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Chapter 4 Recommendations

REC 4.1 Concise management recommendations, as set out in these guidelines, must be included in the report for all cervical screening tests, follow-up tests and co-tests following treatment for high-grade squamous intraepithelial lesion (HSIL) or for adenocarcinoma in situ (AIS).

The recommendation must take account of a person's screening history as recorded with the National Cancer Screening Register (NCSR) and the clinical notes provided on the pathology request form.

The management recommendations should align with the cervical screening result as follows:

Cervical screening result	Management recommendation'
Low risk of significant cervical abnormality	Rescreen in 5 years
Intermediate risk of significant cervical abnormality	Perform follow-up HPV test in 12 months
Higher risk of significant cervical abnormality	Refer for colposcopic assessment
Unsatisfactory HPV test	Repeat HPV test within 6 weeks
Unsatisfactory LBC	Repeat LBC in 6 weeks

In cases where the HPV test has been performed and reflex liquid-based cytology (LBC) is indicated but cannot be performed, the laboratory should not repeat the HPV test on receipt of the repeat sample but should proceed directly to LBC and then issue a combined report taking account of both tests.

Samples taken outside the context of cervical screening such as;

• those that are taken in the context of investigating symptoms that raise the possibility of cervical cancer and

those that are taken in the course of surveillance following treatment for cervical cancer should not be assigned a "cervical screening result" but rather should have an appropriate summary line and recommendation in line with cervical cancer treatment guidelines (The Royal College of Pathologists of Australasia 2021).

REC 5.1

Questions that must be asked before screening

Before offering screening, the healthcare provider should take a history to determine whether the person has any symptoms suggestive of cervical cancer, including unexplained postcoital bleeding or persistent intermenstrual bleeding; postmenopausal bleeding; or unexplained persistent unusual vaginal discharge.

People with these symptoms are not eligible for screening and should instead follow a diagnostic pathway (see section 10).

If the person meets the criteria for screening, the healthcare provider should support informed choice between a clinician-collected and a self-collected CST sample.

REC 5.2

Cervical screening test: sampling options

Anyone who is eligible for cervical screening should be offered the choice of HPV testing on clinician-collected cervical sample or on a self-collected vaginal sample.

Notes:

Both sample collection methods have equivalent sensitivity for the detection of HPV and CIN2+/adenocarcinoma in situ (AIS).

Any screening participant requiring a co-test (HPV test and LBC) is ineligible for self-collection (because a self-collected sample can only be tested for HPV and not for cytology).

People requiring a co-test include:

- those with signs or symptoms suggestive of cervical cancer (e.g. present with an abnormal cervix suspicious of cancer; have unexplained postcoital bleeding or persistent intermenstrual bleeding, postmenopausal bleeding, or unexplained persistent unusual vaginal discharge)[10]
- those who have been treated for adenocarcinoma in situ
- those who were exposed to diethylstilbestrol (DES) in utero.

Co-testing is not required for breakthrough or irregular bleeding due to hormonal contraception or a sexually transmitted infection, heavy menstrual bleeding, or contact bleeding at the time of obtaining a routine CST.

REC 5.3

Self-collection or clinician-collection: supporting informed choice

When deciding between self-collection of a cervical screening test sample or collection by a healthcare provider, screening participants must be given clear information by the supervising healthcare provider about the likelihood that HPV may be detected and, if so, what follow-up will be required. If a person chooses self-collection, then the healthcare provider should give them information about how to collect the sample and how they will receive the test results.

Notes: Explaining what to expect and what happens next

Among those attending for a routine cervical screening test, approximately 2% have HPV (16/18) detected and approximately 6% have HPV (not 16/18) detected (rate varies with age and is higher among younger screening participants).

The next step depends on the result of the cervical screening test:

- If **oncogenic HPV** is **not detected**, the person can be advised to return for repeat screening in 5 years.
- If **HPV (16/18)** is **detected**, the person is referred directly for colposcopy. They do not need to return to the healthcare provider for an LBC test, as this will be taken at the time of colposcopy.
- If **HPV** (not 16/18) is detected on a self-collected sample, the healthcare provider needs to recall the person for an LBC cervical sample taken via a speculum, within 6 weeks. The LBC finding will inform the risk-based recommendation for follow-up. This potential need for an additional visit when the sample is self-collected must be explained to participants when deciding whether to choose self-collection or collection by a healthcare provider.

If a person with **HPV** (not 16/18) detected on a self-collected sample does not return for 9 months or more, a follow-up self-collected HPV test can be offered, rather than a LBC, because this will determine if the HPV has now been cleared and the person can then return to routine screening.

REC 5.4

Follow-up HPV tests after initial routine screening result indicating intermediate risk

When follow-up HPV testing is required after an initial screening result indicating intermediate risk, the sample may be self-collected or collected by a healthcare provider.

Healthcare providers should advise screening participants of the follow-up that will be recommended if HPV is detected and explain that a clinician-collected sample allows for

reflex LBC to be performed on the same sample, potentially avoiding the need for an additional visit to collect a cervical sample for LBC. HPV testing is not repeated on the clinician-collected sample in this circumstance.

Notes:

- Initial routine screening results (in participants aged 25-69 years) are classified as Intermediate risk if HPV (not 16/18) is detected with LBC negative, possible low-grade squamous intraepithelial lesion (pLSIL) or LSIL.
- Among those attending for a follow-up HPV test after initial screening result of
 intermediate risk, the proportion with oncogenic HPV detected is higher than
 amongst participants attending for routine screening, and there is less variation
 between age groups than found in primary screening tests.
- Approximately 60% will have persistent HPV (not 16/18) detected and will need to be recalled to the healthcare provider for an LBC sample taken from the cervix via a speculum to inform the risk-based recommendations within the 'intermediate risk' pathway.

REC 5.5

Settings where self-collection can be performed

Cervical screening on a self-collected vaginal sample must be ordered by a healthcare provider with systems in place to ensure follow-up management of results. Self-collection in a clinic (e.g. in the bathroom or privately behind the clinic curtain) should be encouraged, as sample collection is considered more likely in this context. Note there is no requirement to observe the person collecting their sample unless this is their preference.

Notes:

- 1. There is flexibility for self-collection to occur in any setting that the healthcare provider ordering the test believes is appropriate to maximise screening participation. This can potentially include telehealth models of care.
- 2. Critically, for all non-clinic-based settings, clear and documented lines of responsibility (with a systems-based approach) are required. The health professional ordering the screening test has full responsibility for ensuring the patient has access to the correct sampling devices and information about how to take the test and its delivery to the laboratory, and that there are arrangements in place with the local laboratory for receipt and processing of self-collected samples and for delivery of results back to the healthcare provider.
- 3. The healthcare provider is also responsible for ensuring patients are informed about their results and for arranging and overseeing any required follow-up. Healthcare providers who offer self-collection must have identified pathways to ensure that participants with screen-detected abnormalities can access timely provision of clinician-collected sampling if required as part of recommended follow-up, e.g. for follow-up LBC following detection of HPV (not 16/18). This does not mean that the person providing self-collection must also be able to provide a clinician-collected sample themselves (e.g. for follow-up or if clinician-collected screening is preferred); clinician-collected samples could alternatively be provided by another healthcare provider through an accessible referral pathway.

Within these constraints, healthcare providers and laboratories working together have flexibility to develop models of screening that best meet the needs of their communities.

Only doctors and nurse practitioners can sign the pathology request for tests under current MBS rules.

REC 5.6

Assistance with sample self-collection

Cervical screening participants who have difficulty collecting a lower vaginal sample by themselves can be assisted by the healthcare provider. If requested, assistance could include collection of the sample using a self-collection swab without using a speculum. A sample collected in this way is still classified as self-collection on the pathology request form.

REC 5.7

Genital inspection at sample collection

Routine genital inspection is not indicated in all cervical screening participants, but could still be offered to those choosing self-collection if clinically indicated due to vulvovaginal symptoms or if a person is at high risk for vulvar disease. The reason for offering genital inspection to participants should be clearly explained and understood.

Notes:

Risk factors: HPV infection, immune deficiency acquired or congenital, genital herpes, lichen sclerosis or lichen planus, smoking, age (vulvar cancer is more common among people who are over 70 years old), history of other gynaecologic cancers, history of melanoma or atypical moles.

REC 5.8

Clinician-collected cervical sampling and referral to colposcopy: vaginal dryness

For screening participants with vaginal dryness (e.g. those who are postmenopausal, breastfeeding, or using testosterone, including as transmasculine and non-binary therapy), a short course of topical estrogen therapy should be considered before a clinician-collected cervical screening sample or referral to colposcopy.

The healthcare provider should explain that this is to reduce discomfort associated with the procedure and to improve the diagnostic accuracy of either the LBC or the colposcopy, and that it will not interfere with other hormonal treatments.

Notes: Examples of topical estrogen courses are daily use of cream or pessaries for 3–7 nights before LBC sample collection, and daily use of cream or pessaries for at least 2 weeks before colposcopy, ceasing 1–2 days before the appointment. A 2 week course of estrogen is recommended before colposcopy, and should also be considered before clinician-collected cervical sampling for people who are likely to have severe vaginal atrophy.

REC 5.9

Preparation for clinician-collected sampling

Use models and diagrams to explain to screening participants what will happen during clinician-collected cervical screening test sampling, and give people plenty of time for questions. Ask the person to empty their bladder before the procedure and instruct them to undress from the waist down behind the clinic curtain then lie on their back on the bed. Provide them with a sheet or blanket to cover themselves with.

Explain what is happening throughout all stages of the procedure and ensure the person knows that they can request to stop the procedure at any time.

Notes: As part of trauma-informed care, consider discussing other options such as a different positioning of the participant during the speculum examination, offering self-insertion of the speculum and/or having a support person present (see <u>5.14 Providing trauma-informed care</u>).

REC 5.10

Difficulty visualising the cervix

For screening participants who choose to have a clinician-collected CST sample, or for whom a co-test is required, and where visualisation of the cervix is difficult, the following approaches may be useful:

- For patients with prolapsing vaginal walls obscuring the cervix, placing a condom (or finger of an examination glove) with the closed end cut off over the blades of the speculum can help prevent the vaginal walls obscuring the cervical os. Use a nonlatex condom if the patient is allergic to latex.
- For patients with obesity or disability which prevents them lying on the bed in the traditional modified lithotomy position, consider the left lateral position and use of a Sims' speculum.
- Placing a cushion under the patient's buttocks to tilt the pelvis enables easier
 visualisation of the cervix. It also stops the handle of the speculum from hitting the
 examination bed/couch enabling the healthcare provider to gently manoeuvre the
 speculum to visualise the cervix. Asking the patient to place their fists under their

buttocks, rather than a cushion, is not recommended as this can disempower the patient and increase their sense of vulnerability during the examination.

REC 5.11

Recording Aboriginal and Torres Strait Islander status for data collection

Healthcare providers are strongly recommended to ask all participants whether they identify as Aboriginal and/or Torres Strait Islander, and a person's Aboriginal and Torres Strait Islander status should be recorded on relevant clinical records, including pathology request forms.

Healthcare providers should be aware that not all participants may feel comfortable declaring their status. It is essential to create a safe and respectful environment, so that community members feel comfortable declaring their status.

