NATIONAL CERVICAL SCREENING PROGRAM:

Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding

SHORT FORM SUMMARY OF RECOMMENDATIONS

NATIONAL CERVICAL SCREENING PROGRAM
A joint Australian, State and Territory Government Program

Australian Government
Department of Health

Cancer Council Australia

ENDORSED BY

RACGP Endorsed clinical guideline

RCPA The Royal College of Pathologists of Australasia

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

ASCP

ASGO Australian Society of Gynaecologic Oncologists Inc.
Caring for women since 1986

Date published: June 2016

Disclaimer

This document is a general guide to appropriate practice, to be followed subject to the clinician's judgment and the patient's preference in each individual case. The guidelines are designed to provide information to assist in decision-making. The guidelines are not meant to be prescriptive.

Conflict of interest

The development of the National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding has been undertaken by a non-remunerated Cervical Cancer Screening Guidelines Working Party. Observers/non-voting members are also outlined in this document. Disclosure of their interests can be found online at: http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening/Conflict_of_interest_register

Periodic updates

The incoming literature updates will continue to be monitored for each review question. If there is strong evidence emerging in a specific area, even if not considered previously, the Cancer Council Australia Cervical Cancer Screening Guidelines Working Party will be reconvened to assess if this evidence warrants further systematic review(s) and updating of recommendations. It is recommended that the guidelines should be updated within 5 years.

Suggested citation

Cancer Council Australia Cervical Cancer Screening Guidelines Working Party. Short form summary of the National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding. Cancer Council Australia, Sydney (2016).

The full guidelines and associated documentation (i.e. systematic review, literature search and modelling reports) can be accessed and downloaded at: http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening

Foreword

Australia has an excellent record of successful prevention of cervical cancer through routine screening.

Conventional cervical cytology (Pap smear), combined with effective screening registries, quality-assured pathology services, well-accepted national screening policy and clear guidelines for the management of screen-detected abnormalities, has served us well for 25 years.

The success of the Australian program is demonstrated by annual incidence and mortality rates for cervical cancer that are now amongst the lowest in the world.

Although the National Cervical Screening Program has been very successful, we have some challenges. The significant false-negative rate associated with Pap tests mandates frequent screening to minimise failure to detect disease. However, a newer and more sensitive approach to cervical screening has now been established, which involves testing for the presence of the causal agent for cervical cancer, human papillomavirus (HPV).

In 1984, Professor Harald zur Hausen demonstrated that cervical cancer is due to persisting infection of the cervix with HPV. The knowledge that HPV causes cervical cancer has been further developed through major international epidemiological studies. It is now recognised that HPV comes in many types; some, designated as 'high-risk' or oncogenic types, are associated with a risk of developing cervical cancer in the future if infection persists. The worldwide evidence has also shown that the absence of cervical oncogenic HPV infection is associated with an exceedingly low risk for development of cervical cancer in the next 5 years. The development of automated laboratory tests that enable detection of oncogenic HPV infection in cervical samples thus facilitates the widespread introduction of primary HPV screening. This heralds a new era of more sensitive testing of cervical samples to assess the future risk of cervical cancer.

The discovery of HPV's role in causing cancer has also led to the development a vaccine to prevent cervical cancer. HPV vaccination was introduced into Australia in 2007 and young vaccinated women have already shown a falling rate of cervical abnormalities. These changes make Pap smear-based screening less efficient and the lower incidence of detected cervical abnormalities makes quality control more difficult.

Driven by all these developments, the National Cervical Screening Program has undergone a process of 'renewal' over the last 5 years, and this has resulted in an evidence-based decision to change from 2-yearly Pap smear tests to 5-yearly primary HPV testing. I am confident that the new 5-yearly HPV test based screening policy will provide even greater protection against cervical cancer than the previous program. The renewed program will protect up to 30% more women from cervical cancer, even whilst providing for a later starting age to commence screening and fewer screening tests over a woman's lifetime. HPV-based cervical screening will now provide greater reassurance that all is well, without the need for further investigation in women without detected HPV infection.

This is great news for Australian women, and a testimony to the power of medical research to deliver practical outcomes for Australia. These new guidelines were developed by a team of expert clinicians and scientists. They support the new HPV-based National Cervical Screening Program by providing recommendations for the management of screen-detected abnormalities, symptoms and screening in special circumstances. I commend these guidelines to you and thank, on behalf of all Australians, the team that has evaluated the evidence and put together the recommendations for the benefit of all Australian women.

Professor Ian Frazer AC

The University of Queensland
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Introduction

The management of screen-detected cervical abnormalities in asymptomatic women, and the care of women presenting with symptoms that may be due to cervical cancer or its precursors, involve health professionals across a broad spectrum of disciplines. These guidelines have been developed to assist women and health professionals to achieve the best outcomes.

The target audience for these guidelines includes all health professionals involved in cervical screening and the clinical care of women presenting with symptoms. It may also be of interest to policy makers and researchers.

In October 2011, the Australian Department of Health announced the renewal of the National Cervical Screening Program (NCSP). In April 2014, following a robust and transparent process involving a commissioned evidence review and health outcome and economic modelling, the Australian Medical Services Advisory Committee (MSAC) made several recommendations for the renewed NCSP. These included 5 yearly primary human papillomavirus (HPV) testing with partial genotyping and liquid-based cytology (LBC) triage, self-collection of an HPV sample for under- or never-screened women, and invitations and reminders to be sent to women aged 25–69 years, with exit testing from age 70–74 years.

In December 2017, the NCSP will change from 2 yearly cervical cytology testing to 5 yearly HPV testing for women aged 25–74 years. An HPV test every 5 years is more effective, just as safe, and is expected to result in a significant reduction (24%-36%) in incidence and mortality from cervical cancer in Australian women, compared with the program it replaces, which is based on 2 yearly Pap smears.

In 2005, the evidence based NHMRC endorsed guidelines *Screening to Prevent Cervical Cancer: Guidelines for the Management of Women with Screen Detected Abnormalities*.[1] were published and were introduced into practice in 2006. These guidelines were accepted by health professionals as a useful guide to the management of women with cervical abnormalities detected by cervical cytology. With the change to primary HPV testing, it is necessary and timely to review the 2005 guidelines and to consider recent evidence to formulate guidelines that are relevant to primary HPV testing and triage using LBC.

Following the MSAC recommendations and their acceptance by the Australian Government, the Department of Health requested that the 2005 guidelines be reviewed and updated to assist the implementation of the renewed NCSP. Cancer Council Australia was commissioned and funded by the Department of Health Australia to develop these guidelines with the assistance of an expert clinical management guidelines working party (see Working party members and contributors) and technical support from Professor Karen Canfell and her Cancer Screening Group at Cancer Council NSW.

These guidelines have been developed and published by Cancer Council Australia in accordance with NHMRC recommended processes (see Guideline development process). The web-based wiki platform allows for feedback and easy, regular updating in the light of emerging evidence.

