Histology Requirements
for National Cervical Screening Register

Prepared for the Department of Health
by Janet Phuah

April 1993

Department of Health
TE TARI ORA
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This report has been prepared by Janet Phuah, Senior Consultant, AZIMUTH for the Department of Health. Its purpose is to inform discussion and assist in future policy development. The opinions expressed in the report, therefore, do not necessarily reflect the official views of the Department of Health.

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Management Summary

Introduction

This study was commissioned by the National Co-ordinator, National Cervical Screening Programme of the Department of Health (the DOH). The study commenced on 5 January 1993, and completed on 28 February 1993.

The purpose of the study was to define the requirements for adding histology results to the National Cervical Screening Register (NCSR) which has been in operation since 1989.

Contents of the Report

The report establishes what histology information is currently recorded in New Zealand laboratories, and how it is recorded. It identifies a coding structure for recording histology results, and proposes a practical approach by which the results can be captured on the Register. It documents the findings and related issues, and provides an initial implementation plan for establishing histology in the Register.

A revised data model showing the changes to the present Programme after the inclusion of histology is also provided.

Recommendations

The following recommendations are made and are listed below in no particular order:

1. That this report be circulated to all interested parties, for discussion and feedback on specific aspects.
2. That the implementation plan be accepted and the next steps initiated.
3. That the consultative process with pathologists and other interested parties be maintained.
4. That the current operational procedures of the Register system remain unchanged.
5. That any changes to the Programme consider and include the histology requirements.
6. That SNOMED, after consultation with laboratories, be adopted as the coding system to record histology results in the Register.
7. That the same principles of privacy and confidentiality for the present Programme be maintained.
8. That the wishes of women who have chosen to be excluded from the Register (and consequently from the Programme) are respected and provided for.
9. That the same principles governing the protection of Maori data be maintained.
10. That the histology information be provided to the Registry at the same time as cytology information, and on the same media.
11. That the DOH combine the promotion of the addition of histology results to the Register with other planned campaigns to promote the Programme.

Implementation Plan

The next steps for progressing the addition of histology results to the Register are:

1. Appoint a project manager to oversee and manage the implementation of histology on the Register.

2. Communicate to the laboratories, medical specialists, colposcopists and other related organisations of their obligations under the Health and Disability Services Bill.

3. Extend CALC's (Cytology Advisory Liaison Committee) role with regard to histology on the Register, and seek confirmation and agreement from the committee regarding the requirements outlined in this report.

4. Prepare a technical specification of the expected changes to the present system, and the impact of those changes.

5. Prepare, agree and seek approval for the financial resources for the modification and redevelopment of the Register for histology, and for any associated consequences (such as upgrade costs which result from either hardware or software requirements at the Registries and the laboratories).

6. Modify the present Register to provide for the agreed requirements, with associated relevant documentation and full system testing.

7. Test the modified computerised register at one or two pilot sites to refine the system, making changes where necessary.

8. Accept (sign-off) the new Register at the pilot sites.

9. Publicise the benefits of adding histology to the Register to the laboratories, medical specialists, colposcopists and other related organisations, including the roles (and actions) expected from each of these organisations and how they interact with each other and with the Programme.

10. Implement the new Register across the remaining sites using a phased approach.

11. Conduct a post implementation review.
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A. List of Contributors
B. Glossary of Terms
C. List of Persons/Organisations Advised of Project
1. **Introduction**

1.1 **Scope**

This study was commissioned by the National Co-ordinator, National Cervical Screening Programme of the Department of Health (the DOH). The study commenced on 5 January 1993 and completed on 28 February 1993.

The purpose of the study was to define the histology requirements for the National Cervical Screening Register (NCSR).

This report documents the findings and recommendations of the study and includes a proposed implementation plan.

The study does not attempt to deal with medical or clinical issues or to make judgements on the protocols or current structures relating to the National Cervical Screening Programme or general cancer issues. The report determines the requirements for adding histology to the existing NCSR from an administrative context and documents the issues raised by the interviewed persons. A separate register for recording histology results is not envisaged.

1.2 **Terms of Reference**

The objectives of this project are:

- to specify the requirements for adding histology to the NCSR

- to establish what histology information is currently recorded in New Zealand laboratories, and how it is recorded

- to identify an appropriate coding structure for recording histology results in the NCSR

- to identify mechanisms by which histology results can be captured on the NCSR

- to provide an initial implementation plan for establishing histology results in the NCSR.

1.3 **Background to the Study**

Following the release of the Cartwright report\(^1\) on the cervical cancer inquiry in July 1988, the DOH took steps to initiate a national cervical screening programme.

A prototype computerised cervical screening register was established in March 1989 and two pilot cervical screening programmes were initiated in Marlborough and Wanganui in September and October 1989 respectively. Both programmes included the use of the computerised register.

The national cervical screening programme, supported by the computerised registers, is currently implemented across all 14 area health boards (AHBs) in New Zealand and is collectively referred to as the National Cervical Screening Programme. Each local programme is managed by a programme manager employed by the AHB. The nationwide programme is co-ordinated by a national co-ordinator employed by the DOH.

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The computerised registers operate as standalone systems and are collectively known as the National Cervical Screening Register (NCSR). The NCSR (the "Register") currently captures cervical cytology results and is an integral part of the National Cervical Screening Programme (the "Programme").

In September 1989, the DOH commissioned an independent review of the Programme to establish future directions and policy. The review committee recommended that "the development of the cytology register continue as planned, but that an investigation of methods by which histology results could be incorporated should begin immediately". The addition of cervical histology results to the Register will increase the effectiveness of the Programme, and enable the monitoring of the follow-up of women with abnormal smear test results.

Section 93 of the Health and Disability Services Bill redefines cervical smear tests to include both cytological and histological specimens taken to determine the presence of cancer or non-invasive pre-cancerous lesion in the cervix. The Bill also states that, unless a woman objects, the results of her cervical smear test must be forwarded for inclusion in the Register.

The new legislation is expected to come into effect on 1 July 1993. This report identifies the histology requirements necessary to meet the legislative changes.

Further details on the operation of the New Zealand National Cervical Screening Programme are available from the DOH.

1.4 Study Approach

This study was undertaken in seven phases:

1. Familiarisation with cervical screening programmes in general and the New Zealand programme in particular, through background readings and discussions with the DOH staff and Azimuth consultants who have worked on other aspects of the Programme.

2. Interviewing nominated persons from selected organisations. The list of organisations was agreed with the sponsor and a questionnaire of the areas to be covered which best met the objectives of the assignment was prepared and agreed with the sponsor.

The interviews were conducted to confirm the existing workflows and procedures, to determine what histology information was currently collected and used, to establish anticipated work volumes and to identify interviewee concerns.

3. Identifying the issues which impact the addition of histology results to the Register.

4. Defining the functional requirements and information systems for recording histology on the Register.

6. Proposing an implementation plan.

7. Preparing the report.

A detailed list of the people who contributed to this study is included in appendix A. We thank them for making time and facilities available during the course of the study and for their input.


27 April, 1993
1.5 Assumptions

The following areas of the Programme are taken as givens (non-negotiable issues):

1. Cervical histology results are to be added to the present register. A separate register for histology is not anticipated.

2. Cervical cytological examination is conducted at private diagnostic laboratories and at hospital laboratories, both of which provide results to the Register. Since histological examination is also conducted at laboratories, it is assumed that the laboratories will be the source of the histological results to be provided to the Programme.

3. Legislation for automatic enrolment of women on the Register becomes effective on 1 July 1993 as part of the Health and Disability Services Bill. From then onwards, all women who undergo a cervical smear test will automatically be included on the Register unless they specifically choose to be excluded from the Programme.

4. Laboratories at private hospitals were not interviewed at this stage. The majority of private hospital cytological and histological work are sent to private laboratories for examination.

