cytology at age 23
- c) Re-screen with the HPV test at age 23
- d) A or C; either are acceptable

A is preferable, but people who choose not to delay screening can rescreen with an HPV test in 1 year

Case study 4

Mary is 49 years old with a history of cervical dysplasia. She had a hysterectomy 6 months ago and there was evidence of HSIL histology in the hysterectomy specimen. You perform an HPV test of the vaginal vault and result is HPV-negative. What is the appropriate next step?

- a) Refer to colposcopy
- b) Cease testing
- c) Repeat an HPV test in 2 years

Changes to your practice

Procured partners

Test System Vendor

Laboratory Service Providers (LSPs)

HOLOGIC®

L'feLabs[®]

Aptima: HPV 16 18/45 Genotype Assay The contract of the contra

Dynacare®

North Bay Regional Health Centre



Centre régional de santé de North Bay

Working with LSPs

- Ensure that OCSP tests are sent to one of the procured LSPs
- If you already have an existing agreement with one of the procured LSPs, you can follow your regular approach for ordering supplies and transporting samples
- If you do not have an existing agreement, the procured LSPs will reach out to support onboarding before HPV testing launch

Ordering tests for cervical screening

How to order the HPV test

automatically by the

lab if HPV-positive)

Step 1	Step 2	Step 3	Step 4
Confirm patient eligibility	Collect 1 sample from the cervix	Complete OCSP requisition and label cervical sample	Submit requisition and sample to one of the procured LSPs
People with a cervix ages 25 and older who have ever been sexually active	Only 1 sample is needed for HPV testing and reflex cytology (performed	 Use the new OCSP-specific screening requisition Providers will not be able to order using the Ministry of 	

Health Laboratory Requisition

or a hospital requisition

Collecting a sample

How to collect a cervical sample

- Choose 1 of the following options to collect a sample:
 - o Broom-like device
 - Endocervical brush-spatula combination
- Avoid certain types of lubricants (some may cause invalid test results) or use water to lubricate:
 - If a lubricant needs to be used, use a dime-sized amount of watersoluble and carbomer-free gel lubricant
 - Apply the lubricant only to the outer sides of the speculum blades
- **Do not** leave any part of the collection device in the vial
- Label all samples with the patient's name, date of birth and date of sample collection




Difference between SurePath[™] and ThinPrep[®] vials

- The OCSP uses the ThinPrep[®] system for cervical sample collection in HPV testing
- Some providers may need to transition from using SurePath[™] vials to ThinPrep[®] vials
- ThinPrep[®] tests will be rejected if any part of the collection device is left in the vial



Tips to avoid cervical sample rejection

- Check the expiry dates
- Ensure no part of the collection device, such as the head of the broom, is left in the collection vial
- Label your sample, using legible writing or a printed label
 - Complete all required parts of the label (patient first and last name, date of birth, date of sample collection)
- Pair all cervical samples with a corresponding requisition
 - Make sure the label on the vial and corresponding requisition match
- Tightly close the sample vial to avoid leaking
- Ensure sample is sent promptly to the lab

Additional instructions

Collecting a sample from someone who is pregnant:

- Collection devices should not enter the cervical canal, so the endocervical brush should not be used
- For patient comfort, cervical screening is usually avoided after 24 weeks and can be resumed as early as 6 weeks postpartum

Collecting and labeling samples from people with a double cervix:

- Collect 1 sample from each cervix
- A new collection device should be used for each cervical sample
- Place in separate vials that identify which cervix the sample is from (i.e., right or left)
- Use a single requisition form for both samples

Collecting a sample from the vaginal vault

- Use either the broom or the plastic spatula only (i.e., do not use the endocervical brush)
- Collect sample from the top of the vaginal vault, making full contact
- Use back and forth, horizontal sweeping motion five times

Completing the requisition

New OCSP requisition

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	Glucose Random	Fasting		CBC		Acute Hepatitis
	HbA1C			Prothrombin Time (INR)		Chronic Hepatitis
	Creatinine (eGFR)			Immunology		Immune Status / Previous Exposure
	Uric Acid			Pregnancy Test (Urine) Specify: Hepatitis A		Specify: Hepatitis R
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Ontario Health Cancer Care Ontario

Human Papillomavirus (HPV) and Cytology Tests Requisition -For Cervical Screening

Lab Use Only

· Eligibility Criteria: People with a cervix age 25 and older who have ever been sexually active and have a valid OHIP number.