These new guidelines offer guidance to health professionals and women as to best practice in the clinical management of women with positive oncogenic HPV test results and abnormalities detected on subsequent LBC. These guidelines address the current epidemiology of cervical cancer in Australia, the benefits and harms of cervical screening, the natural history of cervical HPV infection, the terminology for HPV testing, LBC, cervical histopathology and colposcopy, management of older women and those undergoing exit testing, management of women with positive oncogenic HPV test results, colposcopy, management of histologically confirmed squamous and glandular abnormalities, screening in specific populations, screening for women who are transitioning from the old into the new program, psychosocial issues and economic issues.

INTRODUCTION

For the first time, guidance on the management of symptomatic women has been included, with a particular focus on those with signs or symptoms suggestive of cervical cancer, such as postcoital, intermenstrual and postmenopausal bleeding. These guidelines do not address issues related to the quality control aspects of the cervical screening test or detailed information about the treatment of invasive cervical cancer.

There are specific recommendations regarding the adoption of a new system for reporting cervical histopathology based on the Lower Anogenital Squamous Terminology (LAST) Standardization Project and new terminology recommended by the International Federation for Colposcopy and Cervical Pathology for use in reporting colposcopic findings and treatment.

The development of these guidelines has involved widespread consultation with relevant professional bodies and a wide range of clinicians and consumers. These guidelines have been reviewed and endorsed by The Royal Australian College of General Practitioners (RACGP), The Royal College of Pathologists of Australasia (RCPA), The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), The Australian Society for Colposcopy and Cervical Pathology (ASCCP) and The Australian Society of Gynaecologic Oncologists (ASGO).

Clinicians must, of course, make individual decisions in consultation with their patients, based on individual clinical circumstances. However, it is anticipated that, in most circumstances, women with screen-detected abnormalities would be managed according to these guidelines. It is important that the NCSP monitors compliance with these guidelines using the NCSP Quality Framework developed by the Quality and Safety Monitoring Committee.

These guidelines are a distillation of the latest research and data, brought together by some of the leading experts in this field. We commend the guidelines to you in the belief that they will result in further significant improvements in the care and treatment of Australian women.

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References

1. National Health and Medical Research Council. *Screening to prevent cervical cancer: guidelines for the management of asymptomatic women with screen detected abnormalities*. Canberra: NHMRC; 2005.

Background

This document provides a summary of recommendations from the *National Cervical Screening Program: Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding*.

These guidelines offer guidance to health professionals and women as to best practice in the clinical management of women with positive oncogenic HPV test results and abnormalities detected on subsequent liquid-based cytology (LBC). The development of these guidelines involved widespread consultation with relevant professional bodies and a wide range of clinicians and consumers.

The recommendations outlined in this short form summary address the management of older women and those undergoing exit testing, management of women with positive oncogenic HPV test results, colposcopy, management of histologically confirmed squamous and glandular abnormalities, screening in specific populations, and screening for women who are transitioning from the old into the new program.

For the first time, guidance on the management of symptomatic women has been included, with a particular focus on those with signs or symptoms suggestive of cervical cancer or its precursor lesions, such as postcoital, intermenstrual and postmenopausal bleeding.

There are also specific recommendations regarding the adoption of a new system for reporting cervical histopathology based on the Lower Anogenital Squamous Terminology (LAST) Standardization Project and new terminology recommended by the International Federation for Colposcopy and Cervical Pathology for use in reporting colposcopic findings and treatment.

For a detailed overview of the evidence summaries and considerations leading to the recommendations, please access the detailed full text guidelines. In addition, the detailed full text guidelines cover the current epidemiology of cervical cancer in Australia, the benefits and harms of cervical screening, the natural history of cervical HPV infection, the terminology for HPV testing, LBC, cervical histopathology and colposcopy, psychosocial issues and economic issues.

The full text guidelines and associated documentation (i.e. systematic review, literature search and modelling reports) can be accessed and downloaded at: http://wiki.cancer.org.au/australia/Guidelines:Cervical_cancer/Screening

Summary of recommendations

The summary of recommendations contain evidence-based recommendations (EBR), consensus-based recommendations (CBR) and practice points (PP) as defined in the key below.

This is a summary of the recommendations in these guidelines, numbered according to chapter to which they relate. Please note that some chapters do not have associated recommendations.

KEY TO TYPES OF RECOMMENDATIONS IN THESE GUIDELINES

EVIDENCE-BASED RECOMMENDATION

Recommendations formulated by the guideline development group based on a systematic review of quality evidence and graded according to an NHMRC-approved method

MSAC EVIDENCE-BASED RECOMMENDATION

A recommendation formulated after a systematic review of the evidence, indicating supporting references, from the 2014 Medical Services Advisory Committee review.

NCSP RECOMMENDATION

Recommendations based on National Cervical Screening Program policy.

CONSENSUS-BASED RECOMMENDATION

Recommendations formulated by the guideline development group, using a consensus-reaching process, when a systematic review was undertaken and insufficient quality evidence was found on which to base a recommendation.

* Consensus-based recommendation based on 2005 NHMRC-approved guidelines formulated by the guideline development group, using a consensus-reaching process.

PRACTICE POINT

A recommendation on a subject that is outside the scope of the search strategy for the systematic review, based on expert opinion and formulated by a consensus process.

4. UNSATISFACTORY CERVICAL SCREENING RESULTS

PRACTICE POINT

REC4.1: Attempt adequate repeat preparations for an unsatisfactory LBC test

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

PRACTICE POINT

REC4.2: Report cellular abnormality for LBC specimens with abnormal cells

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

PRACTICE POINT

REC4.3: Recall women in 6–12 weeks if they have an unsatisfactory screening report

A woman with an unsatisfactory screening report should have a repeat sample collected in 6–12 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.

6. MANAGEMENT OF HPV TEST RESULTS

Oncogenic HPV types not detected

MSAC EVIDENCE-BASED RECOMMENDATION

REC6.1: Oncogenic HPV types not detected at routine screening

Women who have a screening HPV test in which oncogenic HPV types are **not** detected should rescreen in 5 years.

Oncogenic HPV types 16 and/or 18

MSAC EVIDENCE-BASED RECOMMENDATION

REC6.2: Women with a positive HPV (16/18) test result

Women with a positive oncogenic HPV (16/18) test result should be referred directly for colposcopic assessment, which will be informed by the result of reflex LBC.

CONSENSUS-BASED RECOMMENDATION*

REC6.3: Referral to gynaecological oncologist for LBC prediction of invasive disease

Women who have a positive oncogenic HPV (16/18) test result with a 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.

