Institut national d'excellence en santé et en services sociaux
Québec

QUEBEC'S NATIONAL MEDICAL PROTOCOL

No. 888039

Initiating an HPV test and following up on results for cervical cancer screening

Developed in collaboration with an advisory committee consisting of Québec clinicians from various areas of expertise.

CLINICAL SITUATION OR TARGET POPULATION

Immunocompetent individual between the ages of 25 and 65 years who has a cervix and who has not been screened with an HPV test in the past 5 years or with a Pap test in the past 3 years

OR

Immunocompromised individual (see description in Section 1.1) between the ages of 25 and 65 years who has a cervix and who has not been screened with an HPV test in the past 3 years or a Pap test in the past year

CONTRAINDICATIONS TO APPLYING THIS PROTOCOL

- Total hysterectomy
- Postmenopausal bleeding
- Individual under medical surveillance for cancerous or precancerous cervical lesions to whom return to regular screening has not been recommended
- Use of a vaginal gel, cream, lubricant or douche in the past 24 hours

INSTRUCTIONS

1. HEALTH STATUS ASSESSMENT

During pregnancy, the recommendations concerning screening procedures and management of abnormal results (HPV and cytology) are the same as those devised for non-pregnant individuals.

1.1 Health and medication history

Check for the following items, which confirm the clinical situation:

- Immunocompromised individual

Situations in which recommendations for immunocompromised individual should be followed

- Those living with HIV;
- Those who have had a solid organ transplant or an allogeneic hematopoietic stem cell transplant
- Those with disseminated lupus erythematosus;
- Those being treated with an immunosuppressant for inflammatory bowel disease or rheumatoid arthritis;
- Those with congenital (primary) immunodeficiency.

- Date of last screening result with HPV test or Pap test.

If the year when the last test was performed is unknown, screening is indicated.

Check for the following situation, to assess whether the individual is immunocompromised:

- Receiving chemotherapy or radiation therapy.

Check for the following items, which are contraindications to applying this protocol:

- Total hysterectomy. If for a malignant condition or if the reason is unknown, a medical assessment is required.
- Being under medical surveillance for cancerous or precancerous cervical lesions to whom return to regular screening has not been recommended.
- The use of a vaginal gel, cream, lubricant or douche during the past 24 hours, **as they can cause a false-negative result.** Postpone screening.

1.2 Signs and symptoms

Check for the following symptom, which is a contraindication to applying this protocol:

- Postmenopausal bleeding.

Check for the following symptoms, for which testing is still indicated. However, the individual requires a medical assessment with a physician or SNP, without waiting for the screening result :

- Unexplained intermenstrual or postcoital bleeding, unexplained and persistent pain during sexual intercourse.
- Unusual and persistent vaginal discharge.

2. SCREENING TEST

2.1 Objective

The objective of screening is to reduce the incidence of cervical cancer and the number of deaths due to cervical cancer by detecting, monitoring and treating (if applicable) lesions at an early stage.

2.2 Choice of sampling method

If self-sampling is an available option, the individual should be given the choice between cervical sampling and self-sampling. If self-sampling is chosen, they should be informed that sampling must be performed in-clinic and that they will have to return for a Pap test if the HPV test is positive.

2.3 Sampling

- *Please read the manufacturer's instructions and those of the laboratory at your facility to ensure that an adequate sample is obtained.*
- *Using a carbomer-containing lubricant during the physical examination may cause a false-negative result. Check the list of ingredients of the lubricant used at your facility to ensure that the lubricant used is carbomer-free.*
- *The presence of a large amount of blood with the specimen may result in the sample being rejected.*

2.3.1 Cervical sampling

- ► Explain to the individual how the pelvic examination and cervical sampling will proceed and tell them that they may experience some discomfort or pain or bleeding when the specimen is being collected.
- ► Obtain consent to perform an examination and to collect a specimen.
- ► Perform the physical examination per standard practice.
- ► Collect the specimen:
  - Eliminate the excess mucus from the cervix before you collect the specimen.
  - Collect a cytology specimen from the cervix, including the endocervix and exocervix, using the procedure set out in the instruction manuals for the specimen collection devices and storage medium used.
  - Fill out the laboratory test requisition form and send the specimen in accordance with the current instructions at your facility.