Notes:

- Aboriginal and Torres Strait Islander status should be recorded in line with the ABS Indigenous Status Standard (Aboriginal; Torres Strait Islander; Both Aboriginal and Torres Strait Islander; Neither Aboriginal nor Torres Strait Islander)
- Aboriginal and Torres Strait Islander status influences clinical management of tests in some cases, including in the intermediate risk pathway. See 6.4 <u>Oncogenic HPV</u> <u>types 16 and/or 18</u>).

REC 5.12

Support for under-screened participants

Under-screened participants, especially those who have had a CST on a self-collected sample, may need additional and individualised support to progress along the screening pathway, and may need access to follow-up services where they will receive sensitive treatment. This additional support may involve, for example, reassurance and explanation of the screening pathway and follow-up procedures, scheduling longer appointments, or providing additional follow-up contact.

Consensus recommendation

REC 5.13

Aboriginal and Torres Strait Islander people: NCSP participation

Eligible Aboriginal and Torres Strait Islander people should be invited and encouraged to participate in the NCSP and have a 5-yearly HPV test, as recommended for all Australian participants.

Notes: Translated <u>resources in multiple Aboriginal and Torres Strait Islander languages</u> are available to support screening with both self-collected and clinician-collected samples on the NCSP website.

REC 5.14

Aboriginal and Torres Strait Islander people: cervical screening services

Specific efforts at all levels of the healthcare system should be made to provide accessible and culturally safe screening, diagnostic and treatment services to Aboriginal and Torres Strait Islander people.

More information and resources are available (see NCSP Healthcare Provider Toolkit).

REC 5.15

Aboriginal and Torres Strait Islander people: eligibility for screening on self-collected sample

Aboriginal and Torres Strait Islander people, as for all eligible screening participants, should be offered the choice of HPV testing on a self-collected vaginal sample or on a clinician-collected sample.

REC 5.16

Recording Aboriginal and Torres Strait Islander status for data collection

Healthcare providers are strongly recommended to ask all screening participants whether they identify as Aboriginal and/or Torres Strait Islander, and the person's Aboriginal and Torres Strait Islander status should be recorded on relevant clinical records, including pathology request forms, in accordance with the Australian Bureau of Statistics classification and standards.

It is important to create a safe environment to support the patient with their decision to disclose their Aboriginal or Torres Strait Islander status; this may be uncomfortable for some due to historical and local social contexts.

Notes: Aboriginal and Torres Strait Islander status influences clinical management of tests in some cases, including in the intermediate risk pathway. See 6.4 <u>Oncogenic HPV types 16</u> and/or 18).

REC 5.17

Clinician-collected cervical sampling and referral to colposcopy: vaginal dryness

For screening participants with vaginal dryness (e.g. those who are postmenopausal, breastfeeding, or using testosterone, including as transmasculine and non-binary therapy), a short course of topical estrogen therapy should be considered before a clinician-collected CST sample or referral to colposcopy.

The healthcare provider should explain that this is to reduce discomfort associated with the procedure and to improve the diagnostic accuracy of either the LBC or the colposcopy, and that it will not interfere with other hormonal treatments.

Notes: Examples of topical estrogen courses are daily use of cream or pessaries for 3–7 nights before LBC sample collection, and daily use of cream or pessaries for at least 2 weeks before colposcopy, ceasing 1–2 days before the appointment. A 2 week course of estrogen is recommended before colposcopy, and should also be considered before clinician-collected cervical sampling for people who are likely to have severe vaginal atrophy.

REC 5.18

Supporting screening participants with a history of sexual assault

If a screening participant discloses sexual assault, provide additional support and referrals as required (see <u>5.14 Providing trauma-informed care</u> and <u>5.15 Managing anxiety and distress</u>):

- Consider offering participants referral to a cervical screening provider who is experienced in working with people who have experienced sexual assault.
- Ensure cervical screening providers of the participant's preferred gender are available, if requested.
- Offer the choice of self-collection, as this may be a more comfortable and acceptable screening option.
- If the person opts for a clinician-collected sample, the following may assist:
 - Offer people the opportunity to perform the test in a different position (e.g. lying on their side rather than their back, letting them have their hands and arms free during the examination).
 - Consider using a smaller speculum.
 - Some people may prefer to insert their own speculum, and it can be helpful to offer this option.

Providing instructions on calming and deep breathing techniques can also help the person to relax.

Strong recommendation against

REC 5.19

Routine cervical screening: starting age

Routine cervical screening is not recommended for people under the age of 25 years.

Notes: NCSR sends invitations for screening when a person turns 24 years and 9 months; screening from this age attracts a Medicare rebate.

See Pregnancy section

Consensus recommendation

REC 5.20

Cervical screening: early sexual contact

Cervical screening is not recommended for people aged less than 25 years, even when they have experienced early sexual contact. For those who experience their first sexual contact at a young age (<14 years) and who had not received the HPV vaccine before sexual debut, a single HPV test at age 20–24 years could be considered on an individual basis, but is not required. The HPV test could be self-collected or collected by a healthcare provider, depending on the person's preference.

Consensus recommendation

REC 5.21

Postcoital or intermenstrual bleeding

People at any age who have signs or symptoms suggestive of cervical cancer or its precursors, such as post-coital or intermenstrual bleeding, where other common causes of abnormal vaginal bleeding such as a sexually transmitted infection have been excluded, should have a co-test and be referred for appropriate investigation to exclude genital tract malignancy.

Notes: For more information regarding signs or symptoms suggestive of cervical cancer or its precursors (see <u>10. Signs and symptoms of cervical cancer</u>). Co-testing (HPV and LBC) is recommended as the presence of blood has the potential to adversely affect the sensitivity of the HPV and/or LBC tests.

REC 5.22

Screening at age 70–74 years: oncogenic HPV not detected (exit testing)

Women and people with a cervix can be discharged from the NCSP if they are aged 70–74 years and have a screening test at which oncogenic HPV is not detected.

Consensus recommendation

REC 5.23

Screening at age 70–74 years: oncogenic HPV detected on screening test

Screening participants aged 70–74 years who have oncogenic HPV (any type), i.e. HPV 16/18 and/or HPV (not 16/18), detected on a cervical screening test result should be referred directly for colposcopic assessment, which should be informed by the LBC result. If the sample was collected by a healthcare provider, the laboratory will perform reflex LBC. If the sample was self-collected, a cervical sample for LBC should be collected at the time of colposcopy.

REC 5.24

Cervical screening in people aged 75 years or older by request

Women and people with a cervix who are 75 years or older who have never had a cervical screening test, or have not had one in the past 5 years, may request a test and can be screened. The sample can be self-collected or collected by a healthcare provider, according to the person's choice.

REC 5.25

Clinician-collected cervical screening samples: cervical screening participants aged 75 years and over

A short course of topical estrogen therapy could be considered before collecting the sample. For example, estrogen cream or pessaries for 3–7 nights, ceasing 1–2 days prior to the appointment. The healthcare provider should explain that the purpose of this treatment is to reduce discomfort from the speculum and to improve the diagnostic accuracy of LBC.

REC 5.26

Management of HPV test results: cervical screening participants aged 75 years and over

Results of HPV tests for cervical screening in those aged 75 or older should be managed in the same way as those for participants attending for an exit test when aged 70–74 years:

- If oncogenic HPV is not detected, no further screening is required.
- If oncogenic HPV (any type), i.e. HPV 16/18 and/or HPV (not 16/18), is detected on a cervical screening test, participants should be referred directly for colposcopic assessment, which should be informed by the LBC result. If the sample was collected by a healthcare provider, the laboratory will perform reflex LBC. If the sample was self-collected, a cervical sample for LBC should be collected at the time of colposcopy.

Chapter 6 Recommendations

Strong recommendation

REC 6.1

Oncogenic HPV types not detected at routine screening

Women and people with a cervix who have a screening HPV test in which HPV **is not** detected should rescreen in 5 years.

Strong recommendation

REC 6.2

Screening test result: HPV (16/18) detected

Screening participants in whom **HPV (16/18)** is detected should be referred directly for colposcopic assessment, which will be informed by the liquid-based cytology (LBC) result. If the sample has been collected by a healthcare provider from the cervix, reflex LBC will be performed by the laboratory. If the sample has been self-collected, a sample for LBC should be collected at the time of colposcopy.

Notes: Participants with HPV (16/18) detected on a self-collected sample are also referred directly for colposcopy without the need to return to the healthcare provider for a LBC test, which will be taken at the time of the colposcopy.

Consensus recommendation

REC 6.3

Screening test result: HPV (16/18) detected and LBC prediction of invasive cancer

Screening participants in whom HPV (16/18) is detected, with a reflex LBC report of invasive cancer (squamous, glandular or other), should be referred to a gynaecological oncologist or gynaecological cancer centre for urgent evaluation, ideally within 2 weeks.

REC 6.4

Screening test result: HPV (16/18) detected and LBC prediction of pHSIL/HSIL or any glandular abnormality

Screening participants in whom HPV (16/18) is detected and with a reflex LBC prediction of possible high-grade squamous intraepithelial lesion (pHSIL), HSIL, or any glandular abnormality, should be referred for colposcopic assessment at the earliest opportunity, ideally within 8 weeks.

REC 6.5

Screening test result: HPV (16/18) detected and LBC unsatisfactory

When HPV (16/18) is detected on a cervical screening test, colposcopic referral is required regardless of the LBC result, and the screening episode should be classified as 'Higher risk for cervical cancer or precursors'. If reflex LBC is unsatisfactory or the screening sample has been self-collected, a cervical sample for LBC should be collected at the time of colposcopy.

Strong recommendation

REC 6.6

Screening test result: HPV (not 16/18) detected and LBC prediction of Negative, pLSIL or LSIL

For screening participants in whom HPV (not 16/18) is detected and with a LBC report of negative, possible low-grade squamous intraepithelial lesion (pLSIL) or LSIL, a follow-up HPV test should be performed in 12 months.

Notes:

LBC must be performed when oncogenic HPV (not 16/18) is detected on a cervical screening test.

- If the **sample was collected by a healthcare provider**, then the laboratory will perform reflex LBC.
- If the sample was self-collected, the screening participant should return to their healthcare provider within 6 weeks to have a cervical sample collected for LBC. If the person does not return until 9 months or more after the HPV test, a follow-up self-collected HPV test can be offered, rather than a LBC, because this will determine if the HPV infection has now been cleared and the person can then return to routine screening.

Consensus recommendation

REC 6.7

Oncogenic HPV (not 16/18) detected at routine screening with LBC prediction of invasive disease: referral to gynaecological oncologist

Screening participants in whom HPV (not 16/18) is detected with a LBC prediction of invasive cancer (squamous, glandular or other) should be referred to a gynaecological oncologist or gynaecological cancer centre for urgent evaluation, ideally within 2 weeks.

REC 6.8

Oncogenic HPV (not 16/18) detected at routine screening with LBC prediction of pHSIL, HSIL or any glandular abnormality: referral to colposcopy

Screening participants in whom HPV (not 16/18) is detected and with a LBC prediction of pHSIL/HSIL or any glandular abnormality should be referred for colposcopic assessment at the earliest opportunity, ideally within 8 weeks.

