# Ministry of Health:
# Progress in Implementing the Recommendations of the Cervical Screening Inquiry

# Foreword

Cervical screening is an internationally recognised means of reducing the incidence of invasive cervical cancer. The reduction in both the incidence of cervical cancer and death rates from cervical cancer in New Zealand over the last 15 years demonstrates the importance of regular cervical screening.

The Ministerial Inquiry into the under-reporting of cervical smear abnormalities in the Gisborne Region raised some serious concerns about whether the National Cervical Screening Programme is as effective as it could be. The Committee of Inquiry's report, released in April 2001, made recommendations for future action to improve the Programme.

We examined the progress made and the work remaining to be done to implement the Committee of Inquiry's recommendations. We conducted our examination at the same time as a review by an independent expert, Dr Euphemia McGoogan, whom the Minister of Health engaged to provide independent advice on the progress being made in implementing the Committee of Inquiry's recommendations.

The two independently produced reports draw broadly similar conclusions, and together provide strong assurance to the Minister, Parliament and the public about the progress made so far and the work remaining to be done.

We conclude that good progress is being made in a number of important areas, but effective monitoring, audit, and evaluation of the Programme require action.

We intend to keep the progress in implementing the Committee of Inquiry's recommendations under review.

D J D Macdonald
14 February 2002

# Contents

# Summary

## Introduction

The most common type of cervical cancer – squamous cell carcinoma – is largely preventable if changes in the cervical cells are detected at the pre-cancerous stage. Cervical screening, through regular cervical smear tests, can detect changes in cervical cells and identify women who have pre-cancerous lesions. The success rate for adequate treatment at this stage is nearly 100%.

Women's confidence in New Zealand's National Cervical Screening Programme (the Programme) was severely undermined by the weaknesses that were brought out in the Committee of Inquiry on under-reporting of cervical smear abnormalities in the Gisborne region.[1] When the Committee of Inquiry's report was released in April 2001, the Government announced its commitment to implementing the report's recommendations.

There is no doubt that cervical screening in New Zealand saves some women's lives. Continuing concerns relate to *how* effective the screening programme is and *whether it is as effective as it could be*. It is important in addressing these concerns that the simple message to women about the importance of having regular cervical screening tests remains clear.

## Our Review

For the reasons explained in Part 1 on pages 13-14, we examined the progress being made to address the serious concerns that the Committee of Inquiry raised in relation to the Programme. We are publishing our report at the same time that the Minister of Health is publishing the report of an expert whom she engaged to provide her with independent advice on progress being made in implementing the Committee of Inquiry's recommendations. The independent expert's report[2] is available at www.csi.org.nz.

Though independently produced, the two reports – ours (from a lay perspective) and the report of the expert – draw broadly similar conclusions. We believe that this congruence provides particularly strong assurance to the Minister, Parliament and the public about the progress made so far and the work remaining to be done. We also consider that it places a particular onus on the Ministry of Health to address the issues raised in both reports and to act upon their recommendations.

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1 Report on the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region – AP Duffy QC, DK Barrett CNZM, MA Duggan MD FRCPC, April 2001, ISBN 0-478-24354-5 (book), ISBN 0-478-24355-3 (Web – at www.csi.org.nz).

2 Progress in Implementing the Cervical Screening Inquiry Recommendations – independent report by Dr Euphemia McGoogan, Consultant Cytopathologist and Associate Medical Director, Lothian University Hospitals NHS Trust, Edinburgh, Scotland.

# Overall Conclusions

Good progress is being made on establishing a structure – including systems and procedures – to make the necessary changes to implement the recommendations of the Committee of Inquiry. And there is effective reporting of progress on how successfully the recommendations are being implemented.

Good progress is also being made in respect of the recommendations relating to implementing standards for laboratories and the Programme.

In respect of the other specific recommendations of the Committee of Inquiry, we found a mixture of good, fair and slow progress. For example, changes relating to effective monitoring, evaluation, and audit[3] of the Programme are continuing to prove the most intractable; some of the changes required are not straightforward to achieve.

The first of the Committee of Inquiry's 46 recommendations is that the remaining two of the three phases of a national evaluation[4] should proceed. The Committee of Inquiry considered that, without this evaluation, it could not exclude the possibility that there is a systemic problem of under-reporting of cervical smear abnormalities in laboratories. And, accordingly, the safety of all women participants in the Programme is potentially at risk.