1.6 Definition of Terms

In this report the terms cytology and histology are used to refer specifically to cervical cytology and cervical histology.
2. **Current Situation**

2.1 **Functions of the Register**

The goal of the National Cervical Screening Programme is to reduce the incidence of, and death rate associated with, cervical cancer through the prevention of the development of invasive cervical cancer.

Under the current Government policy for national cervical screening, the objectives of the Register are to:

- ensure that women with abnormalities are identified and adequately treated
- provide information about past cervical smear tests to laboratories to assist them in interpreting smears and making recommendations on treatment
- provide information to general practitioners and other health providers so that they can provide the most efficient and effective service to women
- make sure all women screened will be recalled at appropriate intervals, including women who have moved from one area health board region to another
- provide women with their own results
- monitor the quality of smear tests
- measure the population coverage achieved.

2.2 **Cervical Cytology, Colposcopy and Histology**

Cervical cytology gives only an indication of risk and cannot distinguish absolutely between women with certain presymptomatic disease and those without. An abnormal cytology (smear test) result indicates that abnormal cells were detected in the cervical area and, depending on the degree of abnormality, the woman is referred to appropriate follow-up action according to the DOH handbook on "National Consensus on a Treatment Protocol of Management of Abnormal Cervical Smears". In other words, a request for colposcopic examination is usually generated as a result of a positive (ie abnormal) cytological finding.

Women with normal smear test results are recalled for routine smear tests. Women with low grade smear test results are recalled for repeat smear tests in accordance with the treatment protocol.

Women with high-grade or repeated low-grade abnormal smear test results are referred to colposcopy. Colposcopic examination involves looking for abnormalities of the cervix through a colposcope by a gynaecologist or colposcopist. It is usually (but not necessarily) accompanied by a biopsy. The tissue from the biopsy is sent to the diagnostic laboratories for histological examination.

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Symptomatic women who may have a normal smear test result may be referred to colposcopic examination. Again, the examination may or may not be accompanied by a biopsy.

2.3 Advantages of Adding Histology

The following advantages will be gained through incorporating histology results into the Register:

- the follow-up treatment of women with abnormal smear test results will be more accurately tracked through to completion of recommended treatment
- the ability to compare and correlate cytology results with the histology results
- the ability to detect discordant results and make appropriate decisions regarding quality assurance
- the provision of additional epidemiological information for monitoring of the Programme.

2.4 Current Laboratory Workflow and Practice

The overall workflow is reasonably consistent across all laboratories visited, and is outlined below. Any detectable differences are very minor (such as whether a manual logbook was used in conjunction with other worksheets, using worksheets to track the workflow and internal quality control, handwriting or dictating the results, card or computerised indexes to maintain records of previous results, use of different automated equipment to process or stain the slides, and so on) and are because the laboratories have different equipment or computer systems and have modified the processes to suit the environment.

A typical laboratory workflow is as follows:

The tissue specimen arrives at the laboratory in a clearly marked pottle of formalin and is accompanied by a laboratory request (or referral) form. Each form is a request for a histological examination and will result in one histology report.

The laboratory assigns a unique number for each request. This unique number is referred to as the test number, the accession number, the episode number or the laboratory (or lab) number.

There is one histology request per woman per episode, regardless of the number of tissue specimens received. Where multiple tissue specimens are taken from the same woman and each specimen is stored in its own pottle, then each pottle is marked with the same test number with a suffix of A, B, C (or i, ii, iii), and so on.

Requests and specimens may be batched for internal control or convenience before processing.

The nature of each specimen is identified (e.g. cervix biopsy, cervix biopsy anterior, etc). The unique test number, the request form details and the nature of the specimen are then entered (logged) into system. Subsequently, each specimen is examined and described; this process being referred to as the macroscopic or gross description and which may include a diagram of the specimen.

Worksheets of the specimens received may then be printed to track and manage workflow. In laboratories where work-in-progress (WIP) histology reports are used, they are printed for later matching with the slides. WIP histology reports are one-page printouts of each histology examination request and contains the request details (woman, name, address, etc) and the
specimen name and macroscopic description. Where available and matched, the woman's cytological and histological history may also be printed.

Having been described and, if necessary, dissected and sliced, each specimen is then processed (placed in labelled cassettes, "washed" in increasing concentrations of alcohol and then xylol, and then impregnated with paraffin wax). Large specimens are cut into smaller specimens before processing. Each specimen is then embedded in wax and thinly sliced. Each section is placed onto a slide and the slide is labelled. The slides are stained and the stained sections protected with a thin glass cover for microscopic examination.

The slides are then examined, described and diagnosed by the pathologist(s). A report is either written or dictated for typing, printing, and final reporting.

Although both the macroscopic and microscopic descriptions are provided for each specimen, a diagnostic summary is given for each histology request (eg if three tissue specimens were received for one woman, the final histology report will contain three specimen names, three macroscopic descriptions, three microscopic descriptions and a summary).

The reports are verified and signed out by the pathologist before being sent to the clinician requesting the histology examination. Copies are sent to any other practitioner specified on the request form.

The laboratory copy of the reports are filed, as are the slides. Where records are kept of the woman's previous histological results, those records are updated with the latest summary diagnosis and a reference to the laboratory test number.

Some laboratories use two systems to report histology results; a word processing system to report and print the narrative aspect of the macroscopic and microscopic descriptions and diagnosis of the histology examination, and the main laboratory management system to store the diagnosis in SNOMED (Systematized Nomenclature of Medicine) codes and for billing. A brief outline of SNOMED is provided in sections 3.2.3 and 3.5 of this report.

In laboratories which have implemented the SNOMED module of the laboratory system, the module recognises certain words in the summary diagnosis and provides the equivalent SNOMED code for the diagnosis. The SNOMED codes are used by the laboratories for analysis and are often not printed on the final histology report.

2.5 Current Information Exchanged and Held

Although not identical, the information exchanged is reasonably uniform and consistent.

2.5.1 Histology Request

There is currently no national standard which defines what information should be provided on a laboratory request form. A common laboratory request form which covers all laboratory tests is used to request smear and histology examinations. A new national cervical screening form will be produced for cervical screening tests.

The present request forms are printed by each laboratory and supplied to the doctors. The private laboratories' forms differ only slightly from each other, but the difference between the private and some hospital laboratories' forms may be more marked.
The current histology request form typically comprises four parts:

- a letterhead which is usually pre-printed and contains details which identify the laboratory such as the name, address and contact numbers
- woman details:
  - family name(s)
  - first name(s)
  - date of birth
  - patient number (or doctor’s reference, although this is sometimes not provided)
  - gender
  - address (sometimes not provided for hospital laboratories as it is obtainable via the patient number through the main hospital system)
- referring physician details:
  - referring doctor’s name (or an identifying code)
  - name (or an identifying code) of the other person to whom a copy of the report is to be sent
- specimen details (which may be provided either on the request form or labelled on the pottle or both):
  - specimen source (eg cervix)
  - characterisation of separate specimens (eg A cervix posterior, B cervix anterior, and so on).

The laboratory pathologists state that the following clinically useful information is often not provided:

- clinical history (including previous cytology and histology results)
- biopsy site (eg at 3:00 pm)
- biopsy technique (eg biopsy/cone biopsy/Lletz biopsy)
- orientation of specimen (anterior/posterior).

Other additional information may also be provided but these are used for internal laboratory (or hospital) processing, vary from laboratory to laboratory and are not significant for this project. Examples of such information are ward number, date and time when specimen taken and so on.

2.5.2 Laboratory Test Details

Each laboratory has its own system to manage and control workflow and quality of processing.

The following details are common for all laboratories and are added to the histology request to uniquely identify the request:

- test number
- the date and time of receipt of specimen
- specimen suffix (to match the unique ID on the specimen pottle, where necessary).

