# REPORTING FOR THE NCSP: WHAT PATHOLOGISTS NEED TO KNOW

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NCPTS

November 2021

# NCSP POLICIES AND STANDARDS

…sets out the policies and standards of practice for NCSP service providers

Purpose

- To support all those who are involved in the NCSP to achieve its aims and objectives by ensuring high standards and national consistency of service at each step of the screening pathway, and allowing new developments to be incorporated if they have been shown to provide improved services.

# OBJECTIVES

All lab services that are a part of the cervical screening pathway must comply

- hrHPV testing, gynaecological cytology and histology services are reviewed regularly to ensure continual improvement in the quality of services. Laboratories providing services to the NCSP are audited annually to ensure compliance with ISO15189 and NCSP Policies and Standards
- Laboratory performance is measured by NCSP audits, laboratory internal quality assurance processes, contract monitoring reports and NCSP monitoring reports.
- Section 5 policies and standards are reviewed regularly by the NCSP.

# CULTURAL AND EQUITY CONSIDERATIONS

Laboratory staff must consider the values and beliefs held by the various groups of people residing in New Zealand and ensure they handle all samples and specimens with respect without prejudice based on ethnicity, gender or age. Respectful and timely communication must occur with those who want their material returned.

Staff must recognise the cultural significance of human tissue for Mâori particularly with regard to the importance of the cervix as part of Te Whare Tangata, the sacred "house of humanity".

Kei motu te hono tangata.

Let the human link not be broken.

# CULTURAL SENSITIVITY AND APPROPRIATENESS

Laboratories must have written protocols for handling, retaining, returning and disposing of human tissue, cells or any other samples containing human genetic material.

These protocols need to incorporate cultural considerations and comply with current legislation in New Zealand.

All responses to requests from individual/s regarding the handling, retaining, returning and disposing of human cell and/or tissue samples must follow local DHB tikanga protocols.

- If a request cannot be meet by the laboratory, the reason/s for declining the return must be clearly stated and understood by all involved.
- If the individual/s who made the request do not agree with the decision, an appropriate person designated by the laboratory will meet with them to attempt to reach agreement.
- The discussion and outcome must be documented.

# QUALIFICATIONS: PATHOLOGISTS

Every pathologist working in gynaecological cytology or histology must:

- be a fellow of The Royal College of Pathologists of Australasia (RCPA) or hold an equivalent qualification recognised by the Medical Council of New Zealand
- have received sub-speciality training in general pathology, histopathology and/or cytopathology as appropriate for the subspecialty practised
- hold a current annual practising certificate issued by the Medical Council of New Zealand, with a scope of practice of anatomical pathology or general pathology.
- all cytopathologists reporting gynaecological cytology must first have completed an appropriate training course in accordance with manufacturer's requirements for the LBC type used.

# LEADERSHIP

NCSP services at each laboratory site must be led by a named and suitably qualified pathologist, referred to as the Lead NCSP Services Pathologist.

Each laboratory service must also have a named Lead Scientist responsible for the provision of each of hrHPV testing, cytology and/or histology.

# RESPONSIBILITIES OF THE LEAD NCSP SERVICES PATHOLOGIST

- deliver the agreed services according to Section 5
- carry the responsibility for all NCSP services in the laboratory
- ensure all staff are appropriately trained and meet ongoing professional competency requirements
- document and coordinate the clinical leadership structure
- ensure adequate liaison exists between experts in anatomical pathology and HPV testing
- be available in the laboratory every working day or delegate this responsibility to another pathologist

# CONTINUING EDUCATION: HPV TESTING

All pathologists supervising or working in hrHPV testing services must:

- demonstrate external and in-house educational activity (excluding routine daily practice) directly related to HPV testing, totally an average of 20 hours per annum averaged over three years.
- attend a relevant HPV-related education event at least once every two years.

Relevant educational activities acceptable under the RCPA CPD programme will be accepted by the NCSP.

# CONTINUING EDUCATION: CYTOLOGY

All cytopathologists reporting gynaecological cytology must:

- demonstrate external and in-house educational activity (excluding routine daily practice) directly related to cervical pathology, totalling an average of 20 hours per annum averaged over three years.
- participate in external individual and laboratory-based External Quality Assurance Programmes.
- participate in cytology/histology correlation reviews regularly.