We were concerned to find that satisfactory completion of the evaluation is being delayed because of unresolved issues on access to personal health information. We explore these issues in our findings in Part 5 on pages 39-46.

The Committee of Inquiry's recommendations were prefaced by the following important commentary on page 255 of its report:

> *Counsel assisting the Committee submitted in respect of Term of Reference Eight[5] that it is a sad fact that practically all of the most obvious recommendations that might be suggested have either already been made or have been generally recognised for years as being important features of cervical screening programmes. The Committee fully agrees with this submission. Many of the recommendations the Committee makes in this report have been made*

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3 The terms monitoring, evaluation and audit are not easy to differentiate, and the three techniques tend to overlap. Generally however:

- *Monitoring* involves continuous and/or periodic review of an activity, often involving comparison of performance data against targets to identify trends.
- *Evaluation* assesses the effectiveness of an activity measured between one period and another by establishing data at the start point and re-collecting the data at some future point – evaluations are often done over a period of years.
- *Audit* is similar to evaluation but is retrospective and generally makes use of available data to arrive at the best available assessment within the constraints of that data. It usually involves going back to source records or other evidence to establish what actually happened and/or to determine whether the correct process was followed.

4 The national evaluation involves establishing the data required for monitoring and audit; examining the follow-up treatment of women with abnormal smears; and undertaking an audit of invasive cervical cancer (details of the evaluation are provided in Appendix 3 on pages 71-72).

5 This is the term of reference requiring the Committee of Inquiry to make recommendations as to any future action the Government or its agencies should consider taking.

> *before. Many of the improvements which have recently been made to the Programme in response to the Gisborne incident .... were also recommended from the early stages of the Programme.*

Obvious recommendations should not have to be repeated because they have not been implemented. In the course of our review we saw evidence of much determination – particularly among the Ministry staff responsible for the Programme – that this sad history will not be repeated again, and that recommended changes to the Programme will be made.

We intend to keep progress in implementing the Committee of Inquiry's recommendations under review.

## Part One

# Background to Our Review

## What Was the Purpose of Our Review?

1.1 In April 2001 a Committee of Inquiry reported to the Minister of Health on the under-reporting of cervical smear abnormalities[6] in the Gisborne region. The issues were widely reported in the media, and attracted considerable public interest. When the report was published, the Government announced its commitment to implementing the Committee of Inquiry's recommendations.

1.2 Our role is to provide assurance to Parliament and the public that government organisations are operating, and accounting for their performance, in accordance with Parliament's intentions. Under the Public Audit Act 2001, the Auditor-General may examine any matter concerning a public entity's use of its resources. The Ministry of Health (the Ministry) is a public entity.

1.3 The National Cervical Screening Programme (the Programme) consumes significant public resources – $29.5 million is budgeted for the Programme for the year ending 30 June 2002, which includes the costs of laboratory testing, health promotion and co-ordination of the Programme. An additional $3.9 million has been made available to cover specific costs of implementing the Committee of Inquiry's recommendations. (These costs do not include the costs of taking smears, which are subsidised by District Health Boards for some patients.) The Programme's impact on the health of women is directly related to the effective operation of the Programme.

1.4 We therefore wanted to ensure that progress is being made to address the serious concerns that the Committee of Inquiry raised in relation to the Programme. In particular, we sought to establish that:

- A structure – including systems and procedures – has been established to make the necessary changes to implement the Committee of Inquiry's recommendations.
- The Ministry is monitoring and evaluating, and using independent experts, to assess whether the Committee of Inquiry's recommendations are being implemented effectively.
- Satisfactory progress is being made to implement the changes.

1.5 The Minister of Health (the Minister) has engaged an expert cytopathologist[7] from Scotland, Dr Euphemia McGoogan, to provide her with independent advice on progress being made in implementing the Committee of Inquiry's recommendations. Dr McGoogan has substantial expertise in the operation of screening programmes. She visited New Zealand for ten days in October/ November 2001 as part of the terms of her engagement, and has subsequently provided a report directly to the Minister on progress over the six months since

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6 The cervical smear test is a recognised and widely used method of detecting abnormalities in cervical cells that can develop into cancer of the cervix.