 Ontario Cervical Screening Program's cervical screening recommendations and cessation criteria can be found at ontariohealth.ca/OCSP-recommendations.

• Immunocompromised populations include people who are living with HIV/AID5 (regardless of CD4 cell count), congenital (primary) immunodeficiency, systemic lupus erythematosus (regardless of whether they are receiving immunosuppressant treatment), renal failure and require dialysis, transplant recipients (solid organ or allogeneic stem cell transplants) or people requiring treatment (either continuously or at frequent intervals) with medications that cause immune suppression for 3 years or more.

Referral to a specialist is required for any visible cervical abnormalities.

Requester Information Requester type (check ONE):	Patient Identification (Enter information as indicated on OHIP card.			
Physician Midwife Nurse practitioner	Can be replaced by a stic	ker.)		
CPSO or CNO number:	Last name:			
Practitioner billing number:	Middle name: (optional)			
Last name:	First name:	7		
Middle name: (optional)	Date of birth: yyyy/mm/dd	S	ex: 🗌 Male 🔲 Female	
First name:	OHIP number:	OHIP	version:	
Address:	Patient Cor correspond	address for result let	ters and other	
Copy to: Primary care provider	Building Street	Street name:		
Last name:	Apt p	City:		
First name:		Postal Code:		
Address: (optional) Fax: ()	()	E) (o Vork Cell	ktension: ptional)	
Testing Indication for Cervical Scre.	Specimen			
A. HPV test (includes reflex cytology if HPV-post	Site: Cervical/endoc	ervical 🗌 Vaginal	Double cervix	
Average risk screening: every 5 years	Special considerations fo	r cytology interpretation:		
Immunocompromised screening: every 3 years	Intrauterine device	e (IUD) 🛛 🔲 Postpartum		
 HPV-positive (other high-risk types) with normal or low-grade (NILM/ASCUS/LSIL) cytology: 2-year follow-up (moderate risk) 	 Menopausal horm therapy (MHT) 	one Pregnancy Subtotal hys	terectomy	
More frequent screening post-colposcopy:	Post-menopausal	Transition-re	elated hormone therapy	
2-year rollow-up (moderate fisk) People with histologic evidence of dysplasia in the cervix at	Specimen collection date: (yyy/mm/do) Last menstrual period (first day): (yyy/mm/do) Clinical information			
the time of hysterectomy and people with a history of early cervical cancer: 1-time post-hysterectomy vaginal vault testing				
B. Cytology test only				
 Repeat after a previous HPV-positive (other high-risk types) with unsatisfactory cytology result 				
Requester Verification		Date: (yyyy/mm/dd)		

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, info@ontariohealth.ca. Document disponible en français en contactant info@ontariohealth.ca

Main requisition changes



Human Papillomavirus (HPV) and Cytology Tests Requisition For Cervical Screening

· Eligibility Criteria: People with a cervix age 25 and older who have ever bee active and have a valid OHIP number

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 Immunocompromised populations include people who are living with HI immunodeficiency, systemic lupus erythematosus (regardless of whether th require dialysis, transplant recipients (solid organ or allogeneic stem cell tra frequent intervals) with medications that cause immune suppression for 3 v Referral to a specialist is required for any visible cervical abnormalities

Practitioner billing number: Last name: Middle name: potoenal First name: Address: Fax: () Phone: () Copy to: Primary care provider Last name:	Midd (option) • Referral to a specialist is required for the specialist is req
First name: Address: [optional] Paix: () Phone: ()	Province: Postal Code: Phone:) Extension: (optional) Type: Home Work Cell
Itesting Indication for Cervical Screening (check ONE): A. HPV test (includes reflex cytology if HPV-positive) A verage risk screening: every 5 years Immunocompromised screening: every 3 years HPV-positive (other high-risk types) with normal or low-grade (NLLM/ASCUS/LSIL) cytology: 2-year follow-up (moderate risk) More frequent screening post-colposcopy: 2-year follow-up (moderate risk) People with histologic evidence of dysplasia in the cervix at the time of hysterectomy and people with a history of early cervical cancer: 1-time post-hysterectomy vaginal valit testing B. Cytology test only Repeat after a previous HPV-positive (other high-risk types)	Specimen site: Cervical/endocervical Vaginal Double cervix special considerations for cytology interpretation: Intrauterine device (IUD) Postpartum Menopausal hormone Pregnancy therapy (MHT) Subtotal hysterectomy Specimen collection date: Intraution-related hormone therapy Last menstrual period (first day): (Intraution difference) Clinical information Clinical information