# CONTINUING EDUCATION: HISTOLOGY

All histopathologists reporting gynaecological histology must:

- attend a specific gynaecological pathology education event at least once every three years.

# RETURNING TO WORK

All staff returning to work following an extended absence must demonstrate competency in the tasks they undertake.

- if the absence is 12 months or longer, the Lead NCSP Services Pathologist must specify an individualised re-training and supervision programme for the returning staff member to complete.
- if the absence is 6-12 months, the Lead NCSP Services Pathologist must determine a suitable course of action and/or supervision to support the returning staff member's reintroduction to their role.

# CYTOLOGY: VOLUMES AND WORKLOADS

Each pathologist that reports gynaecological cytology must report a minimum of 500 gynaecological LBC samples per annum.

# CYTOPATHOLOGIST REPORTING

All results confirmed abnormal (G2 or G3) after full rescreening must be sent to a cytopathologist for reporting.

All cases reported by a pathologist must first be fully screened by at least two cytoscreeners.

# ENSURING CORRECT RECOMMENDATIONS IN CYTOLOGY REPORTS

Laboratories must ensure that a woman's complete current screening event history from the NCSP register is readily available and considered by all laboratory staff involved at each stage of the cytology screening and reporting process.

Recommendations for recall or referral must be based on the clinical details and the cytological findings of the current sample, as well as the woman's complete NCSP screening event history in accordance with the *Clinical Practice Guidelines for Cervical Screening in New Zealand 2020.*

# HISTOLOGY

All gynaecologic histology specimens must be handled, described and prepared for examination and reporting in accordance with:

- ISO15189 http://www.ianz.govt.nz/resources/documents-2/supplementary-criteria/
  - including the IANZ Specific Criteria Medical Testing Second edition November 2014 Appendix 4 Requirements for Minimising Errors in Medical Histology Laboratories
- RCPA Anatomical Pathology Macroscopic Cut-up Manual: www.rcpa.edu.au/Library/Practising-Pathology/Macroscopic-Cut-Up
- RCPA Structured Reporting Protocol for Excisions and Colposcopic Biopsies performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia (1st Ed. 2017)
- RCPA Cervical Cancer Structured Reporting Protocol (1st Ed. 2013)

# HISTOLOGY: ADDITIONAL NZ REQUIREMENTS

**Cervical punch biopsies** must have:

- an initial six levels of the tissue examined, with consideration to keeping extra levels for immunoperoxidase staining, if required.
- further levels examined to identify all pathology (if additional tissue is still present in the block/s)
  - if there is a discrepancy between initial levels and referral cytology especially if the cytology report is of higher grade than the initial histology levels reveal.

# LLETZ BIOPSIES

**Loop excisions (LLETZ) and Cone biopsies**:

- LLETZ and cone biopsies should have three levels examined on all tissue blocks, with further levels if indicated by clinical information or findings on the three initial levels.
- Pathologists may use their discretion regarding the number of initial and subsequent levels, depending on clinical circumstances and findings in the initial sections examined.

# HYSTERECTOMIES

The cervix must be amputated and handled in accordance with cone biopsy protocols with all cervical tissue processed for histologic examination, when:

- the hysterectomy is done wholly or in part to treat the cervical abnormality (e.g. a woman with AIS who decides to proceed to hysterectomy, a woman with HSIL and another gynaecological issue such as large fibroids and menorrhagia who decides to proceed to hysterectomy to deal with both issues).
- an identified high-grade abnormality has not been treated or resolved (e.g.. previous HSIL without successful completion of a Test of Cure).
- an identified low-grade abnormality has not resolved (the woman has not returned to regular interval screening prior to hysterectomy)
  - and there is a concurrent hrHPV Detected test result (any subtype) or her hrHPV status is unknown.

# HYSTERECTOMIES

The hysterectomy specimen can be handled according to usual hysterectomy protocols if:

- a previous high-grade abnormality was resolved prior to hysterectomy (e.g. previous HSIL treated with subsequent successful completion of Test of Cure)
- a woman with a previous LSIL/CIN1 has returned to usual interval screening after follow-up, or had LSIL/CIN1 with a concurrent hrHPV Not Detected test result.