Strong recommendation

REC 6.9

Follow-up HPV test at 12 months following initial HPV (not 16/18) detected and LBC negative or pLSIL/LSIL: HPV not detected or HPV (16/18) detected

At follow-up HPV testing **12 months after** a detection of HPV (not 16/18) and LBC results of negative or pLSIL/LSIL:

- If oncogenic **HPV** is **not detected**, then the person should be advised to return to routine 5-yearly screening
- If **HPV** (16/18) is detected (see <u>Oncogenic HPV types 16 and/or 18</u>), then the person should be referred for colposcopic assessment. If the follow-up sample was collected by a healthcare provider, then the laboratory will undertake reflex LBC. If the follow-up sample was self-collected, a sample for LBC should be collected at the time of colposcopy.

REC 6.10

Follow-up HPV test at 12 months following initial test result of HPV (not 16/18) detected and LBC negative or pLSIL/LSIL: oncogenic HPV (any type) detected in specific groups

If HPV (any type) is detected at a 12-month follow-up test, then the person should be referred for colposcopic assessment if any of the following conditions apply:

- They were overdue for screening by at least 2 years at the time of the index screening test.
- They identify as Aboriginal and/or Torres Strait Islander.
- They are aged 50 years or older.

If the follow-up sample was collected from the cervix by a healthcare provider, the laboratory will then undertake reflex LBC. If the follow-up sample was self-collected, a sample for LBC should be collected at the time of colposcopy.

Consensus recommendation

REC 6.11

Follow-up HPV test at 12 months following initial test result showing HPV (not 16/18) detected with LBC negative or pLSIL/LSIL: HPV (not 16/18) detected and LBC prediction of invasive cancer, pHSIL/HSIL, or glandular abnormality

For screening participants in whom HPV (not 16/18) again is detected at the follow-up test, LBC should be performed.

If the follow-up sample was collected by a healthcare provider, then the laboratory will undertake reflex LBC. If the follow-up sample was self-collected, then the person should be advised to return to their healthcare provider so that a sample can be collected for LBC.

- If the **LBC** predicts invasive cancer (squamous, glandular or other), then the person should be referred to a gynaecological oncologist or gynaecological cancer centre for urgent evaluation, ideally within 2 weeks.
- If the LBC predicts pHSIL, HSIL or any glandular abnormality, then the person should be referred for colposcopic assessment at the earliest opportunity, ideally within 8 weeks.

Notes: This recommendation does not apply to screening participants in any of the specific groups: those who were overdue for screening by at least 2 years at the time of their initial screening test result showing oncogenic HPV (not 16/18) detected; those who identify as Aboriginal and/or Torres Strait Islander; those aged 50 years or older.

Consensus recommendation

REC 6.12

Follow-up HPV test at 12 months following initial HPV (not 16/18) detected and LBC negative or pLSIL/LSIL: HPV (not 16/18) detected and LBC negative or pLSIL/LSIL

For screening participants in whom HPV (not 16/18) is again detected at the 12 month followup, a LBC test is required.

If the follow-up sample was collected by a healthcare provider, then the laboratory will undertake reflex LBC. If the follow-up sample was self-collected, then the person should be advised to return to their healthcare provider so that a sample can be collected for LBC.

• If the LBC is reported again as negative, or predicts pLSIL orLSIL, screening participants should have a second follow-up HPV test in a further 12 months (24 months after initial screening test).

Notes: This recommendation does not apply to screening participants in any of the specific groups: those who were overdue for screening by at least 2 years at the time of their initial screening test result showing oncogenic HPV (not 16/18) detected; those who identify as Aboriginal and/or Torres Strait Islander; those aged 50 years or older.

Consensus recommendation

REC 6.13

Second follow-up HPV test at 12 months after first follow-up where test results were HPV (not 16/18) detected and LBC negative or pLSIL/LSIL

At the second follow-up HPV test, 12 months after a first follow-up HPV test:

- If **oncogenic HPV (any type)** is **detected**, the person should be referred for colposcopic assessment. When the follow-up sample has been collected by a healthcare provider, then the laboratory will perform reflex LBC. When the follow-up sample was self-collected, then a sample should be collected for LBC at the time of colposcopy.
- If **HPV** is **not detected**, the person should be advised to return to routine 5-yearly screening.

REC 6. 14

LBC test: Unsatisfactory

In the case of unsatisfactory LBC, laboratories should ensure that adequate repeat preparations are attempted, after dealing with potentially remediable technical problems.

Notes:

When reflex LBC is reported unsatisfactory in a case where it was required to determine whether the person should be referred for colposcopic assessment or should have a follow-up test in 12 months, the following actions should be taken:

- The screening episode should be classified as 'Unsatisfactory'.
- Repeat testing in 6 weeks should be recommended.
- At repeat testing, the sample should not be tested for HPV.
- At repeat testing, the laboratory should undertake LBC and then prepare a cervical screening report combining the results of the original HPV test and the repeat LBC (see Preparation of cervical screening reports in chapter 4. Terminology, classification systems and report preparation).

When reflex LBC is unsatisfactory, but the screening participant requires colposcopic referral regardless of the LBC result, the screening episode should be reported as 'Higher risk for significant cervical abnormality'. LBC should then be performed at the time of colposcopy.

REC 6.15

LBC test: cellular abnormality

Any LBC specimen with abnormal cells should **not** be reported as 'Unsatisfactory'. Instead, the identified cellular abnormality should be reported.

REC 6.16: LBC report: unsatisfactory

A screening participant with an LBC test reported as 'unsatisfactory' should have a repeat sample collected in 6 weeks. If the reason for the unsatisfactory sample has been identified then this problem should be corrected – if possible, before the repeat sample is collected.

Chapter 7 Recommendations

REC 7.1

Cervical screening history during antenatal and postpartum care

Routine antenatal and postpartum care should include a review of the person's cervical screening history. Those who are due or overdue for screening should be screened.

Routine antenatal and postpartum care is an important opportunity to reach under-screened and-never screened people who may not otherwise attend health services.

REC 7.2

Cervical screening in pregnancy: clinician-collected sample

Cervical screening can be safely performed at any time during pregnancy, provided that the correct sampling equipment is used. An endocervical brush should not be inserted into the cervical canal because of the risk of associated bleeding, which may be distressing.

Notes: See Figure 14.1 and 14.2 respectively, for cyto-broom (recommended) and endocervical brush (not recommended) examples.

Figure 7.1. Cyto-broom: recommended for use in pregnant women to collect a cervical screening specimen



Image source: Australian Centre for the Prevention of Cervical Cancer

Figure 7.2. Endocervical brush: NOT recommended for use



Image source: Australian Centre for the Prevention of Cervical Cancer

REC 7.3

Cervical screening in pregnancy: self-collection sample

All women and people with a cervix who are due for cervical screening during pregnancy may be offered the option of self-collection of a vaginal swab for human papillomavirus (HPV) testing. Check with your laboratory that the swabs provided to you are validated for self-collection in pregnancy.

Those with HPV (not 16/18) detected on a self-collected sample should be advised to return so that a cervical sample for liquid-based cytology (LBC) can be collected by the healthcare provider.

Healthcare providers should advise screening participants of the follow-up that will be recommended if HPV is detected and explain that a clinician-collected sample allows for reflex LBC to be performed on the same sample, potentially avoiding the need for an additional visit to collect a cervical sample for LBC. HPV testing is not repeated on the clinician-collected sample in this circumstance.

Notes: See Figure 7.3 for self-collection swab example.

Figure 7.3. Self-collection swab



Image source: Australian Centre for the Prevention of Cervical Cancer

Consensus recommendation

REC 7.4

Oncogenic HPV (not 16/18) detected with LBC prediction of negative, pLSIL or LSIL in pregnancy

Pregnant screening participants in whom oncogenic HPV (not 16/18) is detected, with a LBC prediction of negative, possible low-grade squamous intraepithelial lesion (pLSIL) or LSIL should have a follow-up HPV test in 12 months.

Consensus recommendation

REC 7.5

Oncogenic HPV (not 16/18) detected with LBC prediction of pHSIL, HSIL or any glandular abnormality in pregnancy

Pregnant screening participants in whom oncogenic HPV (not 16/18) is detected with a LBC prediction of possible high-grade squamous intraepithelial lesion (pHSIL), HSIL or any glandular abnormality should be referred for early colposcopic assessment as soon as practical. This should not be deferred until the postpartum period.

Consensus recommendation

REC 7.6

HPV (16/18) detected in pregnancy

Pregnant screening participants in whom HPV (16/18) is detected should be referred for early colposcopic assessment as soon as practical, regardless of the LBC prediction. This should not be deferred until the postpartum period.

If the screening sample was collected by a healthcare provider, then the laboratory will undertake reflex LBC. If the screening sample was self-collected, then a sample for LBC should be collected at the time of colposcopy.

Consensus recommendation

REC 7.7

Referral of patients with invasive disease detected during pregnancy

Pregnant screening participants should be referred and seen within 2 weeks by a gynaecological oncologist/gynaecological cancer centre for multidisciplinary team review and management if any of the following are reported:

- LBC prediction of invasive disease
- colposcopic impression of invasive or superficially invasive squamous cell carcinoma of the cervix
- histologically confirmed diagnosis of invasive or superficially invasive squamous cell carcinoma of the cervix.

Consensus recommendation

REC 7.8

Colposcopy during pregnancy: aim of the procedure

The aim of colposcopy during pregnancy is to exclude the presence of invasive cancer and to reassure the person that their pregnancy will not be affected by the presence of an abnormal cervical screening test result.

REC 7.9

Colposcopy during pregnancy

Colposcopy during pregnancy should be undertaken by a colposcopist experienced in assessing colposcopic findings during pregnancy.

Consensus recommendation

REC 7.10

Cervical biopsy during pregnancy

Biopsy of the cervix is usually unnecessary in pregnancy, unless invasive disease is suspected on colposcopy or reflex LBC predicts invasive disease.

Consensus recommendation

REC 7.11

Deferral of treatment until after pregnancy

Definitive treatment of a suspected high-grade lesion, except invasive cancer, may be safely deferred until after the pregnancy.

REC 7.12

Follow-up assessment after pregnancy

If postpartum follow-up assessment (colposcopy and/or HPV test and reflex LBC if necessary) is required, it should be done no less than 6 weeks after delivery and preferably at 3 months. This interval is optimal to reduce the risk of reflex LBC interpretation difficulties or unsatisfactory reflex LBC.

The cervical sample (for HPV test and reflex LBC if necessary) could be collected at the time of postpartum check or at the time of the colposcopic assessment.

REC 7.13

Referral to postpartum colposcopy during breastfeeding: use of topical estrogen

During breastfeeding, a short course of topical estrogen therapy should be considered prior to referral to colposcopy. The healthcare provider should explain that this is to reduce discomfort associated with the procedure and to improve the visualisation of the cervix and the quality of any cervical sample for LBC.

Notes: Examples of topical estrogen courses are daily use of cream or pessaries for 3–7 nights before LBC sample collection, and daily use of cream or pessaries for at least 2 weeks before colposcopy, ceasing 1–2 days before the appointment.

Consensus recommendation

REC 7.14

Screening in immune-deficient people: screening interval

Immune-deficient participants who are assessed as being at substantially increased risk of cervical cancer and in whom oncogenic HPV is not detected should be screened every 3 years with a HPV test.