7 An anatomical pathologist (medical specialist) with expertise in cytology, which is the study of cells by examining them under the microscope for signs of abnormality.

the Committee of Inquiry reported its findings. The Minister announced during Dr McGoogan's visit that her report would be made public.

1.6 We arranged two meetings with Dr McGoogan during her visit to New Zealand – at the beginning and end of her stay. Her review was more extensive than ours, as ours was intended to be a relatively limited review of progress based on information provided by Ministry staff.

1.7 We seriously considered suspending our review because of the risk of overlap with Dr McGoogan's review, particularly once we knew that the Minister intended publishing Dr McGoogan's report. However, we decided to continue with our review on the basis that:

- our reporting mandates are different – we report to Parliament and can provide a view of the scheme from a lay perspective that complements Dr McGoogan's review;
- by keeping in touch with Dr McGoogan, we were able to avoid unnecessary overlap between the two reviews; and
- although she is an international expert, Dr McGoogan felt that our involvement could support and add weight to her review if it was able to confirm her findings and conclusions from our different perspective.

1.8 Dr McGoogan's and our reports draw broadly similar conclusions. We believe that this congruence provides particularly strong assurance to the Minister, Parliament and the public about the progress made so far and the work remaining to be done. We consider that it places a particular onus on the Ministry to address the issues raised in both reports and to act upon their recommendations.

1.9 Both Dr McGoogan's and our reports are understandable to the lay person. However, for the lay person who wishes to gain an understanding of the background to the Programme and the setting-up of the Committee of Inquiry, we recommend reading our report first. Dr McGoogan's report is available at www.csi.org.nz.

## How Did We Carry Out Our Review?

1.10 Our review involved:

- Meetings with the manager of the Ministry's National Screening Unit (NSU) and the Deputy Director-General of Public Health.
- Review of relevant documentation.
- Meetings with Dr McGoogan, as described in paragraph 1.6 above.

- Telephone and e-mail contact with the University of Otago about progress in relation to the third element of the national evaluation, the Cancer Audit.[8]

- A meeting with a member of the Committee of Inquiry.

- Consultation, and a meeting, with the Privacy Commissioner about issues of access to personal medical information.

## Structure of Our Report

1.11 Part 2 of our report sets out the background to the Programme and the setting-up of the Committee of Inquiry. We then examine the arrangements that have been put in place to ensure that the Committee of Inquiry's recommendations are implemented (Part 3).

1.12 The remainder of the report follows the structure of the Committee of Inquiry's key recommendations, which are outlined in paragraph 2.20 on pages 22-23 of this report:

- quality standards and monitoring (Part 4);

- evaluation of the Programme (Part 5);

- ethics committees (Part 6);

- capability of people undertaking the Programme (Part 7); and

- communication with women (Part 8).

[8] One way of testing the effectiveness of a cervical screening programme is to carry out an investigation into the smear history and clinical treatment of women who develop invasive cervical cancer. This is known as a Cancer Audit.

## Part Two

# Background to the National Cervical Screening Programme and the Committee of Inquiry

## Why Have a Cervical Screening Programme?

2.1 The Programme was set up in response to a recommendation in the Report of the Cervical Cancer Inquiry 1988 (also known as the Cartwright Inquiry).[9] The Programme is based on a "well woman" philosophy – where a defined population of healthy women are given the opportunity to be screened for pre-cancerous lesions of the cervix, which may be amenable to early treatment.

2.2 Unlike most cancers, the most common type of cervical cancer – squamous cell carcinoma – is largely preventable. In some women, cells of the cervix go through changes which, if not detected and treated, may develop into cervical cancer.

2.3 The aim of cervical screening is to identify women who have pre-cancerous lesions of the cervix before this happens – through a cervical smear test that can detect changes in cervical cells. Where the test indicates pre-cancerous lesions and these are subsequently confirmed by diagnostic tests, the success rate for adequate treatment is nearly 100%.

2.4 Cervical screening is an internationally recognised means of reducing cervical cancer. Between 1987 and 1997, the incidence of women in New Zealand developing cervical cancer fell by 39%, and death rates due to cervical cancer fell by 44%. These reductions occurred against a background of predicted growth in cervical cancer in New Zealand.