The specimen suffix becomes the suffix to the request.
2.5.3 Histology Report

Again, while there is no national standard which defines a histology report, the information in the report is uniform and consistent. The report is a narrative description and provides the pathologists with freedom and flexibility in their diagnoses.

A histology report typically comprises four parts:

- a letterhead which is usually pre-printed and contains details which identify the laboratory such as the name, address and contact numbers
- woman details as provided in the request form
- referring physician details as provided in the request form
- result details:
  - test number
  - the date of receipt of specimen (optional)
  - report date
  - name (or ID) of the examining pathologist
  - name (or ID) of the pathologist who signed out the result (often the same as the examining pathologist, in which case only one name is shown)
  - for each tissue specimen:
    - specimen suffix (if applicable)
    - specimen name
    - macroscopic (or gross) description
    - microscopic description
  - summary (for the entire test).

In one of the laboratories visited, a brief history of previous cytology and histology results was also provided:

- test number
- summary diagnosis.

Where SNOMED codes are used, the summary diagnoses are translated into SNOMED codes and the codes are recorded in the system. The codes are used for internal analysis and are often not printed on the final histology report. Of the seven available SNOMED fields, the T-field (Topography) and the M-field (Morphology) are the most used in cervical histology. One E-field (Etiology) is used to denote HPV infection. A brief discussion on SNOMED coding is provided in sections 3.2.3 and 3.5 of this report.
3. Coding of Histology Results

3.1 Need for a Coding System

As stated earlier, a histology report is uniform and consistent in layout yet different in the style of content. Because it is a narrative description, it provides the pathologists with freedom and flexibility in their writing style and in the words used.

The flexibility provided by narrative descriptions results in inconsistent content and creates difficulties when retrieving or consolidating data.

A set of uniform and acceptable values used for encoding histology results:
- provides a standard and consistent means of describing the results
- facilitates the retrieval and consolidation of data for statistical analysis
- facilitates the monitoring of the epidemiological aspects of a screening programme
- facilitates the automated correlation between cytology and histology results
- allows the Register to process results from many sources in the same way
- facilitates the automated entry of data in the register
- is required for the organisation of data files.

Several coding systems already exist in this area and are outlined in the following section.

3.2 Coding Systems

Several coding systems are used within the New Zealand health system, particularly in relation to cancer and cervical cancer areas. A brief description of those systems is provided below.

3.2.1 Bethesda

The Bethesda coding standard is used by some laboratories and by the Register to record the cytology results of cervical smear tests. The Bethesda system comprises three codes: the adequacy of the smear taken, the smear test result category and additional diagnostic information. The set of codes is currently being extended to provide a wider range of results and to encourage uniform reporting.

The Bethesda system for reporting cervical cytologic diagnosis resulted from a conference workshop held in Bethesda, Maryland, USA in 1988. It was designed to overcome the difficulties of the Papanicolaou system of classifying cytology results.

3.2.2 SNOP/SNOMED

SNOP was developed by the College of American Pathologists in 1965 and was accepted as the standard for nomenclature in pathology. It was limited to the interests of anatomic pathologists which were the identification of lesions at specific sites (Topography) in the body and the naming of the character (Morphology) of such lesions.
SNOP has now been superseded by SNOMED. It is also the basis for ICD-O (International Classification of Diseases for Oncology).

### 3.2.3 SNOMED

SNOMED is accepted as the standard for nomenclature in pathology in New Zealand. It is either currently being used or intended to be used by some laboratories to record histology results.

SNOMED is an extended, coded nomenclature of medical terms and concepts developed from SNOP. It was published following consultation with other nomenclature committees to include Etiology (cause or association), Function (functional abnormalities, signs or symptoms), Disease (classification of lesion), Procedure (treatment of lesion) and Occupation (occupation of patient with lesion).

By agreement with the World Health Organisation, the two Morphology sections (M-8**** and M-9*****) in SNOMED dealing with neoplasms are identical to the Morphology section of the ICD-O. Although the Morphology sections are identical, the Topography sections of SNOMED and ICD differ widely. The ICD has less topography codes than SNOMED.

### 3.2.4 ICD

The ICD (International Classification of Diseases) system was developed by a number of working parties and committees brought together by the World Health Organisation and the International Agency for Research of Cancer (IARC).

The ICD-O and the ICD-9-CM (International Classification of Diseases Revision 9 Clinical Modification) are used by the Cancer Registry to classify and record the cases of malignant tumour diagnosed in New Zealand that were reported to the Cancer Registry. Registrations are made in the primary tumour cases distinguished by differences in topography and histology. The Cancer Registry uses the topography and morphology codes of the ICD-O.

The ICD-O was based on SNOP.

### 3.2.5 READ Codes

The Read Clinical Classification System (Read Codes) was designed by Dr James Read specifically for use by clinicians in day-to-day patient care. The codes enable a complete medical record to be coded and stored in a computer system, and contain mapping fields which enable the data to be linked to other commonly used international classifications.

It has been accepted by the standard for British General Practice, and for use in the New Zealand Health Management Information (HMI) system.

### 3.3 Proposed Coding System

SNOMED appears to be the most logical choice as the coding system to be used to record histology results in the Register. Of the seven SNOMED fields available, only two fields need to be recorded for cervical histology and these are the T-field (Topography) and the M-field (Morphology).
The M-field has codes which denote the adequacy of the specimen as received at the laboratories.

The advantages of using SNOMED in preference to the others are as follows:

- it provides a standard and consistent means of describing the histology results with ensuing advantages
- it is generally accepted by histopathologists as a standard for nomenclature in pathology in New Zealand
- it is either currently being used, or intended to be used by laboratories to record histology results
- the M-codes in ICD-O (as used by the Cancer Register) are identical to those in SNOMED
- both the Cancer Registry and the laboratories which have implemented SNOMED use the T-field and the M-field.

The disadvantages of using SNOMED are:

- it is but one of the many coding systems used in New Zealand
- the Read Codes claim to provide a more detailed nomenclature, and difficulties may arise during the mapping of SNOMED to the HMI Read Codes.

### 3.4 Diagnoses to be Classified

One of the basic principles to follow in order to encourage frequent and widespread use of a system is the KISS (Keep It Simple, Stupid) philosophy. The simplicity aspect extends to the range of codes to be used, and grouping (or classifying) several codes into one general code which is sufficiently specific to meet the objectives of the system.

It is noted that the role of the computerised Register excludes interference in the doctor-patient relationship, and tracking the volume and type of histological work performed at the laboratories. The laboratories may record a greater level of detail for internal research and analysis. The Register, however, need only record the results at a level and range which is sufficient to meet its objectives (refer section 2.1) and be able to correlate cytology with histology results.

The following diagnostic descriptions are proposed as the appropriate values for use when recording the histology results in the Register. Consultation and agreement will need to be obtained from the pathologists and epidemiologists as to:

- the clinical and epidemiological suitability of these descriptions
- the SNOMED codes to be used by the laboratories to denote the descriptions.

In addition, agreement will be needed to determine the biopsy sites covered by the Programme (cervical biopsies only or all gynaecological biopsies).

The proposed descriptions are:

- Negative result - normal tissue
- Benign Atypia
- Condyloma, HPV infection, Koilocytosis, Koilocytosis with atypia
- CIN I (mild squamous dysplasia)
- CIN II (moderate squamous dysplasia)
- CIN III (severe squamous dysplasia), Carcinoma in situ
- MicroInvasive Squamous Cell Carcinoma
- Invasive Squamous Cell Carcinoma
- Benign glandular atypia
- Glandular dysplasia
- Adenocarcinoma in situ
- Invasive Adenocarcinoma
- Other
- Surgical margins free of tumour.

3.5 Suggested SNOMED Codes

The following codes are suggested as being suitable for encoding biopsy specimens and diagnoses outlined in section 3.4. The codes (where given and whether singly or with alternatives) are based on codes currently in use. They serve as a focus for discussion. In the final agreement, only one code is to be assigned to one group of descriptions.