Notes: This group should be educated regarding the increased risk from HPV infection and encouraged to attend for regular screening every 3 years. Immune-deficient refers to people with severe acquired or congenital immune deficiency, who are deemed to have, or be at substantially higher risk of cervical precancer and cancer (see Table 7.1).

Consensus recommendation

REC 7.15

Screening in immune-deficient people: management of HPV detected (any type)

Immune-deficient participants who are assessed as being at substantially increased risk of cervical cancer and in whom oncogenic HPV is detected should be referred for colposcopic assessment.

If the screening sample was collected by a healthcare provider, then reflex LBC will be performed by the laboratory. If the screening sample was self-collected, then LBC should be undertaken at colposcopy.

Notes: Immune-deficient refers to people with severe acquired or congenital immune deficiency, who are deemed to have, or be at substantially higher risk of cervical precancer and cancer (see Table 7.1).

Consensus recommendation

REC 7.16

Screening in immune-deficient people: colposcopy assessment and treatment

Assessment and treatment of immune-deficient participants with screen-detected abnormalities should be provided by an experienced colposcopist or in a tertiary centre.

Notes: Immune-deficient refers to people with severe acquired or congenital immune deficiency, who are deemed to have, or be at substantially higher risk of cervical precancer and cancer (see Table 7.1).

Consensus recommendation

REC 7.17

Screening in immune-deficient people: colposcopy of the lower genital tract

The entire lower anogenital tract should be assessed during colposcopy, as the same risk factors apply for cervical, vaginal, vulval, perianal and anal lesions.

Notes: Immune-deficient refers to people with severe acquired or congenital immune deficiency, who are deemed to have, or be at substantially higher risk of cervical precancer and cancer (see Table 7.1).

Consensus recommendation

REC 7.18

Screening in immune-deficient people: treatment of precancerous lesions

If treatment for a cervical precancerous lesion is required for an immune-deficient person, an excisional method should be used.

Notes: Immune-deficient refers to people with severe acquired or congenital immune deficiency, who are deemed to have, or be at substantially higher risk of cervical precancer and cancer (see Table 7.1).

REC 7.19

Screening in immune-deficient people: management of histological abnormalities

Histological abnormalities of the cervix in immune-deficient people should be managed according to the same guidelines as participants who are not immune-deficient.

Notes: Immune-deficient refers to people with severe acquired or congenital immune deficiency, who are deemed to have, or be at substantially higher risk of cervical precancer and cancer (see Table 7.1).

REC 7.20

Screening in immune-deficient people: Test of Cure for HSIL (CIN2/3)

Immune-deficient people who have undergone treatment for HSIL (CIN2/3) should have follow-up with Test of Cure as recommended in these guidelines [see <u>9.2.3 Test of Cure after treatment for HSIL (CIN2/3)</u>]. Immune-deficient screening participants who complete Test of Cure should return to routine 3-yearly screening with an HPV test.

Notes: Immune-deficient refers to people with severe acquired or congenital immune deficiency, who are deemed to have, or be at substantially higher risk of cervical precancer and cancer (see Table 7.1).

REC 7.21

Screening before solid organ transplantation

Women and people with a cervix aged between 25 and 74 years should have a review of cervical screening history when they are added to the organ transplant waiting list and while they remain on the waiting list, to confirm they are up to date with recommended screening for the general population. Participants who are overdue for screening, or become due while on the waiting list, should be screened with a HPV test so that any abnormalities can be investigated or treated as necessary prior to transplantation and commencement of immunosuppressive therapy.

REC 7.22

Screening women and people with a cervix with a new diagnosis of HIV

Women and people with a cervix aged between 25 and 74 years who have a new diagnosis of HIV should have a review of their cervical screening history to ensure they are up to date with screening, in line with the recommended 3-yearly interval for this group.

REC 7.23

Young women and people with a cervix with long-term immune deficiency

For young screening participants who are sexually active and who have been immune-deficient for more than 5 years, a single HPV test between age 20 and 24 years could be considered on an individual basis (regardless of HPV vaccination status). The sample for HPV testing could be self-collected or clinician-collected, depending on the person's preference.

Consensus recommendation

REC 7.24

Screening in DES-exposed cervical screening participants

Screening participants who were exposed to DES in utero should be offered an annual co-test and colposcopic examination of both the cervix and vagina indefinitely.

Consensus recommendation

REC 7.25

Colposcopy referral for abnormalities in DES-exposed cervical screening participants

Screen-detected abnormalities in those exposed to DES in utero should be managed by experienced colposcopists.

REC 7.26

People with a cervix whose birthing parent was exposed to DES in utero

Screening participants whose birthing parent was exposed to DES in utero should be screened in accordance with the standard NCSP policy (5-yearly HPV testing). However, for those concerned about their risk, testing similar to that recommended for their DES-exposed mothers could be considered on an individual basis. Self-collection for HPV testing is not recommended.

Consensus recommendation

REC 7.27

Total hysterectomy for benign disease

Screening participants who undergo hysterectomy for benign disease (e.g. menorrhagia, uterine fibroids or utero-vaginal prolapse) do not require further screening or follow up of they have a normal cervical screening history and have no cervical pathology at the time of hysterectomy.

If unexpected LSIL or HSIL is identified in the cervix at the time of hysterectomy, then these people require follow-up with an annual HPV test on a specimen from the vaginal vault until no oncogenic HPV is detected on two consecutive tests.

Consensus recommendation

REC 7.28

Total hysterectomy after completed Test of Cure

People who have had a total hysterectomy with no evidence of cervical pathology, have previously been successfully treated for histologically confirmed HSIL, and have completed Test of Cure, do not require further follow-up. They should be considered as having the same risk for vaginal neoplasia as the general population who have never had histologically confirmed HSIL and have a total hysterectomy.

If unexpected LSIL or HSIL is identified in the cervix at the time of hysterectomy, then these people require follow-up with an annual HPV test on a specimen from the vaginal vault until no oncogenic HPV is detected on two consecutive tests.

Note: The vaginal vault sample could be self-collected or clinician collected, depending on the person's preference.

Consensus recommendation

REC 7.29

Total hysterectomy after adenocarcinoma in situ (AIS)

People who have had a total hysterectomy, have been treated for AIS, and are under surveillance, should have a co-test on a specimen from the vaginal vault at 12 months and annually thereafter until two consecutive tests show no HPV detected with a LBC report of negative, after which they do not need further testing.

People who have a total hysterectomy as completion therapy or following incomplete excision of AIS at cold-knife cone biopsy or diathermy excision should have a co-test on a specimen from the vaginal vault at 12 months and annually there after until two consecutive tests show no HPV detected with a LBC report of negative, after which they do not need further testing

Consensus recommendation

REC 7.30

Total hysterectomy for treatment of HSIL (CIN2/CIN3) in the presence of benign gynaecological disease

Screening participants who have had a total hysterectomy as definitive treatment for histologically confirmed HSIL in the presence of benign gynaecological disease, irrespective of cervical margins, should have a HPV test on a specimen from the vaginal vault at 12 months after treatment and annually thereafter until no oncogenic HPV is detected on two consecutive occasions.

After two annual consecutive HPV tests with no oncogenic HPV detected, people who have had a total hysterectomy can be advised that no further testing is required.

Note: The vaginal vault sample could be self-collected or clinician collected, depending on the person's preference.

Consensus recommendation

REC 7.31

Total hysterectomy after histologically confirmed HSIL without Test of Cure

People who have been treated for histologically confirmed HSIL, are under surveillance or have returned to routine screening without Test of Cure, and have had a total hysterectomy with no evidence of cervical pathology, should have a HPV test on a specimen from the

vaginal vault at 12 months and annually until two consecutive tests show no oncogenic HPV detected.

After two annual consecutive HPV tests with no oncogenic HPV detected, they can be advised that no further testing is required.

Note: The vaginal vault sample could be self-collected or clinician collected, depending on the person's preference.

Consensus recommendation

REC 7.32

Total hysterectomy and no screening history

People who have had a total hysterectomy with no evidence of cervical pathology, and whose cervical screening history is not available, should have a HPV test on a specimen from the vaginal vault at 12 months and annually thereafter until no oncogenic HPV is detected on two consecutive occasions.

After two annual consecutive HPV tests with no oncogenic HPV detected, they can be advised that no further testing is required.

Note: The vaginal vault sample could be self-collected or clinician collected, depending on the person's preference.

Consensus recommendation

REC 7.33

Adenocarcinoma in situ (AIS) identified in hysterectomy sample

If unexpected AIS is identified in the cervix at the time of hysterectomy, then these people require follow-up with a co-test on a specimen from the vaginal vault at 12 months and annually thereafter until two consecutive tests show no HPV detected with a LBC report of negative, after which they do not need further testing.

REC 7.34

Colposcopy referral for any positive co-test result following total hysterectomy

People who have had a total hysterectomy and are under surveillance with co-testing, and have a test result of oncogenic HPV (any type) detected and/or any cytological abnormality, should be referred for colposcopic assessment.

REC 7.35

Vaginal bleeding following total hysterectomy

Patients who have vaginal bleeding† following total hysterectomy should be assessed by their GP or gynaecologist, regardless of the results of any surveillance tests.

†Vaginal bleeding is quite common in the early weeks following hysterectomy and, where appropriate, should be investigated by the treating gynaecologist.

REC 7.36

Total hysterectomy after genital tract cancer

People who have been treated for cervical or endometrial cancer are at risk of recurrent cancer in the vaginal vault. They should be under the care of a gynaecological oncologist, who will advise and manage ongoing surveillance. Appropriate surveillance for these patients is therefore outside the scope of these guidelines.

REC 7.37

Subtotal hysterectomy

People who have undergone subtotal hysterectomy (the cervix is not removed) should be invited to have 5-yearly HPV testing in accordance with the recommendation for the general population (or continue surveillance according to their most recent recommendation, if indicated by screening history). Any detected abnormality should be managed according to these guidelines.

Chapter 8 Recommendations

REC 8.1

Colposcopy terminology

Colposcopists in Australia should adopt International Federation for Cervical Pathology and Colposcopy 2011 nomenclature.

REC 8.2

Colposcopy procedure

Colposcopy should be conducted:

- by an adequately trained colposcopist who is registered with c-QUIP and undertakes mandated Quality Assurance activities
- within an appropriate setting that respects the participant's privacy
- with appropriate support from nursing and clerical staff to ensure that clinical governance and communication for safety standards are met (<u>National Safety and</u> Quality Health Service (NSQHS) Standards)
- with properly functioning diagnostic and therapeutic equipment.

Information should be provided to the patient (see <u>8.1.7 Colposcopy information for discussion</u> with patient):

- before or during the first colposcopy consultation
- after a treatment
- in a culturally and linguistically appropriate format

REC 8.4

Communication of the results

Results of any procedure or treatment should be communicated to the patient in a timely fashion. Non-attendance should be documented and harm-minimisation strategies implemented. Repeated non-attendance should be reported to the referring source, general practitioner and the NCSR.

REC 8.5

Preparation for colposcopy: vaginal dryness

A short course of topical estrogen therapy could be considered before colposcopy for people with vaginal dryness (e.g. postmenopausal women, breastfeeding women, and people using testosterone therapy including transmasculine and non-binary people).