2.3.2 Self-sampling

- ► Give the individual a self-sampling kit and check that they understand how to use it.
- ► Self-sampling must be done on the premises, and the individual must turn in the specimen before leaving.
- ► Follow the manufacturer's instructions for storing the specimen.
- ► Fill out the laboratory test requisition form and send the specimen in accordance with the current instructions at your facility.

> ⚠ *For individuals receiving chemotherapy or radiation therapy, whose immunocompromise status needs to be assessed, stop the protocol after the clinician cervical sampling or self-sampling.*

3. INFORMATION TO BE PROVIDED

3.1 Prior to screening

- ► Inform the individual :
  - of how they will be notified of the result;
  - when their next screening test will be if their result is negative (5 years for immunocompetent individuals and 3 years for immunocompromised individuals);
  - that in the event of a positive result they will be contacted to discuss the follow-up procedure.

3.2 Upon receiving a positive result

- ► Inform the individual of the result and what the next steps will be, based on the follow-up table in Section 4.
- ► If the algorithm indicates that the result requires another HPV test in 12months, inform them that they will need to schedule this appointment.

3.3 When referring for a colposcopy (consult Appendix I), if applicable

- ► Fill out the requisition form and give the individual the necessary information concerning the purpose of the colposcopy and what it will involve[1].
- ► When requesting a colposcopy consultation, provide the following:
  - the health and screening history;
  - the HPV test and cytology results.

4. FOLLOW-UP

FOLLOW-UP ON RESULT – IMMUNOCOMPETENT INDIVIDUAL	
Negative HPV result	Return to screening in 5 years
Inadequate sample	Inform the individual and schedule a repeat screening test within 6 to 12 weeks after receiving the result. If the reason the test failed is known, the situation should be corrected before the repeat.
Positive HPV result	CERVICAL SAMPLING: See the algorithm in Appendix I to determine how to proceed based on the HPV test and cytology results.
	SELF-SAMPLING: Inform the individual of the result and schedule a cervical sampling visit. See the algorithm in Appendix I for follow-up instructions.
FOLLOW-UP ON RESULT – IMMUNOCOMPROMISED INDIVIDUAL	
Negative HPV result	Return to screening in 3 years
Inadequate sample	Inform the individual and schedule a repeat screening test within 6 to 12 weeks after receiving the result. If the reason the test failed is known, the situation should be corrected before the repeat.
Positive HPV result	CERVICAL SAMPLING OR SELF-SAMPLING: refer for a colposcopy. Recommended time to colposcopy consultation, based on the cytology result: • ASC-H, HSIL, AGC, AIS: as soon as possible. Ideally, within 4 to 6 weeks*; • NILM, ASC-US, LSIL or unsatisfactory: within 12 weeks*. * Calculated from the date of the colposcopy consultation request.

[1] Information about the HPV test and the colposcopy examination is provided on the following MSSS website: https://www.quebec.ca/sante/conseils-et-prevention/depistage-et-offre-de-tests-de-porteur/test-vph.