# REPORTING HISTOLOGY

A histopathologist must examine and report all histology slides.

All specimens should be reported in concordance with the RCPA Structured Reporting Protocol for Excisions and Colposcopic Biopsies performed for the Diagnosis and Treatment of Pre-invasive Cervical Neoplasia and the Cervical Cancer Structured Reporting Protocol.

# REPORTING ADEQUACY RE: THE TRANSFORMATION ZONE

Sampling of the squamo-columnar junction in a small diagnostic biopsy is not required for adequacy as the clinician is targeting the colposcopic abnormality.

Documentation of the tissues present facilitates clinicopathologic correlation.

A specific statement on adequacy by the pathologist is not required as adequacy requires clinical correlation.

# REPORTING MARGINS FOR LLETZ AND CONE BIOPSY EXCISION SPECIMENS (CONTAINING HSIL AND/OR AIS)

Where HSIL or AIS is identified in an excision specimen, the RCPA Structured Reporting mandatory Standard applies:

- The status of all surgical excision margins must be recorded (ectocervical, endocervical and radial/deep stromal).

# ADDITIONAL GUIDELINES

The way that margins are reported "may be determined in conjunction with local clinicians"

After discussion in New Zealand, the following requirements are mandatory:

- For HSIL, measuring distances to surgical margins is not required.
- For AIS and/or SMILE, distances to excision margins (ectocervical, endocervical and radial/deep stromal) that are less than 5 mm must be measured and documented in the report.

Where involvement of the margin cannot be determined (processing artefact, thermal artefact, multiple pieces or poor tissue orientation), should be specified as "indeterminate" and the reason given

If the surface epithelium is stripped, the measurement should be to the end of the intact surface epithelium.

# REPORTING USING LAST AND CIN TERMINOLOGY

- All cervical and vaginal histology specimens where dysplasia or malignancy is reported should be reported using LAST terminology, with the CIN terminology given in brackets. For example: *HSIL (CIN 3).*

Reporting FIGO staging for invasive cervical cancers

- If possible, and particularly when the invasive cancer is completely excised, the histology report must include International Federation of Obstetricians and Gynecologists (FIGO) staging.

# IMMUNOHISTOCHEMISTRY

- Additional investigations (such as immunohistochemistry for difficult-to-grade lesions) should be performed as professionally appropriate.

# CORRELATING RESULTS WHEN REPORTING

The histopathologist must have the complete current NCSP Register screening event history available at the time of reporting any histopathology specimen containing cervical or vaginal tissue and must correlate the most recent cytology result (e.g. the referral to colposcopy sample) with the histology specimen/s result/s when making their report.

If the most recent cytology result reported was possible or definite high-grade and the histology specimen/s being reported is/are less than high-grade then:

1. If the most recent cytology sample *was reported at the same laboratory* as the histology being reported then it is recommended that where possible, the cytology slide be reviewed at the time of histology reporting.
 - If the cytology sample is confirmed as possible or definite high-grade, the cytology review can be communicated to the colposcopist in the histology report and the case referred for consideration for MDM review.
 - If the cytology sample is downgraded from a possible/ definite high-grade, an amended cytology report can be issued and MDM review may not be required.

2. If the most recent cytology sample was *not reported at the same laboratory* where the histology is being reported then it is recommended that the histology report states that the most recent cytology sample has not been reviewed and the case is referred for consideration for MDM review.

# COMMUNICATING RESULTS

Laboratories are responsible for reporting

- all hrHPV test results using NCSP-approved reporting terminology
- cytology results using NCSP-approved Bethesda 2001 (NZ Modified) terminology to sample takers, and
- all histology samples to the referring specialist using the NCSP-approved SNOMED coding,

in a timely manner.

# TURNAROUND TIMES: HISTOLOGY

Laboratories must report:

- 90% of final histology results to referring specialists within 10 working days of receipt of the specimen
- 98% of final histology results to referring specialists within 15 working days of receipt of the specimen.

# REPORTING TO THE NEW ZEALAND CANCER REGISTRY (NZCR)

All cytology results analysed and reported as definite or suspicious of invasive cancer and histology results with a diagnosis of in situ or invasive cancer must be reported to the NZCR (Ministry of Health).