The healthcare provider should explain that this is to reduce discomfort associated with the procedure and to improve the diagnostic accuracy of either the LBC or the colposcopy. For those who are using testosterone for gender affirmation, the healthcare provider should explain that a short course of topical estrogen will not affect their hormone treatment.

Notes: An example of a topical estrogen course is daily use with either cream or pessaries for at least 2 weeks (preferably 4–6 weeks) prior to colposcopy, ceasing approximately 2 days prior to the appointment.

Colposcopy: acetic acid application

Acetic acid should be applied for 2 minutes to allow sufficient time for aceto-white changes to become apparent. This is especially important when the lesion is low grade as it may take more time to become visible.

Notes: If liquid-based cytology (LBC) is required, the cervical sample should be collected before applying acetic acid.

REC 8.7

Colposcopy: use of green filter

In addition to a white light filter, a green filter should also be used during colposcopy, to enhance visualization of atypical blood vessels.

REC 8.8

Indications for LBC sampling at time of colposcopy

It is not necessary to take a cervical sample for LBC at the time of colposcopy except in the following circumstances:

- delay in attending for colposcopy > 3 months after referral LBC
- referral LBC is unsatisfactory
- referral LBC is negative but lacks an endocervical component
- prior LBC is not available because the HPV test was performed on a self-collected sample
- the screening participant has developed symptoms suggestive of cervical cancer since undergoing the screening test.

Notes: If LBC is required, the cervical sample should be collected before applying acetic acid.

Consensus recommendation

REC 8.9

Biopsy of high-grade lesions

The cervix should be biopsied when the LBC prediction is possible high-grade squamous intraepithelial lesion (pHSIL) or HSIL, the colposcopic appearance shows major change, and the abnormal TZ is visible (Type 1 or Type 2 TZ).

Notes: Major (Grade 2) aceto-white changes are defined as (IFCPC 2011 nomenclature):

- dense aceto-white epithelium, rapid appearance of aceto-whitening, cuffed crypt (gland) openings
- coarse mosaic, coarse punctation, sharp border, inner border sign, ridge sign.

Biopsy of visible lesion suspicious for invasion when T3 TZ colposcopy

In some situations, when there is a visible high-grade lesion on the ectocervix but there is a T3 TZ (lesion extends into canal out of visual range), it may be reasonable to take a cervical biopsy of the visible lesion if there is any suspicion of superficially invasive or invasive carcinoma.

REC 8.11

Biopsy of low-grade lesions

Biopsy may not always be required for a screening participant with a LBC prediction of pLSIL or LSIL and a colposcopic impression of low-grade disease or less. However, biopsy is accepted practice for confirmation of the colposcopic impression and exclusion of high-grade disease, and should be considered, especially for less experienced colposcopists and in screening participants with HPV (16/18) detected and possible HSIL or worse.

Consensus recommendation

REC 8.12

Colposcopic assessment before treatment

All cervical screening participants with a screen-detected cervical lesion should have an adequate colposcopic assessment prior to treatment.

Notes: The term 'adequate' applies only when the cervix is clearly seen (<u>IFCPC 2011</u> terminology).

Consensus recommendation

REC 8.13

Histopathological confirmation prior to treatment

Treatment should be reserved for those with histologically confirmed HSIL (CIN2/3) or adenocarcinoma in situ (AIS), except for those requiring diagnostic excisional biopsy.

Consensus recommendation

REC 8.14

Biopsy prior to ablative treatment

Screening participants with a screen-detected cervical lesion should have a cervical biopsy prior to any ablative treatment.

Consensus recommendation

REC 8.15

Pathology review of discordant test results

If there is significant discordance between histopathology results after colposcopy and referral cytology, both specimens should be reviewed by a pathologist from at least one of the reporting laboratories. The pathologist should convey the results of the review to the colposcopist in order to inform the management plan.

REC 8.16

Recommendations for tertiary referral

Referral to a more experienced colposcopist, a gynaecological oncologist, tertiary colposcopy clinic, or gynaecological cancer centre should be offered to those with any of the following:

- adenocarcinoma in situ
- abnormalities in pregnancy
- immune-deficiency
- multifocal lower genital tract disease.

REC 8.17

Second opinion

When there is any concern about diagnosis or patient management, a second opinion should be sought and documented.

REC 8.18

The role of multidisciplinary team review

It is not always practical for a colposcopist to access a multidisciplinary team (MDT) review, which is usually conducted in a tertiary referral centre. However, a MDT review is particularly helpful when:

- dealing with complex cases where there is discordance between histopathology and referral cytology (e.g. LBC prediction of HSIL, with negative or LSIL histology)
- implementation of treatment is not urgent and therefore it is possible to take the required time to review the findings and optimise the management plan.

Colposcopy at time of treatment

All treatments should be performed under colposcopic vision, with the exception of cold-knife cone biopsy.

Treatment is achieved by ablation of the abnormal tissue or the complete excision of the atypical TZ. The modalities currently used in Australia are:

- ablation tissue destroyed by an energy source
 - CO₂ Laser
 - Radical Diathermy
 - Thermal coagulation (also known as Semm or Cold coagulation)
- excision tissue excised by surgery using a scalpel or energy source
 - cold-knife (scalpel) cone biopsy
 - electrosurgery

large loop diathermy; loop electrosurgical excision procedure (LEEP) or large loop excision of the TZ (LLETZ)

fixed profile rotating excision (Fisher cone or Utah type)

fine needle/wire; straight wire excision of the TZ (SWETZ) or needle excision of the TZ (NETZ)

CO₂ laser cone.

Cryotherapy is not currently recommended in Australia (see Supplement. Colposcopy technologies and documentation).

The amount of cervical tissue to be ablated or excised should be determined by:[8][9]

- the Type of TZ
- the size and extent of the lesion
- the known or suspected final histology.

Note: ideally, the planned depth of ablation/excision should be recorded and where possible, the extent of the ablation/excision should be measured.

Consensus recommendation

REC 8.20

Criteria for ablative treatment

Ablative therapy should be reserved for those intending to have children, and when the following conditions have all been met:

- TZ is completely visible (Type 1 or Type 2).
- There is no evidence of invasive or glandular disease.
- A biopsy has been performed prior to treatment.
- HSIL (CIN2/3) has been histologically confirmed.

There is no significant discordance between the histopathology and referral cytology results.

REC 8.21

Depth of ablation

A Type 1 TZ with a HSIL (CIN2/3) requires 6–8 mm (and not more than 10 mm) of cervical ablation to be adequately treated.

Consensus recommendation

REC 8.22

Excision specimen quality and pathology

Excisional therapy should aim to remove the entire TZ with a pre-determined length of cervical tissue, ideally in one piece, with minimal distortion or artefact to the final histological specimen.

Note: Achieving these aims is critical for management of suspected or histologically confirmed AIS.

REC 8.23

Excision specimen quality, pathology and very large ectocervical lesion

A very large ectocervical lesion may require removal in two pieces in order to remove the entire lesion. It is still important that the endocervical and stromal margins are suitable for pathological interpretation and that the specimens are accurately oriented and labelled. Consideration should be given to referral to an experienced therapeutic colposcopist or centre where there is expertise in management of large lesions.

REC 8.24

Excisional techniques and surgical competency

Therapeutic colposcopists should use the excisional techniques with which they are comfortable and competent and that produce the best histological specimen.

REC 8.25

Cold-knife cone biopsy should be performed in an operating theatre, under general anaesthesia, by a gynaecological oncologist or gynaecologist competent in the technique.

Historically, cold-knife cone biopsy has been the recommended procedure in suspected cases of glandular disease and invasion, although a recent prospective randomised controlled trial in Australia and New Zealand comparing LEEP and cold-knife cone biopsy for

the management of cervical AIS found no difference in specimen dimensions or in the proportion of patients with involved margins, but the cold-knife cone biopsy group had more post-operative complications (see $\underline{8.1.4.5}$ Special treatment considerations: Adenocarcinoma in $\underline{\text{situ}}$).

REC 8.26

Loop excisional biopsy technique (LEEP/LLETZ)

A single pass of the loop (side to side or posterior to anterior) to produce a specimen in one piece is optimal.

REC 8.27

Loop 'top-hat' excisions should be avoided (LEEP/LLETZ)

The 'top-hat' excision techniques using a wire loop, in which a second piece of endocervical tissue is removed after the first excision, is not an alternative to a properly performed single-piece Type 3 excision, and should be avoided.

REC 8.28

Cold-knife cone biopsy and AIS

Predicted or histologically confirmed AIS should be treated by a Type 3 excision performed in an operating theatre, under general anaesthesia, by a gynaecological oncologist or gynaecologist competent in the technique.

REC 8.29

Role of repeat excision in management of superficially invasive squamous cell carcinoma

In the presence of a superficially invasive squamous carcinoma, if HSIL (CIN2/3) extends to any excision margin, a repeat excision (usually by cold-knife cone biopsy) is recommended.

REC 8.30

First visit with a LBC report of a low-grade lesion

Screening participants who have a LBC prediction of pLSIL/LSIL should **not** be treated at the first visit.

REC 8.31

Excision for recurrent disease after ablation

If there is recurrence of high-grade disease after previous ablation, treatment should be by excision.

REC 8.32

Incomplete excision of high-grade lesions

Patients who have incomplete excision of HSIL (CIN2/3) with positive endocervical or stromal margins do not necessarily require immediate repeat excision and could be offered test of cure (HPV and LBC) surveillance, with the exception of:

- those aged 50 years or over
- those who may not be compliant with recommended follow-up
- those in whom subsequent adequate colposcopy and follow-up cytology cannot be guaranteed.

REC 8.33

Estrogen is recommended after treatment to reduce chance of cervical stenosis

A course of estrogen is recommended after treatment to reduce the chance of cervical stenosis. Examples of estrogen courses are 2 or 3 times per week, starting from 10 days post-treatment, until subsequent colposcopic review.

REC 8.34

Colposcopist should manage discordant results

When colposcopy results are discordant with a higher level of risk suggestion by the HPV type or LBC prediction, the colposcopist should manage the person's cervical cancer risk until both the screening participant and the colposcopist are satisfied with the proposed management plan.

REC 8.35

Normal colposcopy following LBC prediction of pHSIL/HSIL: cytopathology review

If normal colposcopy is reported after a CST result of oncogenic HPV (any type) detected and an initial LBC prediction of pHSIL/HSIL, cytopathology review is recommended to confirm HSIL before proceeding to excisional treatment.

REC 8.36

Cytopathology review: Type 3 TZ colposcopy following LBC prediction of pHSIL/HSIL

For people with a colposcopy report of Type 3 TZ following a cervical screening test result of oncogenic HPV (any type) detected and an initial LBC prediction of pHSIL/HSIL, cytopathology review and exclusion of vaginal or vulvar lesion should be considered to confirm a high-grade cytological abnormality before excision.

Cytopathology review is particularly important when the LBC prediction is pHSIL, because pHSIL has a lower positive predictive value for high-grade disease than HSIL.

Type 3 TZ indicates failure to visualise the upper limit of the TZ, or the entire TZ is within the endocervical canal. It corresponds to 'unsatisfactory' in previous terminology.

Consensus recommendation

REC 8.37

Type 3 TZ colposcopy, LBC prediction of pHSIL/HSIL confirmed after cytopathology review: Diagnostic excision

For screening participants who have a CST result of oncogenic HPV (any type) detected, a LBC prediction of pHSIL/HSIL after cytopathology review, and Type 3 TZ colposcopy, diagnostic excision of the TZ should be performed.