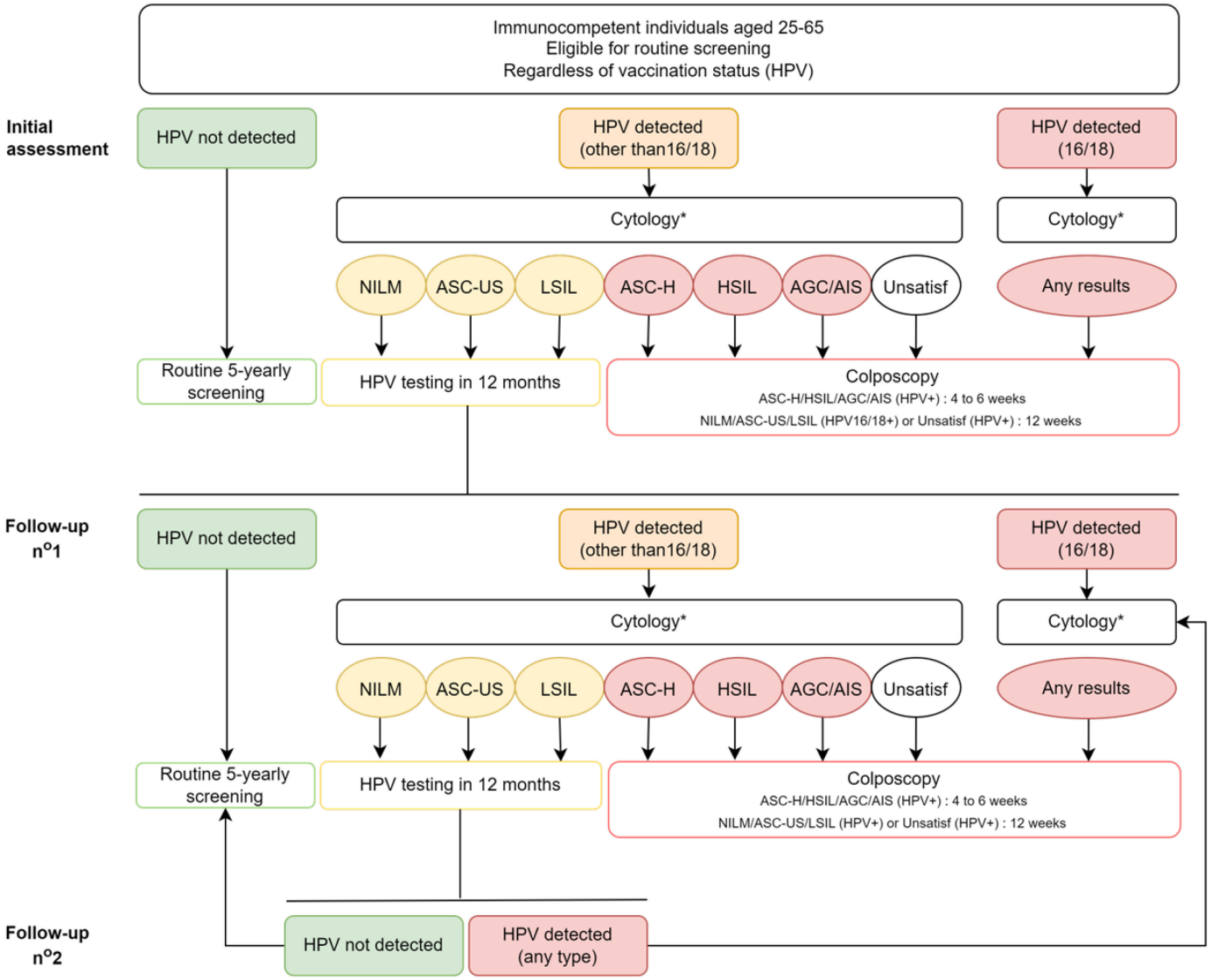
5 SITUATIONS REQUIRING SPECIAL ATTENTION OR A MEDICAL ASSESSMENT

- ► Vaginal atrophy or dryness preventing the insertion of a speculum and visualization of the cervix.
- ► Individual receiving chemotherapy or radiation therapy.
- ► Intermenstrual bleeding.
- ► Postcoital bleeding.
- ► Unexplained and persistent pain during sexual intercourse.
- ► Any abnormality found upon pelvic examination.

REFERENCES

This protocol is based on the latest scientific data and best practice recommendations, which were supplemented with contextual information and the experiential knowledge of Québec clinicians. For details on the development process for this national medical protocol and to consult the references, refer to the INESSS report supporting this protocol.

APPENDIX I - DECISION ALGORITHM



AGC: atypical glandular cells; AIS; adenocarcinoma *in situ*; ASC-H: atypical squamous cells-cannot exclude high-grade squamous intraepithelial lesion; ASC-US: atypical squamous cells of undetermined significance; HPV: human papillomavirus; HSIL: high-grade squamous intraepithelial lesion; LSIL: low-grade squamous intraepithelial lesion; NILM: negative for intraepithelial lesion or malignancy; unsatis: unsatisfactory.

* A cytological examination is automatically required if the result of the HPV test is positive (any type). The specimen preserved in a liquid-based cytology collection medium can be used to perform a cytological examination on the same sample as that sent for the HPV test.

Time to colposcopy consultation is calculated from the date of the colposcopy consultation request.

For further information about this algorithm, please consult the following INESSS website Algorithmes d'investigation, de traitement et de suivi (algorithmes-onco.info).