3.5.1 Adequacy of Specimen

The following codes are suggested as being suitable for encoding the adequacy of the tissue specimen, as received at the laboratory:

<table>
<thead>
<tr>
<th>Value</th>
<th>Suggested Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insufficient material for diagnosis and tissue unsatisfactory for diagnosis</td>
<td>M-09000</td>
</tr>
<tr>
<td>No tissue received</td>
<td>M-09100</td>
</tr>
<tr>
<td>Tissue lost in processing and tissue destroyed in processing</td>
<td>M-09150</td>
</tr>
<tr>
<td>Satisfactory tissue received and processed</td>
<td>M-??????</td>
</tr>
</tbody>
</table>

3.5.2 Site (Topography) of Specimen

The SNOMED codes to be used to record the biopsy sites will result from the consultations with all interested parties. The consultative process will include agreement on the extent of biopsies covered by the Programme (e.g., cervix area only), the level of detail required (e.g., recording endocervix, exocervix separately) or to include other gynaecological biopsies (e.g., hysterectomies).
3.5.3 Summary Diagnosis

Some laboratories use an E-code (E-3345) to indicate HPV infection.

Consultation and agreement will need to be obtained from the pathologists as to whether the E-code is acceptable, or whether an alternative M-code for Condyloma (M-76700) is more appropriate.

<table>
<thead>
<tr>
<th>Value</th>
<th>Suggested Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative result - normal tissue</td>
<td>M-00100</td>
</tr>
<tr>
<td>Benign Atypia</td>
<td>M-69700</td>
</tr>
<tr>
<td>Condyloma (NOS)</td>
<td>M-76700 or E-3345</td>
</tr>
<tr>
<td>HPV</td>
<td></td>
</tr>
<tr>
<td>Koilocytosis</td>
<td></td>
</tr>
<tr>
<td>Koilocytosis with atypia</td>
<td></td>
</tr>
<tr>
<td>CIN I (mild squamous dysplasia)</td>
<td>M-74006</td>
</tr>
<tr>
<td>CIN II (moderate squamous dysplasia)</td>
<td>M-74007</td>
</tr>
<tr>
<td>CIN III (severe squamous dysplasia)</td>
<td>M-74008 or M-80102</td>
</tr>
<tr>
<td>carcinoma in situ</td>
<td></td>
</tr>
<tr>
<td>MicroInvasive Squamous Cell Carcinoma</td>
<td>M-80765</td>
</tr>
<tr>
<td>Invasive Squamous Cell Carcinoma</td>
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</tr>
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<tr>
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<td>Adenocarcinoma in situ</td>
<td>M-81403</td>
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<tr>
<td>Invasive Adenocarcinoma</td>
<td>M-81406</td>
</tr>
<tr>
<td>Other (Morphologic Abnormality)</td>
<td>M-01000</td>
</tr>
<tr>
<td>Surgical margins free of tumour</td>
<td>M-09400</td>
</tr>
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</table>
4. Functional Requirements

4.1 Current Situation

A diagrammatic representation of the present National Cervical Screening Programme is shown in Figure 1.

The Programme is currently supported by sub-registers located at each of the fourteen AHBs throughout New Zealand. They are physically and electronically independent of each other, and altogether comprise the National Register.

The laboratories supply smear test results to the local Registry on floppy diskettes. The information on the diskettes is then loaded into the register by a computer program.

The administrative and other shortcomings of the present Register are already covered in other reports. The significant areas are being reviewed and resolved, and will not be discussed in this report except where they impact the addition of histology to the Register. The areas under review are:

- the effect of health reforms and winding up of AHBs on the hospital laboratories
- the effect of health reforms and the Crown Health Enterprises on the private sector laboratories
- the impact of the above on the Programme
- the provision of additional details by the laboratories to assist in the matching of smear test results to the women in the Register
- the introduction of a national cervical screening form
- the review of the link between the Register and the National Master Patient Index
- the provision of smear test result history information to the laboratories and smear takers where appropriate (it is assumed that, after histology is added to the Register, histology results will be provided wherever cytology results are currently provided)
- the options of reducing the number of registers from fourteen
- alternative methods of collecting data on the Register.

4.2 Proposed Changes to the Programme

Since histology results are to be added to the existing Register, the same considerations, rules, guidelines and constraints which are relevant to the present Register will continue to apply to the extended Register. These are:

- that the same principles of privacy and confidentiality for the present Programme is maintained
- that the wishes of women who have chosen to be excluded from the Register (and consequently from the benefits of the Programme) are respected and provided for
- that the same principles governing the protection of Maori data be maintained

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that the Register will not interfere in the treatment and clinical relationship between the woman and her clinician
- that the consultative process with pathologists and other interested parties is maintained
- that the current operational aspect of the Register system (such as the use of parameters, the menu system, security and audit procedures, backup and restore strategies, contingency and disaster issues, the use of the National Master Patient Index, and so on) remain unchanged
- that any currently proposed changes to the Programme consider and include the histology requirements.

A diagrammatic representation of changes to the National Programme to allow for the recording of histology results is shown in Figure 2.

Women with abnormal smear test results are referred to a specialist for colposcopy, at which time the cervix may be biopsied and the tissue specimen(s) forwarded to the laboratory for examination. If the woman was not previously enrolled in the Register and she chooses to be included in the Register, the specialist sends her enrolment details to the Register. The specimen(s) is processed and examined and the results sent to the referring specialist with a copy being sent to the woman's usual doctor if requested. A subset of the results is also sent to the local Registry for update into the Register.

The method of and medium for data transfer between the laboratories and the Registry is discussed in section 5.4 of this report.

4.3 Impact of Exclusion Options on Histology

Under current legislation, each individual woman gives signed consent for her results to be included into the Register and, therefore, the Programme (ie automatic exclusion unless otherwise advised).

Under the changes in the Health and Disability Services Bill, the woman's results will automatically be included into the Register unless she chooses to be excluded from the Register, and from the benefits of the Programme (ie automatic inclusion unless otherwise advised).

If a woman chooses to be excluded, she signs a self-carbonating Register Exclusion Form. The pink copy of the Exclusion Form is given to the woman as an acknowledgement of her choice and the green copy is held in the patient records. In addition, the referral forms accompanying the smear slide will be affixed with a brightly coloured sticker to indicate to the laboratory that the results of that test are not to be forwarded to the Register.

The Register will not contain any information about women who have chosen to be excluded from the Register. Note that where a woman who had previously chosen to be included in the Register later elects to be excluded, a procedure to remove her details from the Register must be established.

It is proposed that the same method be used to indicate to the laboratory not to send the woman's histology results to the Registry.

Note that the medical specialists will need to advise women referred to them for colposcopic treatment that the women's results will automatically be included in the Register, and of their option for exclusion.
4.4 Impact of Histology on the Proposed National Cervical Screening Form

One of the recommendations of the paper titled, "Operational Requirements for an Opt-Off Cervical Cytology Register" is the introduction of a national cervical screening form. The single self-carbonating form would record all the information required to be held in the Register, as well as being the referral form used by the laboratory. It would request details that are necessary to uniquely identify the woman and to enable efficient matching of the woman and her results.

Both the laboratory and the Register requirements for capturing histology information must be considered during the design of the new national cervical screening form.

4.5 Activating Women on the Register

Section 93 of the Health and Disability Services Bill redefines cervical smear tests to include both cytological and histological specimens taken to determine the presence of cancer or non-invasive, pre-cancerous lesion in the cervix.

The Bill also clearly states that unless a woman objects, the results of her cervical smear test must be forwarded for inclusion in the Register.

An enrolment form will be required to gather the relevant demographic details of women who choose to be included in the Register. The enrolment information is necessary to match the woman to the results and to collect her smear history.