Type 3 TZ indicates failure to visualise the upper limit of the TZ, or the entire TZ is within the endocervical canal. It corresponds to 'unsatisfactory' in previous terminology.

Consensus recommendation

REC 8.38

Downgrading of discordant results

For screening participants with a CST result of oncogenic HPV (any type) detected, Type 3 TZ or normal colposcopy with Type 1/2 TZ, and a subsequent LBC prediction of pLSIL/LSIL or less on cytopathology review, management should be according to the reviewed cytological report (see 8.2.2 *Investigation and management of LBC prediction of negative, possible LSIL or LSIL*).

Consensus recommendation

REC 8.39

Normal colposcopy following LBC prediction of HSIL: diagnostic excision of TZ

For screening participants who have a CST result of oncogenic HPV (any type) detected, normal colposcopy, and a LBC prediction of HSIL on cytopathology review, diagnostic excision of the TZ should be performed.

REC 8.40

Normal colposcopy following LBC prediction of pHSIL: consider diagnostic excision of TZ For screening participants who have a CST result of oncogenic HPV (any type) detected, normal colposcopy, and a LBC prediction of pHSIL on cytopathology review, diagnostic excision of the TZ should be considered. Observation is an alternative option.

REC 8.41

Normal colposcopy following LBC prediction of pHSIL: diagnostic excision or observation

When diagnostic excision of the TZ is recommended due to confirmed LBC prediction of pHSIL on cytopathology review and a CST result of oncogenic HPV detected, despite normal colposcopy, some screening participants and their colposcopist may have concerns about possibly unnecessary treatment.

Those who opt to defer treatment, particularly younger women with concerns about fertility, can be offered observation:

- A HPV test and colposcopy should be repeated at 6 months, and a diagnostic
 excisional procedure should be reconsidered based on the test results (HPV and
 reflex LBC, if performed) obtained at that time.
- If oncogenic HPV is not detected, and the colposcopic impression is unchanged, the HPV test should be repeated in 12 months. If oncogenic HPV is not then detected, routine 5-yearly screening can resume.

REC 8.42

Type 3 TZ colposcopy, LBC prediction of pHSIL confirmed after cytopathology review: Deferral of diagnostic excision

Rarely, someone with confirmed pHSIL at cytopathology review opts to defer diagnostic excision of the TZ, or their clinician advises deferral. In this situation, HPV test and colposcopy should be repeated 6 months later:

 If HPV (any type) is detected and LBC report is negative/prediction of pLSIL/LSIL, repeat HPV test in 12 months.

If HPV (any type) is detected and the LBC has a prediction of pHSIL/HSIL, diagnostic Type 3 excision of the TZ is indicated.

Consensus recommendation

REC 8.43

Normal colposcopy following a LBC report of negative or has a prediction of pLSIL/LSIL For screening participants with a CST result of oncogenic HPV (any type) detected, a LBC

report of negative or has a prediction pLSIL/LSIL, and normal colposcopy, the HPV test should be repeated in 12 months. Management for the person at 12 months is based on their test result (see REC 9.1).

REC 8.44: Cytopathology review prior to observation for LBC negative, or has a prediction of pLSIL/LSIL and Type 3 TZ at colposcopy

For screening participants with a colposcopy report of Type 3 TZ following either an LBC prediction of pLSIL/LSIL or negative LBC in conjunction with HPV (16/18) detected, cytopathology review should be undertaken, and the findings at cytopathology review determine whether observation can be considered:

- If negative, pLSIL/LSIL is confirmed, observation is appropriate (see following recommendation).
- If pHSIL/HSIL is indicated, then diagnostic excision of the TZ should be considered.

Type 3 TZ indicates failure to visualise the upper limit of the TZ, or the entire TZ is within the endocervical canal. It corresponds to 'unsatisfactory' in previous terminology.

Consensus recommendation

REC 8.45

Repeat HPV test after Type 3 TZ colposcopy and referral LBC negative or pLSIL/LSIL

For screening participants who have a CST result of oncogenic HPV (any type)detected with an LBC report of negative or prediction of pLSIL/LSIL (confirmed after cytopathology review), and colposcopy is reported as Type 3 TZ, the HPV test should be repeated in 12 months:

- If oncogenic HPV is not detected at 12 months, the HPV test should be repeated 12 months later. If oncogenic HPV is not detected again at the second repeat HPV test, the person should be advised to return to routine 5-yearly screening.
- If the test result at 12 months is oncogenic HPV (any type) detected, the person should be referred directly for colposcopic assessment, with the LBC report available to inform the assessment.

REC 8.46

Role of ECC in Type 3 TZ colposcopy following LBC prediction of negative, pLSIL/LSIL

For those who are confident and trained in endocervical curettage (ECC) technique and have appropriate equipment, this modality could be considered by for people who have a LBC

report of negative or a prediction of pLSIL/LSIL and colposcopy reported as Type 3 TZ†, in the following situations:

- HPV (16/18) detected in a patient aged 26 years or older who has previously never been screened
- persistent oncogenic HPV (any type) infection with a LBC prediction of persistent pLSIL/LSIL.

A negative ECC may provide additional reassurance for a conservative (observational) approach.

Notes: Type 3 TZ indicates failure to visualise the upper limit of the TZ, or the entire TZ is within the endocervical canal. It corresponds to 'unsatisfactory' in previous terminology.

REC 8.47

Diagnostic excision of the TZ should not be performed if there is no cytological or histological evidence of a high-grade lesion after Type 3 TZ colposcopy

For asymptomatic screening participants with oncogenic HPV (any type) detected test result, Type 3 TZ colposcopy, and no cytological, colposcopic or histological evidence of a high-grade lesion, further diagnostic procedures (such as diagnostic excision of the TZ should not routinely be performed.

Type 3 TZ indicates failure to visualise the upper limit of the TZ, or the entire TZ is within the endocervical canal. It corresponds to 'unsatisfactory' in previous terminology.

Consensus recommendation

REC 8.48

Colposcopy referral for atypical glandular/endocervical cells

Cervical screening participants who have a positive oncogenic HPV (any type) test result with a LBC report of atypical glandular/endocervical cells of undetermined significance should be referred to a gynaecologist with expertise in the colposcopic evaluation of suspected malignancies or a gynaecological oncologist.

Consensus recommendation

REC 8.49

Follow-up after normal colposcopy and LBC prediction of atypical glandular/endocervical cells

Screening participants who have a positive oncogenic HPV test result (any type) with a LBC

prediction of atypical glandular/endocervical cells of undetermined significance and normal colposcopy can be offered repeat co-testing (HPV and LBC) at 6–12 months:

- If the follow-up co-test is negative, co-testing should be repeated annually until two consecutive co-tests are negative, after which 5-yearly screening can be resumed.
- If there is either oncogenic HPV (any type) detected or an abnormal LBC (any report other than negative), the person should be referred for colposcopic assessment, and diagnostic excision of the TZ should be considered.

REC 8.50

Upper genital tract investigation

If no lower genital tract abnormality is detected at colposcopy in a screening participant with a referral LBC report of abnormal glandular cytology (including atypical glandular cells or endocervical cells of undetermined significance), upper genital tract imaging (usually transvaginal ultrasound) should be considered. In some people, further investigation, such as endometrial sampling to exclude an endometrial origin for atypical glandular cells, may be required.

REC 8.51

Exclusion of upper genital tract disease before diagnostic excision

For screening participants with oncogenic HPV (any type) detected and who have atypical glandular/endocervical cells of undetermined significance on cytology, investigation of the upper genital tract (endometrium, fallopian tube or ovary) using endometrial sampling and/or pelvic ultrasound should be considered, before either diagnostic excision of the TZ is performed or the person is advised to return for colposcopy and further tests in 6–12 months, in those with any of the following:

- age over 45 years
- age over 35 years with a body mass index (BMI) greater than 30 Kg/m²
- diagnosis of polycystic ovarian syndrome
- abnormal vaginal bleeding.

REC 8.52

Role of immediate diagnostic excision of TZ versus observation

Immediate diagnostic excision of the TZ can be considered for screening participants with atypical glandular/endocervical cells of undetermined significance if they prefer not to take a conservative observational approach. This might apply to:

- those aged over 45 years
- those who have completed childbearing
- those who are particularly anxious about their cancer risk.

REC 8.53

Follow-up after Type 3 TZ at colposcopy and LBC prediction of atypical glandular/endocervical cells

Endocervical curettage (ECC) and endometrial sampling is recommended for screening participants who have oncogenic HPV (any type) detected with a LBC prediction of atypical glandular/endocervical cells of undetermined significance and Type 3 TZ at colposcopy.

Consensus recommendation

REC 8.54

Colposcopy for possible high-grade glandular lesions

Screening participants who have a CST result of oncogenic HPV (any type) detected with a LBC prediction of possible high-grade glandular lesion should be referred to a gynaecologist with expertise in the colposcopic evaluation of suspected malignancies or a gynaecological oncologist.

Diagnostic excision of the endocervical TZ should be performed in most cases.

REC 8.55

Women and people with a cervix who decline treatment for possible high-grade glandular lesions

Those with a LBC prediction of possible high-grade glandular lesion who decline the recommended excision should be offered surveillance with co-testing (HPV and LBC) and colposcopy in 6 months.

If the co-test result at 6 months is oncogenic HPV (any type) detected or any abnormal LBC, the person should be encouraged to have a diagnostic excision of the TZ.

The managing clinician should ensure that the person fully understands the potential risk of underlying disease (21.5% risk of AIS and 5.5% risk of invasive cancer).

Consensus recommendation

REC 8.56

Colposcopy referral for AIS

Screening participants with a LBC prediction of AIS should be referred to a gynaecologist with expertise in the colposcopic evaluation of suspected malignancies or to a gynaecological oncologist.

Diagnostic excision of the endocervical TZ should be performed.

REC 8.57

Referral to gynaecological oncologist for LBC prediction of invasive disease

Screening participants who have a CST result of oncogenic HPV (any type) detected with a LBC prediction of invasive adenocarcinoma should be referred to a gynaecological oncologist or a gynaecological oncology centre for urgent evaluation, ideally within 2 weeks.

Consensus recommendation

REC 8.58

Specimen for histological assessment of glandular abnormalities

When diagnostic excision of the TZ is performed in the investigation of glandular abnormalities, the method chosen should ensure that a single, intact specimen with interpretable margins is obtained for histological assessment.

REC 8.59

Cold-knife cone biopsy is the 'gold standard' for glandular abnormalities

Cold-knife cone biopsy should be considered the 'gold standard' for the diagnostic assessment of glandular lesions. However, a diathermy excisional procedure may be appropriate in some circumstances and could provide an appropriate surgical specimen when performed by a gynaecologist with appropriate training, experience and expertise.

REC 8.60

Size of cone biopsy

The depth and extent of the cone biopsy should be tailored to the person's age and fertility requirements. A Type 3 Excision of the TZ is usually required.

REC 8.61

LBC sampling at colposcopy

If a cervical screening participant is referred to colposcopy without a valid LBC test result, a LBC sample should be collected at the time of colposcopy, before applying acetic acid, using both a broom-type brush and an endocervical brush.