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, info@ontariohealth.ca Document disponible en français en contactant info@ontariohealth.ca

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V.	Cancer Care Ontario

Human Papillomavirus (HPV) and Cytology Tests Requisition – For Cervical Screening

- Eligibility Criteria: People with a cervix age 25 and older who have ever been sexually active and have a valid OHIP number.
- Ontario Cervical Screening Program's cervical screening recommendations and cessation criteria can be found at ontariohealth.ca/OCSP-recommendations.
- Immunocompromised populations include people who are living with HIV/AIDS (regardless of CD4 cell count), congenital (primary) temic lupus erythematosus (regardless of whether they are receiving immunosuppressant treatment), renal failure and ant recipients (solid organ or allogeneic stem cell transplants) or people requiring treatment (either continuously or at medications that cause immune suppression for 3 years or more.

s required for any visible cervical abnormalities.

Testing Indication for Cervical Screening (check ONE):

- A. HPV test (includes reflex cytology if HPV-positive)
 - Average risk screening: every 5 years
 - Immunocompromised screening: every 3 years
 - HPV-positive (other high-risk types) with normal or low-grade (NILM/ASCUS/LSIL) cytology: 2-year follow-up (moderate risk)
 - More frequent screening post-colposcopy: 2-year follow-up (moderate risk)
 - People with histologic evidence of dysplasia in the cervix at the time of hysterectomy and people with a history of early cervical cancer: 1-time post-hysterectomy vaginal vault testing
- B. Cytology test only
 - Repeat after a previous HPV-positive (other high-risk types) with unsatisfactory cytology result

eligibility information

New requisition

contains

Testing indications specify screening categories and intervals

Lab Use Only

How to complete the new OCSP requisition

Cancer Care Ontario

Human Papillomavirus (HPV) and Cytology Tests Requisition – For Cervical Screening

- Eligibility Criteria: People with a cervix age 25 and older who have ever been sexually active and have a valid OHIP number.
- Ontario Cervical Screening Program's cervical screening recommendations and cessation criteria can be found at ontariohealth.ca/OCSP-recommendations.
- Immunocompromised populations include people who are living with HIV/AIDS (regardless of CD4 cell count), congenital (primary)
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 require dialysis, transplant recipients (solid organ or allogeneic stem cell transplants) or people requiring treatment (either continuously or at
 frequent intervals) with medications that cause immune suppression for 3 years or more.
- · Referral to a specialist is required for any visible cervical abnormalities.

Requester Information Requester type (check ONE): Physician Midwife Nurse practitioner	Patient Identification (Enter information as indicated on OHIP card. Can be replaced by a sticker.)
CPSO or CNO number:	Last name:
Practitioner billing number:	Middle name: (optional)
Last name:	First name:
Middle name: (optionsl)	Date of birth: vvvv / mm / dd Sex: Male Female
First name:	OHIP number: OHIP version:
Address:	Patient Contact (Mailing address for result letters and other
Fax: () Phone: ()	correspondence. Verify with patient.)
Copy to: Primary care provider	Building / Street name:
Last name:	Apt./Unit number: City:
First name:	Province: Postal Code:
Address: (optional)	Phone: () Extension: (optional)
Fax: () Phone: ()	Type: Home Work Cell
Testing Indication for Cervical Screening (check ONE):	Specimen
A. HPV test (includes reflex cytology if HPV-positive)	Site: Cervical/endocervical Vaginal Double cervix
Average risk screening: every 5 years	Special considerations for cytology interpretation:
Immunocompromised screening: every 3 years	Intrauterine device (IUD) Postpartum
HPV-positive (other high-risk types) with normal or low-grade	Menopausal hormone Pregnancy
(NILM/ASCUS/LSIL) cytology: 2-year follow-up (moderate risk)	therapy (MHT) Subtotal hysterectomy
More frequent screening post-colposcopy: 2-year follow-up (moderate risk)	Post-menopausal Transition-related hormone therapy
People with histologic evidence of dysplasia in the cervix at	Specimen collection date: /vvv/mm/dd)
the time of hysterectomy and people with a history of early cervical cancer: 1-time post-hysterectomy vaginal vault testing	Last menstrual period (first day): (yyyy/mm/dd)
B. Cytology test only	Clinical information
Repeat after a previous HPV-positive (other high-risk types)	
with unsatisfactory cytology result	
Requester Verification	Dater