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC6.4: Referral of women with a positive HPV (16/18) test result and unsatisfactory LBC

When reflex LBC is unsatisfactory, but the woman requires colposcopic referral regardless of the LBC result (i.e. when HPV 16/18 is detected), then the screening episode should be classified as 'Higher risk for cervical cancer or precursors'. A cervical sample for LBC should be collected at the time of colposcopy (see Chapter 4. Unsatisfactory cervical screening results).

PRACTICE POINT

REC6.5: Referral of women with a positive HPV (16/18) test result and reflex LBC pHSIL/HSIL

Women with a positive oncogenic HPV (16/18) test result and reflex LBC prediction of pHSIL/HSIL should be referred for colposcopic assessment at the earliest opportunity, ideally within 8 weeks.

Oncogenic HPV types not 16 and/or 18

EVIDENCE-BASED RECOMMENDATION	GRADE
REC6.6: Positive oncogenic HPV (not 16/18) test result at routine screening Women with a positive oncogenic HPV (not 16/18) test result, with a LBC report of negative or prediction of pLSIL/LSIL, should have a repeat HPV test in 12 months.	C

PRACTICE POINT

REC6.7: Referral of women with a positive oncogenic HPV (not 16/18) test result and LBC prediction of pHSIL, HSIL or any glandular abnormality

Women with a positive oncogenic HPV (not 16/18) test result, 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.

CONSENSUS-BASED RECOMMENDATION*

REC6.8: Referral to gynaecological oncologist for LBC prediction of invasive disease

Women who have a positive oncogenic HPV (not 16/18) test result with a 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.

EVIDENCE-BASED RECOMMENDATION	GRADE
REC6.9: Management after repeat HPV test at 12 months, following initial positive oncogenic HPV (not 16/18) test result At repeat HPV testing 12 months after a positive oncogenic HPV (not 16/18) test result with reflex LBC negative or pLSIL/LSIL: • if a woman has a positive oncogenic HPV (any type) test result, reflex LBC will be performed and she should be referred for colposcopic assessment • if oncogenic HPV is not detected, the woman should be advised to return to routine 5-yearly screening.	C

SUMMARY OF RECOMMENDATIONS

Self-collected vaginal samples

MSAC EVIDENCE-BASED RECOMMENDATION

REC6.10: Oncogenic HPV types not detected in self-collected sample

Women who have undergone HPV testing on a self-collected sample and in whom oncogenic HPV is not detected should be invited to re-screen with a HPV test in 5 years and should be advised to have a clinician-collected sample

MSAC EVIDENCE-BASED RECOMMENDATION

REC6.11: Referral of women with positive oncogenic HPV (16/18) test result (self-collected sample)

Women who have undergone HPV testing on a self-collected sample and have a positive oncogenic HPV(16/18) test result should be referred directly for colposcopic assessment. A cervical sample for LBC should be obtained at the time of colposcopy and is not required prior to referral.

CONSENSUS-BASED RECOMMENDATION

REC6.12: Women with a positive oncogenic HPV (not 16/18) test result (self-collected sample)

Women who have undergone HPV testing on a self-collected sample and who have a positive oncogenic HPV (not 16/18) test result should be advised to visit their GP or healthcare professional to obtain a cervical sample for LBC:

- If the LBC test result is negative or pLSIL/LSIL, HPV testing should be repeated in 12 months, preferably by a healthcare professional.
- If the LBC test result is pHSIL/HSIL or any glandular abnormality the woman should be referred for colposcopy at the earliest opportunity, ideally within 8 weeks.

CONSENSUS-BASED RECOMMENDATION

REC6.13: Management of 12 month repeat HPV test result after initial positive oncogenic HPV(not 16/18) test result on a self-collected sample

At 12-month repeat HPV testing:

- Women in whom oncogenic HPV is not detected should return to routine 5 yearly screening, and should be advised to have a clinician-collected sample at that time.
- Women with a positive oncogenic HPV (any type) test result should be referred for colposcopic assessment:
  - If the repeat HPV test was clinician-collected, reflex LBC will be available to inform colposcopic assessment.
  - If the repeat HPV test was self-collected, a cervical sample for LBC should be obtained at the time of colposcopy

PRACTICE POINT

REC6.14: Clinician-collected sample for follow-up HPV test after initial self-collected sample

When follow-up HPV testing is required after an initial positive oncogenic HPV test result, the sample should be collected by a clinician, if possible.

Women should be advised that a clinician-collected sample is preferred because it is more effective and reflex LBC can be performed on the same sample, which avoids a further visit to collect a cervical sample for LBC.

If the woman declines the clinician-collected sample, she can have a self-collected sample and is eligible for reimbursement under the Medical Benefits Schedule.

PRACTICE POINT

REC6.15: Clinician-collected sample after invitation to re-screen

Women who are invited to have a clinician-collected sample, and decline, will not be eligible† for self-collection at that time.

† Not eligible for reimbursement under the Medical Benefits Schedule unless they meet the eligibility criteria for self-collection (aged > 30 years, at least 2 years overdue for cervical screening test, or never been screened) as per NCSP policy.

Women undergoing exit testing

MSAC EVIDENCE-BASED RECOMMENDATION

REC6.16: Women aged 70–74 years in whom oncogenic HPV is not detected (exit testing)

Women 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-BASED RECOMMENDATION

REC6.17: Referral of women aged 70–74 years with a positive oncogenic HPV test result (exit testing)

Women aged 70–74 who have a positive oncogenic HPV (any type) test result should be referred directly for colposcopic assessment, which should be informed by the result of reflex LBC.

Screening in women older than 75

NCSP RECOMMENDATION

REC6.18: Women aged 75 years or older who request screening

Women who are 75 years or older who have never had a cervical screening test, or have not had one in the previous five years, may request a test and can be screened.

7. COLPOSCOPY

Colposcopy terminology

PRACTICE POINT

REC7.1: New colposcopy terminology

The new terminology adopted by the IFCPC in 2011 should be incorporated into Australian practice.

History, examination and investigation

PRACTICE POINT

REC7.2: Colposcopy and acetic acid

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.

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC7.3: Colposcopy and VAIN

When the LBC report predicts a squamous abnormality and there is no colposcopically visible cervical lesion, careful colposcopic examination of the vagina should be performed to exclude VAIN, using acetic acid and Lugol's Iodine.

PRACTICE POINT

REC7.4: Repeat LBC usually not necessary 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 woman has developed symptoms suggestive of cervical cancer since undergoing her screening test.

CONSENSUS-BASED RECOMMENDATION*

REC7.5: Biopsy of high grade lesions

The cervix should be biopsied when the LBC prediction is pHSIL or HSIL and the colposcopic appearance shows major change (see IFCPC definition above) and the abnormal TZ is visible (Type 1 or Type 2 TZ).

PRACTICE POINT

REC7.6: Biopsy visible lesion if 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.