REC 8.62

Review screening history before colposcopy

When a screening participant is referred to colposcopy without a valid LBC result, the colposcopist should review the person's screening history, via PRODA, to inform colposcopy and discussions with the patient.

The colposcopist should explain that there is a possibility that the results of the LBC collected at this colposcopy visit may necessitate another visit. This discussion should be tailored based on the person's individual risk level estimated from the person's previous screening history.

	Rec		Recommended clinical action			
		Screening test	Colposcopy	TZ	Screening history	
:	8.9, 8.10, 8.11	Oncogenic HPV detected (any type)	Any lesion identified	Type 1/2/3	Any	Biopsy
	8.63	Oncogenic HPV detected (any type)	No abnormality detected	Type 1/2	Any	As per LBC collected at colposcopy
Ī	8.66	HPV(16/18)	No abnormality detected	Type 3	Previously unscreened	Consider endocervical curettage*
	8.65	Oncogenic HPV detected (any type)	No abnormality detected	Type 3	Recent HPV negative result (<6 years ago)	As per LBC collected at colposcopy

8.67	HPV(16/18)	No abnormality detected	Type 3 TZ	New screener, aged 25	As per LBC collected at colposcopy
8.68	HPV(16/18)	No abnormality detected	Type 3	Any other screening history (eg no negative HPV result within previous 6 years)	Consider endocervical curettage*
See flowchart	HPV (not 16/18)	No abnormality detected	Type 3	No negative HPV result within previous 6 years	As per LBC collected at colposcopy

Summary of recommendations

Rec		Recommended clinical action			
	Screening test	Colposcopy	TZ	Screening history	
	Oncogenic HPV detected (any type)	Any lesion identified	Type 1/2/3	Any	Biopsy
	Oncogenic HPV detected (any type)	No abnormality detected	Type 1/2	Any	As per LBC collected at colposcopy
	HPV(16/18)	No abnormality detected	Type 3	Previously unscreened	Consider endocervical curettage*

Oncog HPV o (any ty	detected	No abnormality detected	Type 3	Recent HPV negative result (<6 years ago)	As per LBC collected at colposcopy
HPV(16/18)	No abnormality detected	Type 3 TZ	New screener, aged 25	As per LBC collected at colposcopy
HPV(16/18)	No abnormality detected	Type 3	Any other screening history (eg no negative HPV result within previous 6 years)	Consider endocervical curettage*
HPV (16/18)	`	No abnormality detected	Type 3	No negative HPV result within previous 6 years	As per LBC collected at colposcopy

^{*} ECC should only be done by those who are confident and trained in the technique and have appropriate equipment

REC 8.63

Normal colposcopy in absence of prior valid LBC result

If colposcopic assessment is normal (Type 1 or 2 TZ) in a screening participant referred to colposcopy due to a HPV test result in the absence of a valid LBC result, management should be based on the result of the LBC collected at colposcopy (using both a broom-type brush and an endocervical brush).

See <u>8.2.2 Investigation and management of LBC prediction of negative, possible LSIL or LSIL</u>

See <u>8.2.1 Investigation and management of LBC prediction of possible HSIL or HSIL</u>

See 8.2.3 Investigation and management of LBC predicting glandular abnormalities

REC 8.64

Colposcopy Type 3 TZ in the absence of a prior valid LBC result

If the colposcopic assessment is Type 3 TZ, with no lesion visible, for a screening participant referred to colposcopy due to HPV test result in the absence of a valid LBC result, management of cervical cancer risk should take into consideration:

- previous HPV test results
- overall screening history
- findings from LBC collected at colposcopy (using both a broom-type brush and an endocervical brush) see recommendation 8.65
- if available, findings from other samples, including ECC.

REC 8.65

Management based on LBC result after colposcopy Type 3 TZ in the absence of a prior valid LBC result: HPV test within the past 6 years showing no oncogenic HPV detected

For screening participants with a colposcopic assessment of Type 3 TZ with no lesion visible, following referral to colposcopy due to a HPV test result in the absence of a valid LBC result, and a previous HPV test result within the past 6 years showing no oncogenic HPV detected, management could be based on findings from LBC collected at colposcopy (using both a broom-type brush and an endocervical brush).

See <u>8.2.2</u> Investigation and management of LBC prediction of negative, possible LSIL or LSIL

See 8.2.1 Investigation and management of LBC prediction of possible HSIL or HSIL

See <u>8.2.3 Investigation and management of LBC predicting glandular abnormalities</u>

REC 8.66

Management based on LBC result after colposcopy Type 3 TZ in the absence of a prior valid LBC result: HPV (16/18) detected in a previously never-screened person

In previously unscreened* participants with a colposcopic assessment of Type 3 TZ with no lesion visible, following referral to colposcopy due to a test result of HPV (16/18) detected, in the absence of a valid LBC result, endocervical curettage could be considered by those who are confident and trained in the technique and have appropriate equipment. Otherwise, management could be based on findings from LBC collected at colposcopy (using both a broom-type brush and an endocervical brush).

* excludes new screeners attending as recommended at age 25

REC 8.67

Management based on LBC result after colposcopy Type 3 TZ in the absence of a prior valid LBC result: HPV (16/18) detected at first routine screening test

In a new screening participant (aged approximately 25 years) with a colposcopic assessment of Type 3 TZ with no lesion visible, following referral to colposcopy due to a test result of HPV (16/18) detected result in the absence of a valid LBC result, management could be based on findings from a LBC collected at colposcopy (using both a broom-type brush and an endocervical brush).

See <u>8.2.2 Investigation and management of LBC prediction of negative, possible LSIL or LSIL</u>

See 8.2.1 Investigation and management of LBC prediction of possible HSIL or HSIL

See <u>8.2.3 Investigation and management of LBC predicting glandular abnormalities</u>

REC 8.68

Management based on LBC result after colposcopy Type 3 TZ in the absence of a prior valid LBC result: HPV (16/18) detected: no HPV test in past 6 years showing no oncogenic HPV detected

In screening participants with a colposcopic assessment of Type 3 TZ with no lesion visible, following referral to colposcopy due to a test result of HPV (16/18) detected in the absence of a valid LBC result, and no screening test in the past 6 years in which HPV was not detected, endocervical curettage could be considered on a case-by-case basis by those who are confident and trained in the technique and have appropriate equipment. Otherwise, management should be based on findings from LBC collected at colposcopy (using both a broom-type brush and an endocervical brush).

Chapter 9 Recommendations

Consensus recommendation

REC 9.1

HPV test 12 months after colposcopy

Screening participants with oncogenic HPV (any type) detected and a LBC report of either negative or prediction of pLSIL/LSIL, and normal colposcopic findings or histologically confirmed ≤ CIN1 on biopsy, should have a repeat HPV test 12 months later:

• If the test result at 12 months is **HPV not detected**, routine 5-yearly HPV screening can resume.

- If the test result at 12 months is oncogenic HPV (not 16/18) detected and the LBC report is negative or has a prediction of pLSIL/LSIL, the HPV test should be repeated in another 12 months. If test result at 24 months is oncogenic HPV (any type) detected, the person should be referred directly for colposcopic assessment, which will be informed by the result of the reflex LBC (if the test sample was clinician-collected) or a sample for LBC will be collected at colposcopy (if the test sample was self-collected).
- If the test result at 12 months is oncogenic HPV (not 16/18) detected and LBC prediction of pHSIL/HSIL or any glandular abnormality, the person should be referred for colposcopic assessment at the earliest opportunity, ideally seen within 8 weeks.
- If the test result at 12 months is **HPV (16/18) detected and the LBC report is negative**, the HPV test could be repeated in another 12 months before re-referral to colposcopy;
- o otherwise, the person should be referred directly for colposcopic assessment at the earliest opportunity, ideally seen within 8 weeks. Reflex LBC result will inform the colposcopy (if the test sample was clinician-collected) or a sample for LBC will be collected at colposcopy (if the test sample was self-collected).
- o If the HPV test is repeated and the test result at 24 months is oncogenic HPV (any type) detected, the person should be referred directly for colposcopic assessment at the earliest opportunity, ideally seen within 8 weeks. Reflex LBC result will inform the colposcopy (if the test sample was clinician-collected) or a sample for LBC will be collected at colposcopy (if the test sample was self-collected).

REC 9.2

LSIL (≤ CIN1) should not be treated

Cervical screening participants who have a test result of oncogenic HPV (any type) detected with a LBC report of negative or prediction of pLSIL/LSIL, and who have undergone colposcopy with biopsy and have a histologically confirmed LSIL (≤ CIN1), should **not** be treated, because these lesions are considered to be an expression of a productive HPV infection.

Consensus recommendation

REC 9.3

Diagnostic excision when HSIL confirmed on cytopathology review

Cervical screening participants who have a test result of oncogenic HPV (any type) detected with a LBC report of HSIL (confirmed after cytopathology review), and who have undergone colposcopy with biopsy and have a histologically confirmed LSIL (≤ CIN1), should be offered diagnostic excision of the TZ.

REC 9.4

Option for observation following cytological prediction of possible HSIL

Cervical screening participants who have a test result of oncogenic HPV (any type) detected with a LBC prediction of pHSIL (confirmed after cytopathology review), and who have undergone colposcopy with biopsy and have a histologically confirmed LSIL (≤ CIN1), could be offered diagnostic excision of the TZ.

If the colposcopist considers that a period of observation is preferable to treatment, or the person with these findings wishes to defer diagnostic excision, they can be offered observation with a HPV test and colposcopy at 6–12 months:

- If oncogenic **HPV** is **not detected** at the repeat test, the HPV test should be repeated again in 12 months.
 - If oncogenic HPV is again not detected at the second follow-up test, they should return to routine 5-yearly screening.
- If oncogenic HPV (any type) is detected at the repeat test, reflex LBC report is negative or prediction of pLSIL/LSIL, and colposcopic impression is normal or LSIL, the HPV test should be repeated annually.
 - When oncogenic HPV is not detected at two consecutive annual tests, they can return to 5-yearly screening.
- If oncogenic HPV (any type) is detected at the repeat test, and LBC prediction is pHSIL/HSIL or any glandular abnormality, they should have a diagnostic excision of the TZ.

REC 9.5

Criteria for observation following cytological prediction of pHSIL

Cervical screening participants with a cytological prediction of pHSIL should not be offered observation unless the colposcopic assessment meets all the following conditions:

- Colposcopy is adequate.
- TZ is completely visualised (Type 1 or 2 TZ').
- LSIL (≤ CIN1) has been confirmed on histopathological review.

*IFCPC: International Federation of Cervical Pathology and Colposcopy 2011

REC 9.6

Cytology review is essential when test results are discordant

For cervical screening participants who have a CST result of oncogenic HPV (any type) detected with a histologically confirmed LSIL (≤ CIN1) after LBC prediction of pHSIL/HSIL, both the cytology and the histopathology should be reviewed by a pathologist from at least

one of the reporting laboratories, who should then convey the results of the review to the colposcopist in order to inform the management plan.

Consensus recommendation

REC 9.7

Histological diagnosis prior to treatment

For patients with a visible cervical lesion at colposcopy, histological confirmation of HSIL is recommended before undertaking definitive treatment.

REC 9.8

p16 should be used to clarify diagnosis of HSIL (CIN2)

The use of p16 immunohistochemistry is recommended to stratify the management into immediate treatment (HSIL [CIN2]; p16-positive) or a period of observation (LSIL; p16-negative).