## What Are the Problems with Reading Cervical Smears?

2.5 For cervical screening to provide accurate results:

- the smear taker must take and transfer to a slide a sufficient quantity and quality of cells from the cervix (or the neck of the womb); and

- the slide needs to be correctly read by the laboratory.

2.6 The reading of cervical smears is not a precise science. In some cases a smear can be open to different interpretations, and pathologists accept that errors in reading smears can occur.

2.7 Sometimes, a cervical smear will be read as a "false negative" or a "false positive". A "false negative" reading is a failure to identify that a woman has abnormal (or pre-cancerous) cells or cancer of the cervix, when she has abnormal cells or cancer. A "false positive" reading incorrectly identifies a

[9] The Report of the Cervical Cancer Inquiry – Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters, New Zealand, July 1988, ISBN 0-473-00664-2.

woman as having abnormal (or pre-cancerous) cells or cancer of the cervix, when she does not have abnormal cells or cancer.

2.8 A false positive result is normally discovered quickly, because any smear read as positive is followed by a biopsy. Examination of the biopsy sample would reveal no cervical abnormality where the screening had produced a false positive result.

2.9 However, a false negative result (also described as under-reporting) goes undiscovered and therefore untreated. Cervical cancer is usually a slow developing disease, and a single false negative result may not endanger a woman's health or life. But the longer the abnormality is left untreated the more extensive the treatment that may be required, and the greater the danger that the disease will progress to invasive cervical cancer.

2.10 Because of the subjective nature of smear reading, the presence of some under-reporting is an acknowledged element of any cervical screening programme. An important objective of an effective screening programme is therefore to ensure that under-reporting is minimised. And if unacceptable under-reporting – i.e. at a level that puts the integrity of the programme at risk – should occur, the programme should contain measures to ensure that the unacceptable under-reporting is identified quickly, and well before it becomes obvious through regularly screened women presenting with cervical cancer.

## What Happened in Gisborne?

2.11 In 1995 a woman established a claim for medical misadventure with the Accident Compensation Corporation, and filed a complaint with the Medical Council. As a result of the ensuing investigation the Gisborne Laboratories pathologist, Dr Bottrill, was found guilty of "conduct unbecoming a medical practitioner". The complainant then initiated a civil proceeding in the High Court. Although the claim failed, it generated extensive publicity about the case. This encouraged other women whose cervical smear tests had been read at Gisborne Laboratories to come forward.

2.12 The (former) Health Funding Authority consulted with various people – including the Royal College of Pathologists of Australasia – on the need for a re-examination of the cervical smear tests read at Gisborne Laboratories. It also sought advice from an expert advisory group. In light of the consultation and advice, in May 1999 the Health Funding Authority decided to have all the cervical smear readings by Gisborne Laboratories re-examined. This exercise established under-reporting that appeared to be extensive.

## What Was the Committee of Inquiry Asked to Do?

2.13 The Committee of Inquiry was appointed on 15 October 1999 under Section 47 of the Health and Disability Services Act 1993 (now repealed), and

was given the powers of a Commission of Inquiry under the Commissions of Inquiry Act 1908. It was directed to conduct an Inquiry into the reading of abnormalities in cervical smears in the Gisborne region prior to March 1996, taking into account the results of the reviews of cervical cytology and histology[10] samples carried out by the Health Funding Authority.

2.14 The terms of reference for the Committee of Inquiry are reproduced in Appendix 1 on page 63.

## What Did the Committee of Inquiry Find?

2.15 The Committee of Inquiry's report was released on 10 April 2001. It concluded that:

> *...there is ample evidence to show that there was an unacceptable level of under-reporting at Gisborne Laboratories between 1990 and March 1996.*
>
> *...the factors that are likely to have led to the unacceptable reporting in the Gisborne region can be placed in two groups...*[11]

2.16 The first group of contributing factors identified by the Committee of Inquiry related to practices at Gisborne Laboratories. For example, there was:

- no specialised division of labour for reading smears;
- inadequate internal quality control;
- no accreditation with an independent quality control authority; and
- inadequate participation in continuing medical education.