PRACTICE POINT

REC7.7: Biopsy of low-grade lesions is encouraged but not always necessary

Women with a LBC prediction of pLSIL or LSIL and a colposcopic impression of low-grade disease or less may not always require a biopsy. However, biopsy is accepted practice for confirmation of the colposcopic impression and exclusion of high-grade disease, and should be encouraged, especially for less experienced colposcopists.

PRACTICE POINT

REC7.8: Upper genital tract imaging

Upper genital tract imaging should be considered in cases where no lower genital tract abnormality is detected at colposcopy after referral with abnormal glandular cytology (including atypical glandular cells or endocervical cells of undetermined significance). In some women, further investigation, such as endometrial sampling to exclude an endometrial origin for atypical glandular cells, may be required.

SUMMARY OF RECOMMENDATIONS

Treatment

CONSENSUS-BASED RECOMMENDATION*

REC7.9: Colposcopy prior to treatment

All women should have an adequate† colposcopic assessment prior to treatment.

† **adequate:** the cervix is clearly seen (IFCPC 2011 terminology)

CONSENSUS-BASED RECOMMENDATION*

REC7.10: Histopathological confirmation prior to treatment

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

CONSENSUS-BASED RECOMMENDATION*

REC7.11: Biopsy prior to ablative treatment

Women should have a cervical biopsy prior to any ablative treatment.

CONSENSUS-BASED RECOMMENDATION

REC7.12: Pathology review of discordant test results

For women who have had a colposcopy with significant discordance between the histopathology and the referral cytology, both specimens should be reviewed by at least one of the reporting pathologists who should then convey the results of the review to the colposcopist in order to inform the management plan.

PRACTICE POINT

REC7.13: Tertiary referral may be necessary

In some clinical situations, the woman should be referred to a more experienced colposcopist, a gynaecological oncologist, tertiary colposcopy clinic or gynaecological cancer centre:

- adenocarcinoma in situ
- abnormalities in pregnancy
- immune-deficient women
- women with multifocal lower genital tract disease.

PRACTICE POINT

REC7.14: Second opinion

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

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC7.15: The role of multidisciplinary team review

It is not always practical for a colposcopist to access a multidisciplinary team review which is usually conducted in a tertiary referral centre. However, a multidisciplinary team 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.

PRACTICE POINT

REC7.16: Colposcopy at time of treatment

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

CONSENSUS-BASED RECOMMENDATION*

REC7.17: Criteria for ablative treatment

Ablative therapy should be reserved for women 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.

PRACTICE POINT

REC7.18: Depth of ablation

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

CONSENSUS-BASED RECOMMENDATION*

REC7.19: 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.†

† This is critical for management of suspected or histologically confirmed AIS.

PRACTICE POINT

REC7.20: 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.

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC7.21: 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.

PRACTICE POINT

REC7.22: Cold-knife cone biopsy: setting

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

PRACTICE POINT

REC7.23: 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.

PRACTICE POINT

REC7.24: 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.

PRACTICE POINT

REC7.25: Cold-knife cone biopsy and AIS

Predicted or histologically confirmed AIS should be treated by a Type 3 excision (usually a cold-knife cone biopsy) performed in an operating theatre, under general anaesthesia, by a gynaecological oncologist or gynaecologist competent in the technique.

PRACTICE POINT

REC7.26: Role of repeat excision in management of SISCCA

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.

PRACTICE POINT

REC7.27: Do not treat at first visit with a LBC report of a low-grade lesion

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

PRACTICE POINT

REC7.28: Excision required for recurrent disease after ablation

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

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC7.29: Repeat excision not necessarily required for incomplete excision of high-grade lesions

Women 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:

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

8. MANAGEMENT OF DISCORDANT COLPOSCOPIC IMPRESSION, HISTOPATHOLOGY AND REFERRAL LBC PREDICTION

Normal colposcopic findings following LBC prediction of LSIL or HSIL

CONSENSUS-BASED RECOMMENDATION

REC8.1: Normal colposcopy following LBC prediction of negative or pLSIL/LSIL

For women with a positive oncogenic HPV (any type) test result, a LBC report of negative or pLSIL/LSIL, and normal colposcopy, the HPV test should be repeated in 12 months:

- If HPV is not detected at 12 months, the woman should return to routine 5-yearly HPV screening.
- If the woman has a positive oncogenic HPV (not 16/18) test result at 12 months and a LBC report of negative or pLSIL/LSIL, the HPV test should be repeated in another 12 months.
    - If the woman has a positive oncogenic HPV (any type) test at the 24 month HPV test, she should be referred directly for colposcopic assessment, which will be informed by the result of the reflex LBC.
- If the woman has a positive oncogenic HPV (not 16/18) test result at 12 months and a LBC prediction of pHSIL/HSIL or any glandular abnormality, she should be referred for colposcopic assessment at the earliest opportunity, ideally within 8 weeks.
- If the woman has a positive oncogenic HPV (16/18) test result at 12 months, she should be referred directly for colposcopic assessment at the earliest opportunity, ideally within 8 weeks, and the reflex LBC result will inform the colposcopy.

PRACTICE POINT

REC8.2: Normal colposcopy following LBC prediction of HSIL: cytopathology review

Cytopathology review is recommended to confirm HSIL before proceeding to excisional treatment for women with a normal colposcopy after a positive oncogenic HPV (any type) test result and an initial LBC prediction of pHSIL/HSIL.

PRACTICE POINT

REC8.3: Normal colposcopy following LBC prediction of HSIL: exclude VAIN

When colposcopic impression is discordant with a referral LBC prediction of HSIL, colposcopic examination of the vagina is indicated to exclude a vaginal intraepithelial neoplasia **before** diagnostic excisional treatment.

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION

REC8.4: Normal colposcopy following LBC prediction of HSIL: diagnostic excision of TZ

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

CONSENSUS-BASED RECOMMENDATION

REC8.5: Normal colposcopy following LBC prediction of pHSIL: consider diagnostic excision of TZ

For women who have a positive oncogenic HPV (any type) test result, normal colposcopy, and a LBC prediction of pHSIL on cytopathology review, diagnostic excision of the TZ should be considered, though observation is an option.

PRACTICE POINT

REC8.6: Normal colposcopy following LBC prediction of pHSIL: diagnostic excision or observation

Some women with a positive oncogenic HPV test result for whom diagnostic excision of the TZ is recommended due to a confirmed LBC prediction of pHSIL on cytopathology review, despite normal colposcopic findings, may be concerned about the possibility of having unnecessary treatment. The colposcopist may have similar concerns. Women 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 and If oncogenic HPV is not detected, the woman can return to routine 5-yearly screening.

CONSENSUS-BASED RECOMMENDATION

REC8.7: Downgrading of discordant results

For women who have a positive oncogenic HPV (any type) test result, normal colposcopy, and a subsequent LBC report of pLSIL/LSIL or less on cytopathology review, management should be according to the reviewed cytological report (i.e. repeat HPV test in 12 months).