There is, however, an assumption that an enrolment form is no longer required. The retention of the enrolment form under the exclusion scheme must be made known to the smear takers and to the gynaecological specialists and colposcopists (see section 4.5.2).

4.5.1 Women Previously Enrolled in the Register

If a woman was previously enrolled in the Programme, her demographic details are available for matching against the histology results received at the Registry. Processing of the results will follow as outlined in section 4.6 of this report.

4.5.2 Women Not Previously Enrolled in the Register

If a woman was not previously enrolled in the Programme, her demographic details are not available for matching against the histology results received at the Registry.

Such a situation may occur during the transition stage between consent for inclusion to automatic inclusion in the Register where a laboratory may receive a histological request for a woman who is currently under treatment, and who was not previously enrolled. If the laboratory request was not affixed with a sticker indicating that she had opted out of the Programme, her histology results would be forwarded to the Registry.

The woman’s enrolment details are required to enable the matching of the woman to the results. The gynaecological specialist and colposcopists will therefore need to be advised of the requirement to enrol the women.

Processing of the results will then follow as outlined in section 4.6 of this report.
4.6 Processing of Histology Results

As previously outlined in section 2.2, a colposcopy may not necessarily be accompanied by a biopsy for histological examination.

4.6.1 Colposcopy Accompanied by a Biopsy

In instances where a colposcopic examination is accompanied by a tissue biopsy, the specimen is sent to the laboratory for examination. The laboratory is therefore able to report the histological results to the Register and follow-up of the abnormal smear test result is achieved.

Upon receipt of a histology result at the Register, a laboratory interface program for histology will:

- match the result with an individual woman (as the interface program for cytology currently does)
- create the records in the HISTOLOGY and HISTOLOGY DIAGNOSIS entities (new computer program).

The operational procedures and the computer programs required to process a mismatch between an incoming result and the eligible women remain the same as those for the current processing for cytology.

If the woman had a previous abnormal smear test result which recommended a referral to colposcopy, the relevant data is updated to indicate that follow-up referral was completed, together with the steps required to sign the woman back into the routine smear testing programme at an appropriate time.

If the woman did not have a previous abnormal smear test result, follow-up referral was not previously indicated, and no updates are required. The woman's recall dates and an indication of further follow-up referrals, however, need be reviewed with the specialist to take into consideration the histology results.

4.6.2 Colposcopy Not Accompanied by a Biopsy

There may be instances where a colposcopic examination was not accompanied by a tissue biopsy for whatever reason. While such instances may be unlikely, the system must be able to handle the situation. In this case, the recommended clinical requirement for colposcopic referral was completed. However, as there is no specimen to examine there is no result to send to the Register.

If the woman had a previous abnormal smear test result, the Register is expecting a histology result which was not received. The ABNORMAL FOLLOW-UP REFERRAL entity will need to be updated to indicate that colposcopic referral was completed even though a histology result was not received. The operational procedures required to effect the update will need to be resolved between the medical practitioner, the specialist, and Registry management. The report advising Registry management that follow-up treatment was expected but not yet actioned is still required.

If the woman did not have a previous abnormal smear test result, the Register is not expecting histology results and there is no impact on the Register.

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4.6.3 Biopsy without a Previous Abnormal Smear Test Result

Occasionally a woman may have a normal smear test result, yet be referred to colposcopy because of an abnormal clinical appearance of her cervix. In this case, the woman's results would be recorded in the Register if the colposcopy was accompanied by a biopsy (see section 4.6.1).

There is no impact on the Register if the colposcopy was not accompanied by a biopsy in this case.

4.6.4 Biopsy of Unenrolled Women

During the transition stage from automatic exclusion to automatic inclusion, a laboratory may receive a request for histological examination for a woman not previously known to the Register. Unless a coloured exclusion sticker was affixed to the histology request, the woman's results will be sent to the Registry.

If the woman was previously enrolled in the Register, there will be sufficient details in the histology results to match and link the results to her.

If the woman was not previously enrolled in the system, the results cannot be linked to any woman.

Mismatches of this nature will be dealt with in a similar way as the present cytology laboratory interface, where Registry management confirms:

- whether the woman had chosen to be excluded from the Register and her results were inadvertently sent to the Registry
- whether the woman had chosen to be included in the Register and her enrolment details were yet to be received.

Registry management will then take appropriate action depending on the situation.

4.7 Follow-up of Women Under Treatment

To minimise the impact of adding histology to the Register on the present system, no changes to the current procedures for processing an abnormal smear test result are envisaged. The system will continue to automatically generate the ABNORMAL FOLLOW-UP REFERRAL record and to "sign-out" the woman into a heightened surveillance and treatment programme.

The receipt of a histology result following the abnormal smear test result will indicate that follow-up has occurred (unless an ABNORMAL FOLLOW-UP REFERRAL record does not exist - see section 4.6.3).

The system, however, cannot assume that treatment is complete and must not automatically sign the woman back into the routine monitoring and recall programme. Signing the woman back on the Register will cause the system to generate recall letters to her, and would be inappropriate if she was still undergoing treatment.

Sign-in should only occur upon receipt of written notification from the specialist that treatment is complete and that the woman is back in the routine smear testing programme.
4.8 Interface with Diagnostic Laboratories

The laboratories are the source of information regarding histology (see section 4.2 of this report). Laboratories will need to provide information on histology to the Register on a regular basis. This can be achieved by using an agreed specification to define the structure and format of the required data and then mapping this onto the computerised register. Specific details of this interface are discussed in section 5.4 of this report.

4.9 Interface with Health Management Information (HMI)

The requirements for interface with Health Management Information (HMI) system is already covered by the present Programme (refer to the original report titled "Proposal for a Nationally Co-ordinated New Zealand Cervical Screening Programme" by Tom Seaman and Ad van der Tol, Azimuth). Adding histology results to the Register is not expected to change the mappings of the Register information to the HMI entities.

4.10 Interface with Cancer Registry

There is no integration with the Cancer Register at this time.

A likely use of an interface between the two Registers is the monitoring of the performance of the National Cervical Screening Programme by reviewing the incidence of, and mortality from, cervical cancer before and after the implementation of the Programme.
5. Conceptual Data Model

5.1 Design Principles

Any proposed changes to the Register must acknowledge the Programme principles, the laboratory procedures and the current computerised register. For these reasons the design principles for adding histology to the Register are to:

1. Provide information to ensure that follow-up treatment of abnormal smear test results did occur.
2. Provide the ability to compare and correlate cytology to histology results.
3. Provide epidemiological information to monitor the Programme.
4. Collect the minimum amount of data necessary to support the Programme and the Register.

It should be noted that the role of the Programme does not include:

- interference with the clinical relationship between the woman and the clinician managing her case
- management of laboratory tests and workflow.

5.2 Proposed Changes to the Data Model

A diagrammatic representation of the information relationships of the present National Cervical Screening Programme is shown in Figure 3.

Details of the existing entities, relationships and data dictionary are available from the DOH.

The proposed changes to the existing data model are shown in Figure 4.

The additional objects of interest (entities) identified as being required to add histology results to the Register are:

- LABORATORY RESULT entity
- HISTOLOGY entity
- HISTOLOGY DIAGNOSIS entity
- SNOMED CODE entity
- BIOPSY TECHNIQUE entity.

The LABORATORY RESULT entity is a new entity which represents a result from the laboratory, and which can be either a histology result or a smear test result. It is sequenced in date order so that several smear test results may precede and follow one or more histology results.

For example, a woman may have several normal smear test results, a high grade abnormal smear test result, be referred to colposcopy and biopsy, have one or more histology results and, upon completion of treatment, be placed back into an annual smear testing routine for the rest of her
life. In another example, a woman may have several normal smear test results with no histology results whatsoever. In a third example, a woman's laboratory results may start with a histology result with no preceding smear test results, such as during the transition stage to automatic inclusion where the woman who is currently under treatment was not previously enrolled.