2.17 The second group of contributing factors related to the wider delivery of cytology services throughout New Zealand between 1990 and 1996. For example, there was:

- no requirement for laboratories undertaking cervical cytology to follow quality control processes;
- an absence of performance standards for laboratories and reliable data on laboratories' performance;

[10] Histology is the microscopic study of the structure and composition of body tissues and involves taking a section of tissue – for example, a cone biopsy.

[11] Page 8 of the Committee of Inquiry's report.

- deficient operation of the National Cervical Screening Register[12]; and
- no monitoring and evaluation of the performance of the laboratories undertaking cervical cytology.

2.18 The Committee of Inquiry concluded that:

> *...the possibility that unacceptable under-reporting has occurred elsewhere in New Zealand cannot be excluded.*[13]

## What Were the Committee of Inquiry's Recommendations?

2.19 The Committee of Inquiry made 46 recommendations for future action that the Government or its agencies should consider taking. The recommendations are set out in full in Appendix 2 on pages 64-70.

2.20 The recommendations included:

- The Draft Operational Policy and Quality Standards for the Programme (that had been developed and submitted as later evidence to the Inquiry) should be fully implemented and reviewed every two years. Monitoring of the Programme should include statistical analysis of the quality of laboratory performance and of other aspects of the Programme. (Relevant recommendations – 4, 7, 8, 9, 27, 30 and 32.)
- The national evaluation of the Programme[14] should proceed. Arrangements should allow for monitoring and evaluation of the Programme, and for related information to be disclosed to appropriately qualified persons without the consent of women. (Relevant recommendations – 1, 5, 6, 14, 15, 16 and 17.)
- The guidelines for the operation of the ethics committees should be reviewed to explicitly exclude matters of audit, monitoring, and evaluation of past and current treatment. The operation of ethics committees in relation to independently funded evaluation exercises and medical research into cervical cancer should be reconsidered. (Relevant recommendations – 18 to 23.)
- The provision of appropriately skilled and qualified people to undertake the work required to run an effective screening programme should be addressed. (Relevant recommendations 28, 29, 40, 41 and 42.)

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12 The Register contains women's demographic details, their smear results, their histology results (if applicable), and details of smear takers, health centres and laboratories. It is used for follow up of abnormal smears and recall if overdue for a smear, as well as for monitoring aspects of the Programme.

13 Page 10 of the Committee of Inquiry's report.

14 The elements of the national evaluation are set out in Appendix 3 on pages 71-72.

- The Programme needs to improve communication with women by improving responsiveness in relation to complaints and users' views, and by providing information to enable women to make informed decisions about screening and the potential risks and benefits. (Relevant recommendations – 24, 38 and 45.)

2.21 On the release of the Committee of Inquiry's report in April 2001, the Minister accepted all the recommendations and directed the Ministry to implement them.

## Part Three

# Arrangements for Implementing the Committee of Inquiry's Recommendations

## Progress in Establishing the Arrangements

**Good progress has been made in setting up a structure – including systems and procedures – to address the Committee of Inquiry's recommendations.**

3.1 Progress includes:

- the establishment – in November 2000 before the Committee of Inquiry reported its findings – of a separate National Screening Unit (NSU) within the Ministry;
- the engagement of staff and contractors and their assignment to project and subproject teams; and
- the development of a milestone plan and time-frame for the implementation of each recommendation.

## The National Screening Unit

**Some aspects of the NSU are not precisely as the Committee of Inquiry envisaged.**

3.2 The Committee of Inquiry recommended that the NSU should be led by a person with an epidemiology[15] or specialist public health qualification.

3.3 In practice, the NSU's Manager originally qualified as a pharmacist, and her recent experience is in health service management. The NSU's Clinical Director, who is the clinical leader of the NSU, has a specialist public health qualification. The NSU has also recruited two further public health specialists. This arrangement – whereby a person with management skills and experience is employed to free up the time of the clinical leader to enable them to undertake clinical rather than managerial work – is operated in some health services overseas.

3.4 However, Dr McGoogan's report highlights that the Clinical Director has a direct line management relationship to the NSU's Manager, who is not medically qualified. The Clinical Director is also not the direct line manager of any permanent staff. This structure runs the risk that clinical input to the NSU could be sidelined and the Clinical Director excluded from decision-making. We consider it important that this risk is acknowledged and appropriately managed.