Need this information in an accessible format? 1-877-280-8538, TTY 1-800-855-0511, info@ontariohealth.ca Document disponible en français en contactant info@ontariohealth.ca

Requester signature

Lab Use Only

ww/mm/dd

• Enter patient information as indicated on OHIP card

• Ensure patient address information is accurate

• Enter information that applies to the specimen

- Include any additional clinical information that may be relevant
- Sign and date the requisition
- Digitized signature will only be accepted if generated by a certified electronic medical record software

Enter your information
If another primary care provider needs a copy of the result report, enter their information

• Check only **1** of the screening testing indications

 The "cytology test only" option should only be selected after a previous unsatisfactory cytology result

Where to find the new requisition

- Requisition will be available before HPV launch
 - Can be found on the HPV testing implementation resource hub at <u>ontariohealth.ca/hpvhub</u>
 - Will be sent to providers as part of an information package
- Ontario Health (Cancer Care Ontario) is working with OntarioMD to make the requisition available through certified electronic medical records (EMRs)
- Contact your EMR vendor closer to HPV testing launch to explore how the requisition will be made available

The new requisition (and other resources) can also be found on the Waterloo Wellington Regional Cancer Program website at: https://www.grhosp.on.ca/cancerwaterloowellington/health-careproviders/human-papillomavirus-hpv-testing/cervical-screening-providers

Reasons a requisition could be rejected

- Participant is not eligible for cervical screening (e.g., due to age or not due for screening)
- Incomplete or illegible
- Requisition is received without a cervical sample
- Lab received duplicate requisitions
- Inappropriate cytology only request
- More than one testing indications selected
- Missing testing indication

Key takeaway:

It is important to complete the requisition accurately to avoid rejection by the lab

Test results

Screening result reports

- Providers will receive result reports from the procured LSPs
- Reports include screening results (HPV test result and if positive, cytology results) and recommended next steps
- Providers will also be notified of invalid HPV results, unsatisfactory cytology results or reasons for rejection

Accessing screening results history

- Authorized providers can access lab test orders and results from hospitals, community and public health labs via the Ontario Laboratories Information System (OLIS)
- OLIS can be accessed through several channels
- There are technical and non-technical prerequisites for accessing OLIS
- For more information visit: <u>https://ehealthontario.on.ca/en/health-care-professionals/lab-results</u>

Supporting patients

- Patients will continue to receive OCSP correspondence
 - Invitations/recalls
 - o Reminders
 - o Results
- **Physician-linked correspondence (PLC)** includes the name of a patient's physician on personalized correspondence letters
 - Research shows PLC helps increase screening rates
 - For more information and to sign up for PLC*, visit <u>cancercareontario.ca/en/physician-</u> <u>linked-correspondence</u>

*Patient enrollment model (PEM) physicians can enroll in PLC; examples of PEM physicians are members of Family Health Groups (FHGs), Family Health Networks (FHNs), and Family Health Organizations (FHOs)

Key resources

- New OCSP requisition and instructions for completing requisition
- Instructions on how to collect a cervical sample
- Frequently asked questions about HPV testing implementation and changes to the OCSP
- Sample colposcopy declined referral and discharge letter templates
- OCSP guide to cervical screening
- OCSP guide to resuming cervical screening post-discharge from colposcopy

Available on the HPV testing implementation resource hub at <u>ontariohealth.ca/hpvhub</u>

Contact information

 If you have any questions, please contact Ontario Health (Cancer Care Ontario) toll-free at 1-866-662-9233 from Monday to Friday, 8:30 a.m. to 5 p.m. or at <u>cancerinfo@ontariohealth.ca</u>

Questions? E-mail the Waterloo Wellington Regional Cancer Program at <u>WWRegionalCancerProgram@grhosp.on.ca</u>

Thank you!