New guidelines for management of women at intermediate risk

Effective from 1 February 2021, there will be a significant change to the management of women at ‘intermediate risk’ following the detection of HPV, non-16/18 in the National Cervical Screening Program (NCSP).

Since commencement of the renewed program, if a woman tested positive for HPV, non-16/18 and the reflex cytology was negative, possible low-grade squamous intraepithelial lesion (pLSIL) or low-grade squamous intraepithelial lesion (LSIL), a repeat HPV test at 12 months was recommended. If the HPV test remained positive, irrespective of the cytology, these women were then considered at ‘high risk’ and colposcopy recommended.

The revised recommendation is that women who remain HPV positive at 12 months and have a negative pLSIL or LSIL reflex cytology, continue to be managed as ‘intermediate risk’, that is, undertake a repeat HPV test in 12 months rather than immediate colposcopy. If, at the third HPV test, the patient remains positive for any HPV type, irrespective of cytology findings, colposcopy will be necessary.

The test required after any ‘intermediate risk’ result is an HPV test. If positive, a reflex LBC will be automatically performed. If negative, no cytology is needed. You do not need to order a co-test (HPV + LBC).

Why has this change been made?

With the introduction of HPV primary screening, a cautious approach was taken in the development of management guidelines. During the three years that the new program has been in operation, the proportion of women with persistent HPV, non-16/18 infection is much higher than predicted, resulting in large numbers of women being referred for colposcopy.

New Australian data have been analysed for women considered as ‘intermediate risk’ who were undertaking a 12-month follow-up HPV test. This review showed that the risk of developing high-grade lesions, CIN2/3 and cervical cancer is very low in the great majority of women who remain HPV, non-16/18 positive but with a negative pLSIL or LSIL cytology.

In light of this, the NCSP has subsequently recommended that these changes be undertaken.

Are there exceptions to this rule?

Yes. The review showed that there are subgroups of women who remain at higher risk and who will need to be recommended for colposcopy. These are:

- Women 50+ years
- Women who identify as Aboriginal and/or Torres Strait Islander
- Women overdue for screening by at least 2 years

The following groups of women fall outside these new recommendations:

- Women undergoing Test of Cure
- Women who are DES-exposed
- Women who are immune-deficient
- Women 70+ years attending for an exit test
- Women who have a self-collected sample

Please refer overleaf for a flowchart incorporating the changes outlined.

For further assistance, please contact the Gynae Pathology team on (07) 3377 8335. Additional information is available on the Cancer Council Australia website, https://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening
Pathway for routine cervical screening

**ONCOGENIC HPV TEST WITH PARTIAL GENOTYPING**

- HPV not detected: Routine 5−yearly screening
- HPV (not 16/18) detected: Reflex LBC
  - Negative: Repeat HPV test in 12 months
  - pLSIL/LSIL: Repeat HPV test in 12 months
- HPV 16/18 detected: Reflex LBC
  - LBC pHSIL or worse*: Refer for colposcopic assessment
  - Any LBC result or unsatisfactory: Repeat HPV test in 12 months
- Un satisfactory HPV test: Reflex LBC
  - Re test HPV in 6−12 weeks

**Reflex LBC**

- LBC pHSIL or worse*: Refer for colposcopic assessment
- Any LBC result or unsatisfactory: Repeat HPV test in 12 months
- LBC negative/ pLSIL/LSIL: Repeat HPV test in 12 months
- Routine 5−yearly screening

**Re test LBC only in 6−12 weeks**

- HPV not detected: Routine 5−yearly screening
- Unsatisfactory LBC: Repeat HPV test in 12 months

**Risk of cervical cancer precursors**

- Low
- Intermediate
- Higher

*Includes pHSIL, HSIL, cancer or glandular abnormality

Direct referral to colposcopy is recommended for:
- Women 50+ years
- Women who identify as Aboriginal and/or Torres Strait Islander
- Women overdue for screening by at least 2 years