**The NSU is a separate unit within the Ministry.**

3.5 The Committee of Inquiry recommended that the NSU should function as a separate unit within the Ministry. It has been established as a business unit reporting to the Deputy Director-General Public Health and a Ministry

[15] Epidemiology is the study of the distribution and determinants of health and disease in the community.

Advisory Board.[16] The manager of the NSU has delegated authority to manage the NSU, having regard to Ministry rules on matters such as financial management and recruitment.

3.6 Given the NSU's problems with recruitment, which we outline in paragraphs 3.10 to 3.12 below, we asked the NSU's Manager whether she felt that part of the difficulty arose from the NSU's position as a largely operational unit within a Ministry that has a necessarily strong focus on health policy. She said that the main constraint upon her was the difficulty of finding suitable people to recruit into the NSU and the time this process takes.

3.7 However, Dr McGoogan has raised similar concerns in her report about whether the NSU has sufficient authority and independence to perform its functions. In our view there should be a review of the operation of the present arrangements to examine these concerns – the review would need to take into account the public sector governance issues that would arise from increasing the NSU's autonomy.

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**The NSU has recruited extensively over the last 12 months.**

3.8 At the time of the Committee of Inquiry, the NSU had 7.5 full-time-equivalent staff plus access to fixed-term contractors and expert consultants. During the Inquiry, the approved level of permanent staff was increased to 33. In future these additional staff should strengthen the NSU.

3.9 However, in the short term, recruitment of staff and their training in new roles has placed the senior management of the NSU under severe pressure. New Zealand has only a small workforce with experience of screening programmes. Most new staff therefore require extensive training, which creates a large amount of work that can only be undertaken by the few experienced staff in the NSU.

3.10 Experienced staff in the NSU were effectively having to create a new unit at a time when they also had to give a high priority to the many tasks required to address the Committee of Inquiry's recommendations, and to the operation of the NSU's other major programme *BreastScreen Aotearoa*. Lack of capacity to support and develop inexperienced staff continues to cause the NSU's management some concern.

**Recruitment has proved difficult because of the shortage of suitable candidates, and the NSU has not yet successfully recruited for two key posts.**

3.11 The NSU currently does not have access to the services of a permanent epidemiologist, even though the Committee of Inquiry was advised that a part-time epidemiologist would be appointed to the NSU's Quality Monitoring, Analysis and Audit team. The NSU has attempted to recruit an

[16] The Advisory Board comprises: Deputy Director-General Public Health, Director Public Health, Manager Public Health Strategic Development, Special Projects Manager, Group Manager National Screening Unit, and Clinical Director National Screening Unit.

epidemiologist, but we understand that there is a shortage in New Zealand and they are in high demand.

3.12 The NSU has also not yet appointed a manager of the Quality Monitoring, Analysis and Audit team – the position has been re-advertised.

3.13 We did not examine the adequacy of the NSU's staffing to meet its objectives and responsibilities. However, we are concerned by the difficulties the NSU is experiencing in recruiting key staff. Dr McGoogan has expressed similar concerns.

## Monitoring and Reporting Progress

3.14 Monitoring and reporting on the progress made in implementing the recommendations has been established, including:

- monthly reports to the Minister of progress against milestones covering each recommendation, including an explanation of any delays experienced; and

- a report summarising progress for the first six months which was provided to the Minister in November 2001 – this report included a revised timetable that will form the baseline for reporting over the next six to twelve months.

**In our view, the engagement of an independent expert to advise on the progress being made in implementing the Committee of Inquiry's recommendations has significantly strengthened the implementation process.**

3.15 Dr McGoogan has received monthly reports and other documents relating to the implementation, and has participated in monthly teleconferences with the Ministry's Deputy Director-General of Public Health and the manager of the NSU. She visited New Zealand for 10 days in October/November 2001, and provided a report directly to the Minister on progress over the six months since the Committee of Inquiry reported its findings.

3.16 The following table was included in the Ministry's first six-monthly report to the Minister in November 2001. The report details the recommendations that have been completed and those that are still under way – and, if still under way, whether they are on track or have a revised delivery date.

| Status | Recommendation | Total Number |
|---|---|---|
| Complete | 4, 9, 10, 11, 12, 13, 25, 37 | 8 |
| Under way | 1*, 3, 5, 6, 7, 8, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 38, 39, 40, 41, 42, 43, 44, 45, 46 | 37 |
| On track | 5, 6, 15, 18, 19, 28, 29, 31, 32, 33, 40, 41, 42, 43, 45, 46 | 16 |
| Revised Delivery Date | 1, 3, 7, 8, 14, 16, 17, 20, 21, 22, 23, 24, 26, 27, 30, 34, 36, 38, 39, 44 | 20 |

* Recommendation 2 is subject to progress on recommendation 1.