PRACTICE POINT

REC8.8: Colposcopist should manage discordant results

Women with discordant colposcopy and LBC results should have their management supervised by the colposcopist until both the colposcopist and the woman are satisfied with the proposed management plan.

SUMMARY OF RECOMMENDATIONS

Type 3 TZ (previously termed 'unsatisfactory') colposcopy following LBC prediction of LSIL or HSIL

CONSENSUS-BASED RECOMMENDATION

REC8.9: Repeat HPV test after Type 3 TZ colposcopy and referral LBC negative or pLSIL/LSIL

For women who have a positive oncogenic HPV (any type) test result with a LBC report of negative or pLSIL/LSIL, 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 woman should be advised to return to routine 5-yearly screening.
- If the woman has a positive oncogenic HPV (any type) test result at 12 months, she should be referred directly for colposcopic assessment, with the LBC report available to inform the assessment.

† 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.

PRACTICE POINT

REC8.10: Cytopathology review prior to observation for pLSIL/LSIL and Type 3 TZ at colposcopy

When observation is advised, cytopathology review is recommended to confirm the low-grade cytological abnormality.

- If pLSIL/LSIL is confirmed, observation is appropriate.
- If pHSIL/HSIL is confirmed, then diagnostic excision of the TZ should be considered.

PRACTICE POINT

REC8.11: Role of ECC in Type 3 TZ colposcopy following LBC prediction of pLSIL/LSIL

Despite a lack of evidence, endocervical curettage can be considered for women who have a positive oncogenic HPV test result (any type) with a LBC report of persistent pLSIL/LSIL and colposcopy reported as Type 3 TZ.† A negative ECC may provide additional reassurance for a conservative (observational) approach.

† 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-BASED RECOMMENDATION

REC8.12: 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 women who have a positive oncogenic HPV (any type) 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 transformation zone) 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.

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC8.13: Role of diagnostic excision: exceptions to recommendation (8.12) against diagnostic excision of TZ in the absence of high-grade cytology or histology

Diagnostic excision of the TZ can be offered to certain groups of women who have a positive oncogenic HPV test result, a LBC report of negative or pLSIL/LSIL, and colposcopy reported as Type 3 TZ:†

- women who have completed childbearing
- women who are anxious about cancer risk
- women aged over 50 years
- women who may not be compliant with recommended surveillance.

† 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-BASED RECOMMENDATION

REC8.14: Diagnostic excision: Type 3 TZ colposcopy after LBC prediction of pHSIL/HSIL

For women who have a positive oncogenic HPV (any type) test result, 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.

PRACTICE POINT

REC8.15: Cytopathology review: Type 3 TZ colposcopy following LBC prediction of pHSIL/HSIL

Cytopathology review should be considered to confirm a high-grade cytological abnormality before excision, after a positive oncogenic HPV (any type) test result and an initial LBC prediction of pHSIL/HSIL, when there is a Type 3 TZ colposcopy.

This is particularly important when the LBC prediction is pHSIL because pHSIL has a lower PPV for high-grade disease and the subsequent excision specimens show no evidence of cervical pathology in 45–55% of cases.

PRACTICE POINT

REC8.16: Deferral of treatment following cytopathology review: Repeat HPV test and colposcopy in 6 months

Following cytopathology review, rarely the woman or the clinician wish to defer treatment. In this situation the woman should have a repeat HPV test and colposcopy in 6 months.

- If HPV detected (any type) and LBC pLSIL/LSIL, repeat HPV test in 12 months
- If HPV detected (any type) and LBC pHSIL/HSIL, the woman should have diagnostic Type 3 excision of the TZ.

9. MANAGEMENT OF HISTOLOGICALLY CONFIRMED LOW-GRADE SQUAMOUS ABNORMALITIES

CONSENSUS-BASED RECOMMENDATION

REC9.1: HPV test 12 months after histologically confirmed LSIL (≤ CIN1)

Women who have a positive oncogenic HPV (any type) test result with a LBC report of either negative or pLSIL/LSIL, and histologically confirmed ≤ CIN1 on biopsy, should have a repeat HPV test 12 months later:

- If oncogenic HPV is not detected at the repeat HPV test, the woman should return to routine 5 yearly screening.
- If the repeat test is positive for oncogenic HPV (not 16/18) and the LBC report is negative or pLSIL/LSIL, the woman should have a further repeat HPV test in 12 months.
    - If the second follow-up HPV test is negative the woman should return to routine 5-yearly screening.
    - If the second follow-up test is HPV positive, the woman should be referred for colposcopic assessment informed by reflex LBC.
- If the repeat test is positive for oncogenic HPV (not 16/18) and the LBC report is pHSIL/HSIL, the woman should be referred for colposcopic assessment.
- If the repeat test is positive for oncogenic HPV (16/18), the woman should be referred for colposcopic assessment informed by the reflex LBC.

CONSENSUS-BASED RECOMMENDATION

REC9.2: LSIL (≤ CIN1) should **not** be treated

Women who have a positive oncogenic HPV (any type) test result with a LBC report of negative or pLSIL/LSIL, who have undergone colposcopy 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-BASED RECOMMENDATION

REC9.3: Diagnostic excision when HSIL confirmed on cytopathology review

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

CONSENSUS-BASED RECOMMENDATION

REC9.4: Option for observation following cytological prediction of pHSIL

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

If the colposcopist considers a period of observation is preferable to treatment, or the woman with these findings wishes to defer diagnostic excision, she 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 the second follow-up test is negative, the woman should return to routine 5-yearly screening.
- If the woman has a positive oncogenic HPV (any type) test result at the repeat test, her reflex LBC report is negative or pLSIL/LSIL, and her colposcopic impression is normal or LSIL, the HPV test should be repeated annually.
    - When oncogenic HPV is not detected at two consecutive annual tests, the woman can return to 5-yearly screening.
- If the woman has a positive oncogenic HPV (any type) test result at the repeat test, and her LBC prediction is pHSIL/HSIL or any glandular abnormality, she should have a diagnostic excision of the TZ.

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC9.5: Criteria for observation following cytological prediction of pHSIL

Women 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

PRACTICE POINT

REC9.6: Cytology review essential when test results are discordant

For women who have a positive oncogenic HPV (any type) test result 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.

10. MANAGEMENT OF HISTOLOGICALLY CONFIRMED HIGH-GRADE SQUAMOUS ABNORMALITIES

Diagnosis of high-grade squamous abnormalities

CONSENSUS-BASED RECOMMENDATION*

REC10.1: Histological diagnosis prior to treatment

For women who have a visible lesion at colposcopy, histological confirmation of HSIL is recommended before undertaking definitive treatment.

Treatment of high-grade squamous abnormalities

CONSENSUS-BASED RECOMMENDATION*

REC10.2: Treatment for HSIL (CIN2)

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

PRACTICE POINT

REC10.3: p16 should be used to clarify diagnosis of HSIL (CIN2)

The use of p16 immunohistochemistry is recommended to stratify the management of HSIL (CIN2) into immediate treatment or a period of observation.