The HISTOLOGY entity is linked to an individual woman in the ELIGIBLE WOMAN entity through the unique identification code in the same way the SMEAR entity is linked to the woman. The HISTOLOGY DIAGNOSIS is linked to the HISTOLOGY entity to indicate the diagnostic results (in the form of SNOMED codes) from a particular histological examination.

The SNOMED CODE entity is a lookup table containing the agreed values and descriptions of the histology diagnoses, and is used to translate the SNOMED code into narrative description of the diagnosis.

The BIOPSY TECHNIQUE entity is a lookup table containing the agreed codes and descriptions of the different techniques of performing biopsies. The BIOPSY TECHNIQUE may be implemented as the P-field (Procedure) of the SNOMED codes instead of developing a new set of codes.

The items of interest within the entities were identified as:
- the LABORATORY RESULT entity to be sequenced by date in order that the system can confirm that a histology result followed an abnormal smear test result
- the identification of the woman to link the current histology result with previous results (both cytology and histology)
- the biopsy technique
- the adequacy of the tissue specimen received at the laboratory
- the recording of only the summary diagnoses of the woman's biopsies, regardless of the number of specimens that may be sent to the laboratory for examination at the one time
- the summary diagnoses to be recorded must include the highest grade abnormality resulting from a single histology request.

The proposed data has been defined as the minimum required to manage the histology aspect of the Register. There has been no effort made to determine if any additional data items are needed to support detailed epidemiological analysis. If additional data of this nature is required then it must be determined what is to be collected, why it is necessary, how it will be used, who has access, and how it can be collected.

5.3 Accuracy and Completeness

The data dictionary defines integrity rules for the entities, relationships, and attributes. These integrity rules are incorporated into the computerised register and are used to validate the accuracy of data presented for input. It is important to define as many of these integrity rules as possible to provide the highest level of data validation.

Use of integrity rules and coded attributes will not prevent system users from supplying incorrect medical information. This incorrect information can be divided into two types:
- using the wrong code for an attribute when another value was intended
- incorrect medical interpretation.
The first type of error can be reduced by a process of education, practice through usage, and good feedback. The second error type is a matter of medical practice and cannot be controlled by the proposed system. If the data passes the defined integrity rules then it is valid. The proposed system will not replace a medical expert and will not provide for medical integrity. Audit functions should be incorporated in the system to identify incomplete data.

5.4 Laboratory to Registry Mapping

Currently, laboratories provide cytology information to the Register on a regular basis in electronic form via floppy diskettes.

Although the frequency and medium for the provision of histology information should ideally be optimised for both volume (for cost effectiveness) and relevance (the monitoring role of the Programme is downgraded if information is received late), a practical solution is for the histology information to be provided at the same time as cytology information as a separate data file and on the same media.

The issues of costs and timing constraints are briefly discussed in sections 7.1.6 and 7.1.7 under Implementation Issues.

5.5 Data Volumes

The assessment of estimated data volumes for histology is directly related to the expected number of abnormal smear test results which are referred to colposcopy.

The number of eligible women and the expected number of cervical smears are dependent on the screening frequency defined by the recommended Programme protocol tests. These volumes have been reviewed as one of the steps of implementing the automatic inclusion option. For the financial year ending June 1996, it is expected that over 83% of all eligible women will be enrolled in the Register with an estimated annual total of between 428,000 to 450,000 smear tests recorded.

The ratio of the number of abnormal smear test results referred to colposcopy to the total number of smears under the current automatic exclusion option was obtained. This ratio (2.94%) and the estimated total smear tests after the implementation of the automatic inclusion option were used to extrapolate the estimated number of histology examinations.

Using this approach of estimation and assuming 450,000 smear tests and that each abnormal follow-up referral will result in one histology examination, the total number of histology examinations is 13,223 per year.

On a national basis, there is an estimated increase of 1,243 KB (thousand characters) per annum. Individual boards vary in size, from less than 16 KB to nearly 236 KB for the addition of histology alone. Note that these estimates assume that separate estimations are being carried out for the increase in enrolments and in smear test results for automatic inclusion.
6. Reporting Requirements

6.1 Standard Management and Operational Reports

At this stage, it is possible to identify a number of standard reports that would be required at an operational level. The reports are provided to the Registry management, and may already exist for cytology. Some of the existing cytology reports, especially the ones which provide a history of an individual woman's smear test results, may be modified to include the histology results and be renamed accordingly.

This list should not be considered as complete. Before implementation, Registry management and other interested parties should be asked to contribute towards:

- the relevance and suitability of the proposed reports
- any additional new reports
- identifying additional data to be included in existing reports, or new reports.

Taking into consideration the expected increase in data volumes, the reports identify exceptions which require follow-up action by the Registry management. The proposed histology reports include:

- individual woman's cervical history (cytology and histology results)
- missed follow-up of abnormal smear test results (existing report)
- delayed "sign-ins" (existing report)
- quality of tissue specimens received
- histology turnaround times
- quality of processing at the laboratories
- processing volumes at the laboratories.

6.2 Standard Letters

The Register will not generate any new standard letters to the women.

Under the current system, the Register generates standard letters to advise women of their smear test results. Women with high-grade abnormal smear test results who are undergoing treatment do not receive letters from the Register. The system, however, continues to generate reports of missed follow-up of abnormal smear test results and Registry management follow-up the progress of clinical treatment with the woman's smear taker.

The addition of histology to the Register is not expected to change the procedures involved in this area. While the woman is undergoing treatment, any correspondence she may have regarding the treatment is between her and her clinician. The Register must not interfere with the treatment and clinical relationship.
6.3  Feedback Reports

Feedback reports are the reports that the Register sends to the laboratories and medical specialists to provide them with feedback about the results they have provided.

6.3.1  Diagnostic Assistance

There is currently no facility to relay information about a woman's smear history to a laboratory except in the form of the pre-printed laboratory referral. It is agreed, however, that the quality of diagnosis can generally be improved in cases where some or all of the cervical screening history is available.

One of the recommendations of the Programme is that the Register should provide smear history to the laboratories and smear takers where appropriate. When this recommendation is implemented, the history should include the histology results.

With the addition of histology to the Register, the pre-printed laboratory referral must be extended to include histology results.

The laboratories may also request specific results where necessary and if appropriate.

6.3.2  Correlation of Results

One of the functions of the Register is to provide feedback to laboratories about their results and to correlate cytology and histology results for quality assurance.

The absence of histology in the present system means that the correlation of results cannot be achieved. The presence of histology results on the Register will enable such correlation and the range of histology diagnoses (see section 3.4) has been chosen to facilitate its correlation to cytology diagnoses (eg CIN I in histology to CIN I in cytology, and so on).

The Register must, therefore, provide a correlation report for each participating laboratory's cytology results, though not on an individual woman basis.

For the report to be relevant such that discordant results are identified for quality assurance, the algorithms and criteria required to correlate the results must be derived in consultation with the pathologists. The algorithms and criteria should then be documented and distributed to nominated pathologists for comment before extended distribution to all public and private laboratories for broader comment and later implementation.

6.3.3  Other Feedback Reports

It is not possible to identify all of the feedback reports that may be required by laboratories, smear takers or specialists. Other feedback reports should be developed after histology results have been added to the Register, and upon consultation and agreement with the pathologists and Registry management.
6.4 Epidemiological Results

Consultation with the pathologists and epidemiologists regarding the clinical and epidemiological suitability of the diagnoses together with the information held within the Cancer Register should provide sufficient information required for epidemiological purposes.

The epidemiological reports that are required by the Public Health Commission, and other epidemiologists for specific purposes should be developed on consultation with them and are not included in this report.
7. Implementation Plan

7.1 Implementation Issues

The following summarises the main issues outlined in the report.