Consensus recommendation

REC 9.9

Treatment for HSIL (CIN2)

Patients who have a histological diagnosis of HSIL (CIN2) should be treated in order to reduce the risk of developing invasive cervical carcinoma.

REC 9.10

HSIL (CIN2) and observation

In some circumstances, it may be acceptable to offer a period of observation (generally 6–12 months) to people with a histological diagnosis of HSIL (CIN2), and this would usually be supervised by an experienced colposcopist or at a tertiary centre. Observation may be considered for:

- those who have not completed childbearing
- · those with discordant histology and LBC prediction of pLSIL/LSIL
- those with focal minor changes on colposcopy and HSIL (CIN2) on histology
- those recently treated for HSIL (CIN2).

Two papers published prior to the 2012 report from the LAST project, demonstrate that the risk of persistence of CIN2 lesions is influenced by the oncogenic HPV type and the persistence of the HPV infection, with lesions caused by HPV type 16 less likely to regress

than lesions caused by other oncogenic HPV types or non-oncogenic types. (Moscicki et al. 2010; Castle et al. 2009).

Consensus recommendation

REC 9.11

Referral of patients with invasive cervical disease

Anyone with a histologically confirmed diagnosis of invasive or superficially invasive squamous cell carcinoma of the cervix should be referred to a gynaecological oncologist or a gynaecological cancer centre for multidisciplinary team review.

Factors that will inform further management include stage of disease, and the person's age, medical history and general health.

Consensus recommendation

REC 9.12

Test of Cure after treatment for HSIL (CIN2/3)

People treated for HSIL (CIN2/3) should have annual HPV tests, starting at 12 months after treatment, until they have two consecutive tests with HPV not detected.

HPV testing can be performed by the person's usual healthcare provider, on either a self-collected or a clinician-collected sample, depending on the preference of the patient. After two consecutive negative tests, people can return to routine 5 yearly screening.

In the case of positive margins, the treating clinician may elect to perform annual co-testing, rather than HPV alone, on a case-by-case basis.

Note: People undergoing Test of Cure who had a first follow-up negative co-test before July 1st 2024, can have a HPV test 12 months later rather than a co-test. Test of Cure will be considered complete if HPV is not detected on that HPV test.

REC 9.13

Margin Status Reporting

Pathology reports of excised lesions should include margin status (endocervical, ectocervical, and lateral stromal margin, if transected), as this may influence clinical management.

REC 9.14

Abnormal Test of Cure results: HPV (16/18) detected

If oncogenic HPV (16/18) is detected at any time post treatment, the person should be referred for colposcopic assessment. If the Test of Cure sample was collected by a healthcare provider, then the laboratory will undertake reflex LBC and referral should occur regardless of the LBC result. If the Test of Cure sample was self-collected, then a sample for LBC should be collected at the time of colposcopy.

Consensus recommendation

REC 9.15

Abnormal Test of Cure results: oncogenic HPV (not 16/18) detected

If oncogenic HPV (not 16/18) is detected post treatment, LBC is required.

If the Test of Cure sample has been collected by a healthcare provider, then the laboratory will perform reflex LBC. If the Test of Cure sample was self-collected, the person treated should be advised to return to their healthcare provider as soon as practical for collection of a cervical sample for LBC.

Consensus recommendation

REC 9.16

Abnormal Test of Cure results: LBC pHSIL/HSIL or glandular abnormality

If LBC prediction of possible HSIL (pHSIL), HSIL, or any glandular abnormality is reported at any time during Test of Cure, irrespective of HPV type detected, the person should be referred for colposcopic assessment.

Consensus recommendation

REC 9.17

Abnormal Test of Cure results: oncogenic HPV (not 16/18) detected with LBC negative, pLSIL or LSIL

If, at any time post-treatment, oncogenic HPV (not 16/18) is detected with an LBC report of negative or prediction of possible LSIL (pLSIL) or LSIL, the person should continue to have

annual co-testing until HPV is not detected at two consecutive tests, at which time they can return to routine 5-yearly screening.

People with oncogenic HPV (not 16/18) detected and an LBC report of negative or prediction of pLSIL/LSIL on three consecutive annual tests, should be referred for colposcopic assessment.

REC 9.18

Colposcopy is not necessary at the initial post-treatment visit

A post-treatment review at 4–6 months is suggested, to provide reassurance to both the patient and clinician regarding the visual appearance of the cervix and allows for the discussion of any other relevant issues (bleeding, fertility, related symptoms etc.) following treatment.

The post-treatment review should:

- include speculum examination of the vagina and cervix (but colposcopy is not considered necessary in all cases)
- not involve HPV testing or LBC.

Follow-up after excisional cervical and ablative vaginal treatment by colposcopy and cytology (with or without biopsy) may be justified at 4–6 months in the following situations:

- after an excision with possible involvement of endocervical margins (and confirmed involved endocervical margins) in a patient who wishes to avoid early re-excision
- following adequately excised adenocarcinoma in situ (AIS) with no evidence of invasive disease
- in patients with CIN2/3 and one to two foci of early stomal invasion and clear margins
- in patients with immune-deficiency, regardless of the cause
- after ablative treatment of vaginal lesions
- in patients with a strong desire to conceive as soon as possible after treatment
- when no lesion is identified in the excision specimen.

Subsequent post-treatment Test of Cure surveillance should be performed by the person's GP or health professional, who should follow the recommendations for the management of any abnormal test results.

Consensus recommendation

REC 9.19

Repeat excision for incompletely excised AIS

If AIS is incompletely excised or if the margins cannot be assessed, further excision to obtain clear margins should be performed.

REC 9.20

Follow-up of completely excised AIS

Those who have histologically confirmed AIS who have undergone complete excision with clear margins should have annual co-testing (HPV and LBC):†

- If all annual co-tests for 5 years are reported as oncogenic HPV not detected and LBC negative, surveillance testing can be extended from annual to every 3 years.
- If surveillance tests have been performed for 25 years or more since the time of treatment and all tests are reported as oncogenic HPV not detected and LBC negative, management should be as follows:
 - If the person is aged less than 70, they can be returned to routine screening.
 - If the person is aged 70 years or older, they can exit screening if they have already had at least one negative co-test when aged 70 years or older.
- If any abnormal result is obtained on any follow-up co-test, the person should be referred for colposcopic assessment.

† Until sufficient data become available to support 5-yearly testing and/or earlier cessation of surveillance testing.

REC 9.21

Cone biopsy excision margins and multifocal AIS

Multifocal disease has been reported in 13–17% of cases of AIS, though the majority of lesions are unifocal. If the margin is close but apparently excised (less than 5 mm), close surveillance as recommended in these guidelines (above), is considered appropriate. In this situation further excision is not considered necessary.

Consensus recommendation

REC 9.22

Role of hysterectomy in AIS

In women and people with a cervix who have been treated for AIS by excision, with clear margins, there is no evidence to support completion hysterectomy. In this situation, hysterectomy is not recommended.

Hysterectomy may be offered in patients where ongoing surveillance is difficult due to a stenosed or absent cervical os. Patient anxiety may also need consideration.

Chapter 10 Recommendations

Consensus recommendation

REC 10.1

Postcoital and intermenstrual bleeding: co-test indicated

When women and people with a cervix present with postcoital or persistent unexplained intermenstrual bleeding, appropriate investigations, including a clinician-collected cervical sample for a co-test, should be performed and not delayed due to the presence of blood.

Note: A co-test cannot be performed on a self-collected vaginal sample because it includes both a human papillomavirus (HPV) test and liquid-based cytology (LBC). Recent cervical screening history should be considered.

Consensus recommendation

REC 10.2

Postcoital bleeding in pre-menopausal women and people with a cervix: single episode

Pre-menopausal women and people with a cervix who have a **single** episode of postcoital bleeding and a clinically normal cervix do not need to be referred for colposcopy if oncogenic HPV is not detected and LBC is negative.

Consensus recommendation

REC 10.3

Postcoital bleeding in pre-menopausal women and people with a cervix: persistent or recurrent

To exclude genital tract malignancy, pre-menopausal women and people with a cervix who have recurrent or persistent postcoital bleeding, even if a co-test is reported as oncogenic HPV not detected and negative LBC, should be referred to a gynaecologist for appropriate assessment, including colposcopy, and upper genital tract imaging (usually transvaginal ultrasound) should be considered.

REC 10.4

Postcoital bleeding and sexually transmitted infections

Sexually transmitted infections, including chlamydia infection, should be considered in all women and people with a cervix presenting with postcoital bleeding. It is necessary to obtain a sexual health history and perform appropriate tests and investigations.

Consensus recommendation

REC 10.5

Symptoms and LBC prediction of cervical cancer

Patients with symptoms suggestive of cervical cancer and a LBC prediction of invasive cervical cancer should be referred to a gynaecological oncologist or gynaecological cancer centre for assessment, ideally within 2 weeks.

Consensus recommendation

REC 10.6

Unexplained Intermenstrual bleeding: persistent or recurrent

Patients with persistent unexplained intermenstrual bleeding require appropriate investigation and should be referred for gynaecological assessment, which may or may not include colposcopy. Common benign causes, including a sexually transmitted infection or hormonal contraception-related bleeding, should be excluded.

Notes: Hormonal contraception includes combined hormonal contraceptive pill or vaginal ring, progestogen-only pill, progestogen-only injection, implant, or hormonal intrauterine device.

Consensus recommendation

REC 10.7

Vaginal bleeding in postmenopausal women and people with a cervix

Postmenopausal women and people with a cervix who have any vaginal bleeding, including postcoital bleeding, should be referred for a specialist gynaecological assessment (which

may or may not include colposcopy) regardless of test results, to exclude genital tract malignancy.

Notes: Genital tract malignancy includes cervical and also endometrial cancer.

Consensus recommendation

REC 10.8

Circumstances that do not require co-testing or referral for colposcopy

The following circumstances do not require co-testing or referral for colposcopy:

- breakthrough or irregular bleeding due to hormonal contraception
- contact bleeding at time of obtaining a routine cervical screening test sample
- heavy regular periods (heavy menstrual bleeding)
- irregular bleeding due to a sexually transmitted infection (STI), eg. chlamydia or gonorrhoea infection.

Consensus recommendation

REC 10.9

Abnormal vaginal discharge and/or deep dyspareunia

Vaginal discharge and/or deep dyspareunia should be investigated appropriately. If the person is due for cervical screening a routine CST should be performed (rather than a cotest).

Consensus recommendation

REC 10.10

Unexplained persistent unusual vaginal discharge

At any age, unexplained persistent unusual vaginal discharge, especially if malodourous or blood stained, should be investigated with a co-test (HPV test and LBC) and the patient should be referred for gynaecological assessment.

Consensus recommendation

REC 10.11

Unexplained persistent deep dyspareunia

Those with unexplained persistent deep dyspareunia in the absence of bleeding or vaginal discharge should have a CST, if due, and referral for gynaecological assessment should be considered.

REC 10.12

Visible abnormality of the cervix

Those who present with a visible abnormality of the cervix that is suspicious of cancer should be further investigated regardless of age or additional symptoms. A co-test (HPV and LBC) should be performed and the patient referred to colposcopy.