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC10.4: HSIL (CIN2) and observation

In some circumstances, it may be acceptable to offer a period of observation (generally 6–12 months) to women who have 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:

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

CONSENSUS-BASED RECOMMENDATION*

REC10.5: Treatment of HSIL (CIN3)

Women with a histological diagnosis of HSIL (CIN3) should be treated in order to reduce the risk of developing invasive cervical carcinoma.

CONSENSUS-BASED RECOMMENDATION*

REC10.6: Referral of women with invasive disease

A woman with a histologically confirmed diagnosis of invasive or superficially invasive (squamous cell carcinoma) should be referred to a gynaecological oncologist or a gynaecological cancer centre for multidisciplinary team review.

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

CONSENSUS-BASED RECOMMENDATION

REC10.7: Test of Cure after treatment for HSIL (CIN2/3)

A woman who has been treated for HSIL (CIN2/3) should have a co-test† performed at 12 months after treatment, and annually thereafter, until she receives a negative co-test on two consecutive occasions, when she can return to routine 5 yearly screening.

† Co-testing can be performed by the woman's usual healthcare professional.

CONSENSUS-BASED RECOMMENDATION

REC10.8: Abnormal Test of Cure results: positive oncogenic HPV (16/18) test result

If, at any time post treatment, the woman has a positive oncogenic HPV (16/18) test result, she should be referred for colposcopic assessment (regardless of the reflex LBC result).

CONSENSUS-BASED RECOMMENDATION*

REC10.9: Abnormal Test of Cure results: LBC pHSIL/HSIL or glandular abnormality

If, at any time during Test of Cure, the woman has a LBC prediction of pHSIL/HSIL or any glandular abnormality, irrespective of HPV status, she should be referred for colposcopic assessment.

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION

REC10.10: Abnormal Test of Cure results: positive oncogenic HPV (not 16/18) test result

If, at any time post-treatment, the woman has a positive oncogenic HPV (not 16/18) test result and a LBC report of negative or prediction of pLSIL/LSIL, she should continue to have annual co-testing until the she has a negative co-test on two consecutive occasions, when she can return to routine 5-yearly screening.

PRACTICE POINT

REC10.11: Fluctuating Test of Cure results: positive oncogenic HPV (not 16/18) test result and/or pLSIL/LSIL

Some women may experience fluctuating results with a positive oncogenic HPV (not 16/18) test result and/or LBC prediction of pLSIL/LSIL. These women do not need colposcopic review but, if the woman is anxious, a colposcopic assessment may be appropriate to provide reassurance.

PRACTICE POINT

REC10.12: Colposcopy is not necessary at the initial post-treatment visit

A post-treatment colposcopic assessment at 4–6 months has been the usual practice under pre-renewal NCSP guidelines. This practice is not evidence-based, but may 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)
- not involve HPV testing or LBC.

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

11. MANAGEMENT OF GLANDULAR ABNORMALITIES

Investigation of cytological glandular abnormalities

CONSENSUS-BASED RECOMMENDATION*

REC11.1: Colposcopy referral for atypical glandular/endocervical cells

Women 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-BASED RECOMMENDATION*

REC11.2: Follow-up after normal colposcopy and LBC prediction of atypical glandular/endocervical cells

Women 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 the woman has two consecutive negative co-tests, after which she can return to 5-yearly screening.
- If there is either a positive oncogenic HPV (any type) test result or an abnormal LBC (any report other than negative), the woman should be referred for colposcopic assessment, and diagnostic excision of the TZ should be considered

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC11.3: Exclusion of upper genital tract disease before diagnostic excision

For women who have a positive oncogenic HPV test result (any type) 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 diagnostic excision of the TZ is performed or the woman is advised to return for colposcopy and further tests in 6–12 months, in these groups of women:

- women aged over 45 years
- women aged over 35 years with a BMI greater than 30
- women diagnosed with polycystic ovarian syndrome
- women with abnormal vaginal bleeding.

PRACTICE POINT

REC11.4: Role of immediate diagnostic excision of TZ versus observation

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

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

CONSENSUS-BASED RECOMMENDATION*

REC11.5: Colposcopy for possible high-grade glandular lesions

Women who have a positive oncogenic HPV (any type) test result 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.

PRACTICE POINT

REC11.6: Women who decline treatment for possible high-grade lesions

Women 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 in 6 months the woman has a positive result, she should be encouraged to have a diagnostic excision of the TZ.
- It is important that the woman understands the potential risk of underlying disease (21.5% risk of AIS and 5.5% risk of invasive cancer).

CONSENSUS-BASED RECOMMENDATION*

REC11.7: Colposcopy referral for AIS

Women 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.

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION*

REC11.8: Referral to gynaecological oncologist for LBC prediction of invasive disease

Women who have a positive oncogenic HPV (any type) test result 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-BASED RECOMMENDATION*

REC11.9: 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.

PRACTICE POINT

REC11.10: 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.

PRACTICE POINT

REC11.11: Size of cone biopsy

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

PRACTICE POINT

REC11.12: 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 by Test of Cure, as recommended in these guidelines, is considered appropriate. In this situation further excision is not considered necessary.

Follow-up after excisional treatment for AIS

CONSENSUS-BASED RECOMMENDATION*

REC11.13: Follow-up of completely excised AIS

Women with histologically confirmed AIS who have undergone complete excision with clear margins should have annual co-testing indefinitely.†

If any abnormal result is obtained on follow-up co-testing, the woman should be referred for colposcopic assessment.

† Until sufficient data become available to support cessation of testing.

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION*

REC11.14: Repeat excision for incompletely excised AIS

If AIS is incompletely excised (positive endocervical margin and/or deep stromal margin, not ectocervical margin) or if the margins cannot be assessed, further excision to obtain clear margins should be performed.

CONSENSUS-BASED RECOMMENDATION

REC11.15: Role of hysterectomy in AIS

In women 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.

12. SCREENING IN ABORIGINAL AND TORRES STRAIT ISLANDER WOMEN

CONSENSUS-BASED RECOMMENDATION

REC12.1: Cervical Screening for Aboriginal and Torres Strait Islander women

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

PRACTICE POINT

REC12.2: Invitations to screen for Aboriginal and Torres Strait Islander women

Specific efforts should be made to maximise delivery of invitations to Aboriginal and Torres Strait Islander women.

PRACTICE POINT

REC12.3: Cervical screening services for Aboriginal and Torres Strait Islander women

Specific efforts should be made to provide screening, diagnostic and treatment services that are accessible and culturally appropriate to Aboriginal and Torres Strait Islander women.