7.1.1 Legislative Issues

The Health and Disability Services Bill redefines cervical smear tests to include both cytological and histological specimens taken to determine the presence of cancer or non-invasive precancerous lesion in the cervix. The Bill also states that, unless the woman objects, a report of the test must be forwarded for inclusion in the Register.

The laboratories, medical specialists, gynaecologists, colposcopists, and other related organisations must be advised of their obligations under the Bill.

7.1.2 Privacy and Confidentiality

The same principles of privacy and confidentiality for the present Programme must be maintained such that women who participate in the Programme are informed as to who has access to their personal and confidential doctor-patient information.

The system must ensure that the wishes of women who have opted out of the Register and the Programme under the new exclusion option are respected and implemented.

7.1.3 Participation by Laboratories

It is recognised that the laboratories provide the results to the Registry, and that the Programme is reliant on the correctness of the information provided.

It is essential that the consultative process with pathologists and all interested parties is maintained and that the pathologists agree to:

- the use of SNOMED codes as the coding system for recording diagnoses
- the range of diagnostic values to be coded into SNOMED for use in the Register
- the biopsy sites which are to be forwarded for inclusion in the Register
- the transfer of the histology results in the form of floppy diskettes and on a regular basis as per the present cytology results but as a separate data file
- the algorithms to be used in the reports to correlate histology results against the cytology results
- confirmation of the feedback reports that are useful to the laboratories.

The hospitals have separate specialist departments for histology and cytology work, while the pathologists at private laboratories manage both cytology and histology analysis. When histology results are kept on the Register, the programme managers will need to maintain contact with both the histology and the cytology pathologists of the hospitals.
7.1.4 Participation by Medical Specialists

With the addition of histology to the Register, the range of health care providers touched by the Programme is increased to include gynaecological specialists and colposcopists. It is essential that they are also included in the consultative process and be advised of what is required of them and their responsibilities, such as the enrolment of women who choose to be included in the Register, and to indicate to the laboratories which specimens belong to women who have chosen to be excluded.

7.1.5 Consultation with Registry Management and Women’s Groups

Although the Registry management and women’s groups were not, at this early stage, interviewed for their input to the histology aspect of the Register, it is essential that they be consulted as to the impact the changes on, and of the type of reports that are useful to, them.

7.1.6 Costs/Funding for Work

The doubt and uncertainty of the future of both the hospital and private laboratories from the effect of health reforms cannot be overstated, and was raised by all persons interviewed. The additional costs required to supply the information (in terms of changes to the laboratory systems) with minimum perceived benefits together and the competition for a shrinking pool of funds, will impact the speed at which histology is added to the Register.

The issue of costs and benefits (and the funds and resources) associated with adding histology to the Register is outside the scope of this project but is one that needs to be resolved.

7.1.7 Timing Constraints

The Health and Disability Services Bill is expected to come into effect on 1 July 1993, at which time laboratories are required to comply with the legislative changes and forward cervical smear results to the Register.

While the long term and ideal method is to supply the histology results at the same time and on the same media as the cytology results, there may be insufficient time to design, develop, test, and successfully implement the necessary computer programs and interfaces before 1 July 1993. An alternative interim method which allows the laboratories to comply with legislative requirements while the long term permanent method is being developed may be required.

The issue of alternative interim methods of forwarding histology results to the Register is outside the scope of this project but is one that needs to be resolved during the consultative process.

7.1.8 Proposed Changes to Present System

The current operational aspect of the Register system (such as the use of parameters, the menu system, security and audit procedures, backup and restore strategies, contingency and disaster issues, the use of the National Master Patient Index, and so on) should remain the same.
All changes to the present system must take into consideration the histology requirements and issues. Some of the known changes are listed below:

- changes to any forms (eg the new national cervical form, the new exclusion form, 'change-of-status' forms, etc)
- changes to any consolidated reports (eg pre-printed referral forms to include histology results, turnaround reports, etc)
- changes to procedures (eg revised sign-in procedures which now involves the specialists instead of the medical practitioner)
- the review of the National Master Patient Index as an identifier for matching results to woman.

7.2 Implementation Plan

The next steps for progressing the addition of histology results to the Register are:

1. Appoint a project manager to oversee and manage the implementation of histology on the Register.

   The project manager will report to the national co-ordinator, and be responsible for the next stages of implementing histology onto the Register.

2. Communicate to the laboratories, medical specialists, colposcopists, and other related organisations of their obligations under the Health and Disability Services Bill.

3. Extend CALC's (Cytology Advisory Liaison Committee) role with regard to histology on the Register, and seek confirmation and agreement from the committee regarding the requirements outlined in this report, especially where it relates to the data model, data transfer, coding system, processing and reporting requirements.

4. Prepare a technical specification of the expected changes to the present system, and the impact of those changes.

5. Prepare, agree and seek approval for the financial resources for the modification and redevelopment of the Register for histology, and for any associated consequences (such as upgrade costs which result from either hardware or software requirements at the registries and the laboratories).

6. Modify the present Register to provide for the agreed requirements, with associated relevant documentation and full system testing.

   Note that, in keeping with standard practice, the modifications are to be made to a copy of the present system to ensure that the existing operations are not impacted.

   Note too, that the modifications to the computerised register may be undertaken and completed in stages, eg the correlation and epidemiological reports may be deferred till there is sufficient data in the system for meaningful results to be generated.

7. Test the modified computerised register at one or two pilot sites to refine the system, making changes where necessary.

8. Acceptance of the new Register at the pilot sites.
9. Publicise the benefits of adding histology to the Register to the laboratories, medical specialists, colposcopists and other related organisations, and the role (and actions) expected from each of these organisations and how they interact with each other and with the Programme.

10. Phased implementation (including acceptance) of the new Register across the remaining sites.

11. Conduct a post implementation review.
APPENDIX A

LIST OF CONTRIBUTORS
Appendix A - List of Contributors

Names of the list of contributors are shown in alphabetic order by geographic zones from north to south.

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HISTOLOGY REQUIREMENTS FOR NCSR

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APPENDIX B
GLOSSARY OF TERMS
**Appendix B - Glossary of Terms**