## Cytology

- abnormal squamous cells showing changes consistent with squamous cell carcinoma (SC)
- abnormal glandular cells consistent with adenocarcinoma (AC1–4)
- abnormal cells consistent with a malignant neoplasm NOS(AC5)
- abnormal cells consistent with a high grade squamous intraepithelial lesion (HSIL) with features suspicious for invasion (HS2)

## Histology

- CIN 2 or CIN 3
- CIN 2/CIN 3 when reported together
- endocervical AIS
- invasive primary cervical or vaginal malignancies
- other malignancies involving the cervix or vagina.

# REVIEWING HISTOLOGY AND CYTOLOGY: MDM MEETINGS

If a case is being discussed at an MDM

- A pathologist representative from each laboratory that issued the original reports of cervical cytology and/or histology must attend either in person, by videoconference or by live telephone linkage to present their findings and participate in the case discussion directly with the colposcopy team.

Pathologists must only formally review cytology slides for MDM purposes in the same LBC type that they normally report.

# DOCUMENTATION OF MDM OUTCOMES AND SUBSEQUENT RESPONSIBILITIES POLICY

Presenting pathologists are responsible for ensuring that all slide reviews and amended/supplementary reports are issued within 5 working days following the meeting

Outcomes of MDM reviews of pathology material must be recorded and linked to the original result in the laboratory electronic records to provide a clear record of the time of the review, the reviewing pathologist, the outcome of the review and any further actions taken.

Meeting documentation must include a list of those persons present at the meeting and be circulated to all attending.

# CHANGING A CYTOLOGY OR HISTOLOGY RESULT AT MDM REVIEW

If changes are made to a cytology or histology report as a result of a slide review,

- the reviewing pathologist must either issue a written amended report or ensure that an amended report is issued by the laboratory that issued the original report (if this is a different laboratory).

The review outcome must be communicated to all people who were issued with the original report or who are involved in clinical management and to all relevant registers.

# ISSUING AMENDED CYTOLOGY AND/OR HISTOLOGY REPORTS POLICY

All amended cytology or histology results must be notified within 5 working days of the date of the slide review to:

- the sample taker
- all other persons who were issued with the original result report
- the colposcopist managing the case, if appropriate
- the NCSP Register
- the NZ Cancer Registry, if appropriate (including cases where a previous cytology result reported to the NZCR has been downgraded to something not usually reported).

# QUALITY ASSURANCE

All laboratories providing services to the NCSP must be accredited by IANZ

A laboratory that is considering introducing new tests or technologies into the cervical screening pathway must first:

- notify the NCSP
- ensure that the test or technology has been appropriately validated
- ensure that the test or technology has been notified to IANZ
- communicate details of any transition to new tests or technologies to sample takers well in advance

# EVALUATING INDIVIDUAL PERFORMANCE POLICY: PATHOLOGISTS

Monitoring the performance of individual cytopathologists relative to the performance of other pathologists at the same laboratory provides assurance about consistency of reporting.

- The lead pathologist must review all individual cytopathologist reporting profiles every six months, with individual results and the overall reporting profile for the laboratory's pathologists provided to each person monitored.
- If the lead cytopathologist has any concerns about individual cytopathologist performance they must meet to discuss this, and document protocols, outcomes and any remedial actions.

# INTERNAL QUALITY ASSURANCE: PATHOLOGISTS

Correlation of cytology with concurrent/ subsequent histology

When histology confirms a high grade or invasive lesion, this triggers a review of any negative/ benign/ unsatisfactory cyto reported in the previous 42 months

# EXTERNAL QUALITY ASSURANCE

All laboratories reporting gynaecological cytology, histology and HPV testing must participate in a laboratory performance-based External QA Programme for each of the disciplines practiced at that laboratory.

All staff who report gynaecological cytology must participate in the Individual External QAP run by the RCPA QAP

# CONCLUDING COMMENTS

- NCSP policies and standards are important as they define and maintain high-quality reporting in New Zealand laboratories
- All pathologists need to be aware of the standards and comply with them
- The policies and standards are reviewed and updated regularly, as the NCSP continues to evolve and respond to issues that arise within the programme
- The next update will be a major update when HPV primary screening is implemented but the changes will affect scientists and technical staff more that the work of pathologists