3.17 Dr McGoogan's report provides detailed comments on whether the table is a fair reflection of progress made. She expresses some disagreement with the picture reflected in the table – she is not satisfied with progress in relation to recommendations 11, 12, 13 and 25, which are listed as "Complete", or with progress in relation to recommendations 15, 18, 19, 28, 29, 32, 33, 41, 42, 43, and 45, which are listed as "On track". We too noted that some recommendations are not being implemented as precisely as the Committee of Inquiry suggested – a number of exceptions are explained later in our report.

3.18 We believe that the table itself is both problematic and valuable:

- It is "problematic" in that it is inevitably based on subjective judgements.
- It is "valuable" because its very subjectivity generates useful debate on exactly how much progress is being made.

3.19 So long as progress is being independently evaluated, we see value in continuing with the kind of analysis provided in the table.

## Part Four

# Quality Standards and Monitoring of the National Cervical Screening Programme

## Standards for Laboratories

**Compulsory minimum volume standards have been imposed on laboratories.**

4.1 Screeners need to read a minimum number of smears each year in order to maintain their competence. The World Health Bulletin on *Control of Cancer of the Cervix Uteri* stated in 1986 that:

> *In general laboratories that screen fewer than 20,000 specimens annually are not cost-efficient and cannot support either a training programme or full time cytotechnologist. Preferably the annual number of specimens should be 50,000 or more.*

4.2 The American Society of Cytology requires a laboratory to read a minimum of 10,000 gynaecological smears annually.

4.3 In New Zealand, cervical cytology had always been undertaken by any laboratory without minimum volumes being applied. In July 2000,[17] the Health Funding Authority proposed volume standards, including a requirement for laboratories to read a minimum of 12,000 smears a year.

4.4 The Committee of Inquiry recommended that these volume standards be imposed. This recommendation has been addressed, and each laboratory site now has to read a minimum of 15,000 gynaecological cytology cases[18] each year if it is to remain a provider in the Programme. The requirement is designed to ensure that smears are not read by people working alone in an isolated environment.

4.5 Laboratories are also required to ensure that screeners do a primary screen[19] of a minimum of 3,000 cases a year. These requirements have resulted in three public hospitals and two community laboratories ceasing to provide cytology services. There are now 11 community laboratories and two public hospitals providing cytology services.

**Contracts that include the Interim Policy and Quality Standards have been entered into with laboratories.**

4.6 Community Laboratory Agreements (signed in November 2000) and District Health Board Agreements (effective from 1 July 2001) require laboratories to comply with the Interim Policy and Quality Standards, which will be re-evaluated in 2002. This will support the monitoring, evaluation, and audit of laboratory performance.

4.7 The Interim Policy and Quality Standards include standards for under-reporting. All laboratories that find a high-grade abnormality in respect of a

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17 Discussion Paper – Cytology: Minimum Volumes for Laboratories, Screeners and Pathologists.

18 A "case" may comprise more than one "smear" – if two smears are provided from the same woman they count as one "case".

19 Primary screening is the first look at a slide when it comes into the laboratory – as opposed to any confirmatory checks on the result of the first screening.

woman whose previous smears were read as negative (no abnormality) must review the slides for that woman for the previous 42 months. Where the slides are re-read as positive (i.e. the previous read was a false negative), this result must be recorded. A laboratory false negative rate of 20% has been set as the accepted maximum, and the laboratory's actual false negative rate must be reported to the NSU annually.

## Independent Monitoring Group

**An Independent Monitoring Group has been established to assist the NSU to improve the quality of the Programme.**

4.8 The Ministry has established national performance indicators for the Programme. It subsequently contracted with the University of Otago to set up an Independent Monitoring Group. The Group is involved in the production of quarterly monitoring reports which are intended to assist the NSU and providers of services, including laboratories, to improve the quality of the Programme.