PRACTICE POINT

REC12.4: Data collection and recording Aboriginal and Torres Strait Islander status

Healthcare professionals should ask all women whether they identify as Aboriginal or Torres Strait Islander, and a woman's Aboriginal and Torres Strait Islander status should be recorded on the pathology request form in accordance with the ABS classification and standards.

13. SCREENING AFTER TOTAL HYSTERECTOMY

CONSENSUS-BASED RECOMMENDATION*

REC13.1: Total hysterectomy for benign disease

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

CONSENSUS-BASED RECOMMENDATION*

REC13.2: Total hysterectomy after completed Test of Cure

Women 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. These women 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 women require follow-up with an annual co-test on a specimen from the vaginal vault until they have a negative co-test on two consecutive occasions.

CONSENSUS-BASED RECOMMENDATION

REC13.3: Total hysterectomy after adenocarcinoma in situ (AIS)

Women 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, indefinitely.†

Women 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 thereafter, indefinitely.

† Until sufficient data become available to support cessation of testing

CONSENSUS-BASED RECOMMENDATION*

REC13.4: Total hysterectomy for treatment of high-grade CIN in the presence of benign gynaecological disease

Women 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 co-test on a specimen from the vaginal vault at 12 months after treatment and annually thereafter until the woman has tested negative by both tests on two consecutive occasions.

After two annual consecutive negative co-tests, the woman can be advised that no further testing is required.

CONSENSUS-BASED RECOMMENDATION*

REC13.5: Total hysterectomy after histologically confirmed HSIL without Test of Cure

Women 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 co-test on a specimen from the vaginal vault at 12 months and annually until the woman has tested negative on two consecutive occasions.

After two annual consecutive negative co-tests, the woman can be advised that no further testing is required.

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION*

REC13.6: Total hysterectomy and no screening history

Women 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 they have a negative HPV test on two consecutive occasions.

After two annual consecutive negative HPV tests, women can be advised that no further testing is required.

PRACTICE POINT

REC13.7: Colposcopy referral for any positive co-test result following total hysterectomy

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

PRACTICE POINT

REC13.8: Vaginal bleeding following total hysterectomy

Women 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.

PRACTICE POINT

REC13.9: Total hysterectomy after genital tract cancer

Women who have been treated for cervical or endometrial cancer are at risk of recurrent cancer in the vaginal vault. These women should be under ongoing surveillance from a gynaecological oncologist. Therefore, they will be guided by their specialist regarding appropriate surveillance and this is outside the scope of these guidelines.

PRACTICE POINT

REC13.10: Subtotal hysterectomy

Women 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. Any detected abnormality should be managed according to these guidelines.

14. SCREENING IN PREGNANCY

CONSENSUS-BASED RECOMMENDATION

REC14.1: Positive oncogenic HPV (not 16/18) test result with LBC negative or pLSIL/LSIL in pregnancy

Pregnant women who have a positive oncogenic HPV (not 16/18) test result with a LBC report of negative or prediction of pLSIL/LSIL should have a repeat HPV test in 12 months.

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION

REC14.2: Positive oncogenic HPV (not 16/18) test result with LBC pHSIL/HSIL or any glandular abnormality in pregnancy

Pregnant women who have a positive oncogenic HPV (not 16/18) test result with a LBC prediction of pHSIL/HSIL or any glandular abnormality should be referred for early† colposcopic assessment.

† When practical and not deferred until the postpartum period.

CONSENSUS-BASED RECOMMENDATION

REC14.3: Positive HPV (16/18) test result in pregnancy

Pregnant women who have a positive oncogenic HPV (16/18) test result should be referred for early† colposcopic assessment regardless of their LBC test result.

† When practical and not deferred until the postpartum period.

CONSENSUS-BASED RECOMMENDATION*

REC14.4: Referral of pregnant women with invasive disease

Pregnant women should be referred and seen within 2 weeks by a gynaecological oncologist/gynaecological cancer centre for multidisciplinary team review and management in the following situations:

- 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-BASED RECOMMENDATION*

REC14.5: Colposcopy during pregnancy

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

PRACTICE POINT

REC14.6: Colposcopy during pregnancy

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

CONSENSUS-BASED RECOMMENDATION*

REC14.7: Cervical biopsy in pregnancy is usually unnecessary

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

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION*

REC14.8: Defer treatment until after pregnancy

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

PRACTICE POINT

REC14.9: 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.

PRACTICE POINT

REC14.10: Vaginal oestrogen prior to postpartum colposcopy

For women who are breastfeeding, the use of intra-vaginal oestrogen cream or pessary† prior to colposcopy may improve visualisation of the cervix and the quality of any cervical sample for LBC.

† Daily for two weeks and cease approximately 3 days before colposcopy.

PRACTICE POINT

REC14.11: Cervical screening in pregnancy

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

PRACTICE POINT

REC14.12: Cervical screening in pregnancy

A woman can be safely screened at any time during pregnancy, provided that the correct sampling equipment is used. A cytobrush or combi-brush should **not** be inserted into the cervical canal because of the risk of associated bleeding, which may distress women.

PRACTICE POINT

REC14.13: Self-collection in pregnancy

Self-collection for HPV testing is not recommended in pregnancy.

15. SCREENING IN WOMEN WHO EXPERIENCED EARLY SEXUAL INTERCOURSE OR HAVE BEEN VICTIMS OF SEXUAL ABUSE

MSAC EVIDENCE-BASED RECOMMENDATION

REC15.1: Routine cervical screening is not recommended in young women

Routine cervical screening is not recommended in women under the age of 25 years.

CONSENSUS-BASED RECOMMENDATION

REC15.2: Early sexual activity and cervical screening in young women

For women who experienced first sexual activity at a young age (<14 years) and who had not received the HPV vaccine before sexual debut, a single HPV test between 20 and 24 years of age could be considered on an individual basis.

CONSENSUS-BASED RECOMMENDATION

REC15.3: Women with abnormal vaginal bleeding

Women at any age who have signs or symptoms suggestive of cervical cancer or its precursors, should have a co-test† and be referred for appropriate investigation to exclude genital tract malignancy.

† Co-testing (HPV and LBC) is recommended as the presence of blood has the potential to adversely affect the sensitivity of any of the available tests.

16. SCREENING IN IMMUNE-DEFICIENT WOMEN

CONSENSUS-BASED RECOMMENDATION

REC16.1: Immune-deficient women in whom oncogenic HPV is **not** detected

Immune-deficient women who have a HPV test in which oncogenic HPV types are **not** detected should be screened every 3 years with a HPV test.

CONSENSUS-BASED RECOMMENDATION

REC16.2: Colposcopy referral: positive oncogenic HPV test result (any type) in immune-deficient women

Women who are immune-deficient and have a positive oncogenic HPV (any type) test result should be referred for colposcopic assessment informed by the reflex LBC.