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenoma</td>
<td>A benign epithelial tumour with a gland-like structure.</td>
</tr>
<tr>
<td>Atypia</td>
<td>Irregular, not conforming to type.</td>
</tr>
<tr>
<td>Benign Tumour</td>
<td>A tumour which usually remains a uniform shape, enclosed in a sack of fibres. It does not spread to other parts of the body.</td>
</tr>
<tr>
<td>Bethesda Coding</td>
<td>A way of reporting cervical smear results, in the form of up to three codes, which give comment on the adequacy of the smear taken, the smear result category, additional diagnostic information, and a recommendation for follow-up treatment.</td>
</tr>
<tr>
<td>Biopsy</td>
<td>Removal of pieces of tissue from the body for examination under a microscope, to assist in the diagnosis of a disease.</td>
</tr>
<tr>
<td>Cancer</td>
<td>A general term for a large number of diseases which all display uncontrolled growth and spread of abnormal cells. Also called a malignant tumour.</td>
</tr>
<tr>
<td>Carcinogen</td>
<td>Any agent that can cause cancer.</td>
</tr>
<tr>
<td>Carcinoma</td>
<td>A cancer made up of epithelial cells.</td>
</tr>
<tr>
<td>Carcinoma In Situ</td>
<td>CIS - A high grade abnormal growth of cells confined to the tissue layer which it is covering. Without treatment it is likely to develop into invasive cancer.</td>
</tr>
<tr>
<td>Cervical Intra-Epithelial-Neoplasia CIN</td>
<td>Abnormal, often pre-cancerous tissue on the cervix.</td>
</tr>
<tr>
<td>CIN-1</td>
<td>Low grade (or mildly) abnormal cell growth.</td>
</tr>
<tr>
<td>CIN-2 &amp; CIN-3</td>
<td>High grade (or markedly) abnormal cell growth.</td>
</tr>
<tr>
<td>Cervical Smear</td>
<td>Taking of cells from the cervix for examination under a microscope to identify the presence of any abnormal cells. Used to be known as Pap smear.</td>
</tr>
<tr>
<td>Cervix</td>
<td>The neck or lower part of the uterus which protrudes into the vagina.</td>
</tr>
<tr>
<td>Colposcope</td>
<td>An instrument like a microscope which allows the cervix and vagina to be examined closely.</td>
</tr>
<tr>
<td>Colposcopy</td>
<td>Looking at the cervix through a colposcope. It enables the doctor to see abnormalities of the cervix and vagina which cannot be seen by the naked eye.</td>
</tr>
<tr>
<td>Colposcopic Biopsy</td>
<td>A biopsy taken during colposcopy. Frequently (but not necessarily) a punch biopsy.</td>
</tr>
<tr>
<td>Cone Biopsy</td>
<td>Surgical removal of a cone-shaped section of the cervix, under a general anaesthetic.</td>
</tr>
<tr>
<td>Cryosurgery</td>
<td>Treatment to destroy abnormal cells on the cervix by freezing. It can be carried out at an out-patients' clinic. Also called cryocauterity.</td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
</tr>
<tr>
<td>----------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cytology</td>
<td>The study of cells. The cells (after staining) are examined under a microscope for signs of abnormality.</td>
</tr>
<tr>
<td>Diathermy</td>
<td>A means of destroying abnormal cells by heat treatment.</td>
</tr>
<tr>
<td>Dysplasia</td>
<td>Abnormal cells which are not cancer but may progress to cancer if not treated. Can be mild, moderate or severe. Now more often referred to as CIN, or low/high grade intraepithelial lesion.</td>
</tr>
<tr>
<td>Epithelium</td>
<td>Cells which make up the lining of the internal and external surfaces of the body, i.e., the skin, the linings of the stomach, the lining of the cervix.</td>
</tr>
<tr>
<td>Histology</td>
<td>The study of tissue. The tissue after thin sectioning and staining, is examined under a microscope.</td>
</tr>
<tr>
<td>Human Papilloma Virus (HPV)</td>
<td>A group of wart viruses, some of which are sexually transmitted. Research findings link certain types of HPV to the development of cervical cancer.</td>
</tr>
<tr>
<td>Hyperplasia</td>
<td>Abnormal multiplication or increase in number of normal cells in normal arrangement in a tissue.</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>The surgical removal of the uterus.</td>
</tr>
<tr>
<td>IARC</td>
<td>International Agency for Research of Cancer.</td>
</tr>
<tr>
<td>ICD-O</td>
<td>International Classification of Diseases for Oncology. A system of classifying diseases developed by working parties and committees brought together by the World Health Organisation and the IARC.</td>
</tr>
<tr>
<td>Lesion</td>
<td>An area of altered tissue due to disease or injury.</td>
</tr>
<tr>
<td>Malignant Tumour</td>
<td>A cancer (see above).</td>
</tr>
<tr>
<td>Metaplasia</td>
<td>The change in the type of mature cells in a tissue to a form which is not normal for that time or site.</td>
</tr>
<tr>
<td>Metastases</td>
<td>Deposits of malignant cells which have spread (often by lymph or blood vessels) from a cancer somewhere else in the body.</td>
</tr>
<tr>
<td>Neoplasm</td>
<td>A mass of new tissue which persists and grows independently of its surrounding structures and which has no physiologic use.</td>
</tr>
<tr>
<td>NOS</td>
<td>Not otherwise specified.</td>
</tr>
<tr>
<td>Os</td>
<td>The opening of the cervical canal into the vagina, the central hole of the cervix.</td>
</tr>
<tr>
<td>SNOMED</td>
<td>Systematized Nomenclature of Medicine.</td>
</tr>
<tr>
<td>SNOP</td>
<td>Systematized Nomenclature of Pathology, Chicago, Ill, College of American Pathologists (1965).</td>
</tr>
<tr>
<td>Speculum</td>
<td>A metal or plastic instrument used to gently open the vagina so that the cervix can be seen.</td>
</tr>
</tbody>
</table>
APPENDIX C

LIST OF PERSONS/ORGANISATIONS ADVISED OF PROJECT
1. Suppliers of laboratory systems:

Magix Computer Systems Ltd
Magix House
189 Willis St
WELLINGTON

Delphic Medical Systems
PO Box 56080
Mt Eden
AUCKLAND

Neville Davis
Medlab Grafton
PO Box 4120
AUCKLAND

Andrew Dunshea
ICS Auckland
PO Box 9460
AUCKLAND

2. Laboratories - list on other pages

3. Obstetrics and Gynaecologists Society

Dr M A H Baird
Honorary Secretary
Royal New Zealand College of Obstetricians and Gynaecologists
PO Box 7148
WELLINGTON STH

4. Special interest groups

Alison Roxburgh
The President
National Council of Women
PO Box 12-117
WELLINGTON

Aroha Pariti-Crofts
The President
Maori Women's Welfare League
Box 12-072
WELLINGTON
Judi Strid
Convenor
Federation of Women's Health Councils
PO Box 853
AUCKLAND

Lynda Williams
Fertility Action
PO Box 4569
AUCKLAND

5. health profession

NZ Nurses Society
PO Box 3195
AUCKLAND

Gay Williams
NZ Nurses Association
PO Box 2128
WELLINGTON

The Secretary
NZ General Practitioners Assoc.
PO Box 156
WELLINGTON

The Secretary
Royal New Zealand College of
General Practitioners
23 Palmer St
WELLINGTON

The General Practitioners Society
PO Box 44080
LOWER HUTT

6. general managers of 14 area health boards

7. 4 regional health authorities

8. others

Gillian Durham
Public Health Commission
PO Box 1795
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Judith Johnson
Group Manager
NZ Health Information Service
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- AUCKLAND, Dr Hitchcock
Dr A R Bierre
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- AUCKLAND, Dr Bierre
Dr E J Chapman
Hamilton Medical Laboratory
P O Box 52
- HAMILTON, Dr Chapman
Dr D Bruton
Waikato Pathology Laboratory
P O Box 20166
- HAMILTON, Dr Bruton
Dr I M M Taylor
Tauranga Medlab
P O Box 130
- TAURANGA, Dr Taylor
Dr R W Ensor
Rotorua Medical Laboratory
P O Box 481
- ROTORUA, Dr Ensor
Dr A E White
Diagnostic Laboratory
P O Box 708
- NEW PLYMOUTH, Dr White
Dr M Bottrill
Gisborne Laboratories
P O Box 174
- GISBORNE, Dr Bottrill
Dr P D Pedlow
Royston Laboratory
Knight Street
- HASTINGS, Dr Pedlow
Dr Sh Chan
Wanganui Diagnostic Laboratory
Suite 5
Wicksteed Terrace
Victoria Avenue
- WANGANUI, Dr Chan
Dr C R E Temple-Camp
Medical Diagnostic Laboratory Services
P O Box 293
- PALMERSTON NORTH, Dr Temple-Camp
Dr K P Wood
Valley Diagnostics Laboratories
P O Box 30-044
LOWER HUTT, Dr Wood
Dr C A Teague
Medical Laboratory
CMC Building
89 Courtenay Place
WELLINGTON, Dr Teague
Dr M S S Clark and Dr C W Cameron
Nelson Diagnostic Laboratory
1 Harley Street
NELSON, Dr Clark and Dr Cameron
Dr J W Hamer
Medlab South Limited
P O Box 25-091
CHRISTCHURCH, Dr Hamer
Dr R Cummings
Cardinal Community Laboratories Ltd
P O Box 202
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INVERCARGILL, Dr Anderson
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Histology requirements for national cervical screening

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