CONSENSUS-BASED RECOMMENDATION*

REC16.3: Colposcopy assessment and treatment in immune-deficient women

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

SUMMARY OF RECOMMENDATIONS

CONSENSUS-BASED RECOMMENDATION*

REC16.4: Colposcopy of whole lower genital tract in immune-deficient women

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

CONSENSUS-BASED RECOMMENDATION*

REC16.5: Treatment in immune-deficient women

When treatment of the cervix is considered necessary in immune-deficient women, it should be by excisional methods.

PRACTICE POINT

REC16.6: Histological abnormalities of the cervix in immune-deficient women

Women with histologically confirmed abnormalities should be managed according to the same guidelines as women who are not immune-deficient.

PRACTICE POINT

REC16.7: Test of Cure for treated immune-deficient women

Women who are immune-deficient and treated for HSIL (CIN2/3) should have follow-up with Test of Cure as recommended in these guidelines. Women who complete Test of Cure should return to routine 3-yearly screening with a HPV test.

PRACTICE POINT

REC16.8: Screening before solid organ transplantation

Women 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. Women 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.

PRACTICE POINT

REC16.9: Screening women with a new diagnosis of HIV

Women 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.

PRACTICE POINT

REC16.10: Other groups that may require special consideration

The groups listed below could be considered for screening every 3 years with a HPV test in accordance with the recommendation for HIV-positive women and solid organ transplant recipients:

- women with congenital (primary) immune deficiency
- women who are being treated with immunosuppressant therapy for autoimmune disease (e.g. inflammatory bowel disease, systemic lupus erythematosus, rheumatoid arthritis, neuromyelitis optica, sarcoidosis)
- allogenic bone marrow transplant recipients treated for graft versus host disease.

SUMMARY OF RECOMMENDATIONS

PRACTICE POINT

REC16.11: Regular screening for immune-deficient women

Women who are immune deficient should be educated regarding the increased risk from HPV infection and encouraged to attend for regular screening.

PRACTICE POINT

REC16.12: Young women with long term immune deficiency

For young women who are sexually active and who have been immune deficient for more than 5 years, a single HPV test between 20 and 24 years of age could be considered on an individual basis (regardless of HPV vaccination status).

PRACTICE POINT

REC16.13: Guidance for immune-deficient women and their healthcare professionals

It is important that immune-deficient women and their healthcare professionals are guided by a clinical immunology specialist when using these guidelines.

17. SCREENING IN DES-EXPOSED WOMEN

CONSENSUS-BASED RECOMMENDATION

REC17.1: Screening in DES-exposed women

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

CONSENSUS-BASED RECOMMENDATION*

REC17.2: Colposcopy referral for abnormalities in DES-exposed women

Women exposed to DES in utero who have a screen-detected abnormality should be managed by an experienced colposcopist.

PRACTICE POINT

REC17.3: Daughters of women exposed to DES

These women should be screened in accordance with the NCSP policy (5-yearly HPV testing). Evidence of an adverse effect on the daughters of women exposed to DES in utero has not been found.

However, if these women have concerns, 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.

18. INVESTIGATION OF ABNORMAL VAGINAL BLEEDING

CONSENSUS-BASED RECOMMENDATION

REC18.1: Women with abnormal vaginal bleeding

Women at any age who have signs or symptoms suggestive of cervical cancer should have a co-test, and referral for appropriate investigation to exclude genital tract malignancy should be considered.

CONSENSUS-BASED RECOMMENDATION

REC18.2: Abnormal vaginal bleeding and testing for HPV and LBC

When women present with abnormal vaginal bleeding, appropriate investigations, which may include a cervical sample for a co-test,† should be performed and not delayed due to the presence of blood.

† The woman's recent cervical screening history should also be considered.

CONSENSUS-BASED RECOMMENDATION

REC18.3: Postcoital bleeding in pre-menopausal women

Pre-menopausal women 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.

If postcoital bleeding recurs or persists despite a negative co-test women should be referred to a gynaecologist for appropriate assessment, including colposcopy, to exclude genital tract malignancy.

PRACTICE POINT

REC18.4: Postcoital bleeding and sexually transmitted infections

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

CONSENSUS-BASED RECOMMENDATION*

REC18.5: Symptomatic women with LBC prediction of cervical cancer

Women with symptoms and a LBC prediction of invasive cervical cancer should be referred to a gynaecological oncologist or gynaecological cancer centre for assessment.

CONSENSUS-BASED RECOMMENDATION

REC18.6: Women with intermenstrual bleeding may require specialist referral

Women with persistent and/or unexplained intermenstrual bleeding require appropriate investigation and should be referred for specialist gynaecological assessment, regardless of any test results.

CONSENSUS-BASED RECOMMENDATION

REC18.7: Postmenopausal women with vaginal bleeding require specialist referral

Postmenopausal women with any vaginal bleeding, including postcoital bleeding, should be referred for a specialist gynaecological assessment, to exclude genital tract malignancy.

20. TRANSITION TO THE RENEWED NATIONAL CERVICAL SCREENING PROGRAM

PRACTICE POINT

REC20.1: HPV test replaces the Pap test

All Pap tests are replaced by HPV testing.

Conventional Pap tests are no longer used.

Reflex LBC will be performed on any sample with a positive oncogenic HPV (any type) test result.

Co-testing (HPV and LBC) to be performed only as recommended in these guidelines, in the follow-up of screen-detected abnormalities or the investigation of abnormal vaginal bleeding.

PRACTICE POINT

REC20.2: HPV testing for women in follow-up after pLSIL/LSIL

Women who are in follow-up for pLSIL/LSIL cytology in the previous program (pre-renewal NCSP) should have a HPV test at their next scheduled follow-up appointment.

- Women with a positive oncogenic HPV (any type) test result should be referred for colposcopic assessment informed by reflex LBC.
- If oncogenic HPV is not detected, the woman can return to 5-yearly screening.

PRACTICE POINT

REC20.3: Colposcopic management of a prior screen-detected abnormality should continue

Women who have been referred for colposcopic assessment following any cytological abnormality in the pre-renewal NCSP should continue their colposcopic management according to these guidelines.

PRACTICE POINT

REC20.4: Prior treatment and Test of Cure

Women who have been treated for HSIL (CIN2/3) in the pre-renewal NCSP and are undergoing, or have not yet commenced Test of Cure, should start or continue Test of Cure in accordance with these guidelines.

Women should have an annual co-test (HPV and LBC) performed at 12 months after treatment, and annually thereafter, until both tests are negative on two consecutive occasions, when they can return to routine 5-yearly screening.

PRACTICE POINT

REC20.5: Prior treatment for AIS

Women who have been treated for AIS in the pre-renewal NCSP, and are undergoing or have not yet commenced surveillance, should have annual co-testing (HPV and LBC) indefinitely.†

† Until sufficient data become available that may support a policy decision that cessation of testing is appropriate.

APPENDIX

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APPENDIX

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