4.9 So far two monitoring reports have been produced – covering October to December 2000 and January to March 2001. The reports contain a large range of indicators such as:

- the percentage of women in the target 20-69 age group who are enrolled on the Programme;
- the speed of histology reporting for women whose cytology report indicated high-grade or more serious cytology; and
- various indicators of laboratory reporting – such as the percentages of cytology reports predicting high-grade abnormalities and all abnormalities – which are designed to provide further indicators of possible under-reporting.

4.10 The reports also make detailed recommendations to help improve the Programme – the first report contained four recommendations on data issues and 18 on the services provided.

4.11 The reports comprise detailed material that is analysed, collated and checked with District Health Boards and community laboratories. They are currently taking six to eight months to finalise from the end of the quarter they relate to – final publication of the October to December 2000 report was in July 2001.

4.12 Because of the overlap between one report being finalised and the period covered by the next report, there is some duplication between the reports (particularly in recommendations being repeated because the NSU had not been in a position to take them up). The NSU has formal processes to follow up issues from the monitoring reports, which may include writing to providers to seek direct explanations of their performance. The NSU also has plans to

establish provider compliance audits similar to those used for *BreastScreen Aotearoa*, and it is currently preparing an audit plan.

## Annual Statistical Reports

**There are plans for annual statistical reports to help assess the Programme, but these have been delayed because of the lack of an available epidemiologist to evaluate them.**

4.13 Annual statistical reports, compiled from data on the National Cervical Screening Register and the Cancer Register,[20] are to be used to help assess the Programme. The first report, covering 1996 to 1998, is due for publication in March 2002.

4.14 The reports are to be evaluated by epidemiologists, but this evaluation has been delayed by the lack of an available epidemiologist. A second report, covering 1999 to 2000, has also been delayed and is expected to be available in December 2002.

[20] The Cancer Register records all instances of cervical cancer (and other cancers) and is used to identify the people relevant to cancer audits.

## Part Five

# Evaluation of the National Cervical Screening Programme

# The National Evaluation

**The Committee of Inquiry's timeline for evaluating the Programme has not been met.**

5.1 The Committee of Inquiry considered that:

> *The remaining two phases of the national evaluation designed by the Otago University team must proceed.* ***Until those phases are completed the Programme's safety for women cannot be known. It is imperative that this exercise be completed within the next six months.*** (Our emphasis).[21]

5.2 In May 1999, the Ministry contracted with a team from the University of Otago to evaluate the Programme in three phases – Appendix 3 on pages 71-72 outlines the evaluation. The first phase of this evaluation had been completed when the Committee of Inquiry reported its findings in April 2001.

5.3 The second phase – a review of the adequacy of diagnosis, treatment and follow-up of women with abnormal smears – has since been completed. The report of the review drew a number of useful and largely reassuring conclusions. However, there was a low response rate from women asked to approve access to their records[22] for the purpose of the review.

5.4 We understand from the report that the review may have therefore resulted in an under-estimation of problems in the management of cervical smear abnormalities. The report suggested that it is not possible from the review "to ascertain the success of fail-safe procedures".

# Third Phase of the Evaluation – The Cancer Audit

**The third phase of the evaluation – the Cancer Audit – has not yet been started.**

5.5 As illustrated in the Committee of Inquiry's report, the issues related to the Cancer Audit are complex and longstanding. In particular, the report showed that statutory barriers on access to health information were inhibiting the comprehensive evaluation of the Programme.

5.6 We understand from the Ministry that the reasons for the delay in starting data collection for the Cancer Audit include:

- issues relating to the application to ethics committees for carrying out the Cancer Audit;
- issues relating to the ability of external agencies to access data on the National Cervical Screening Register under current legislation;

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21 Recommendation 1, set out in full on page 64.

22 The overall response rate was 56%. Access was refused by 19.2% of women and 24.3% of women could not be located. The response rates for Maori and Pacific women were 28% and 31% respectively.

- the need to plan for a slide review, which was excluded from the original protocol for the Cancer Audit; and

- the need to develop more fully the framework and protocol for the Cancer Audit and involve other experts, including experts from overseas.

5.7 To help overcome the problem of access to the National Cervical Screening Register by external agencies, the Ministry suggested that the University of Otago team members undertaking the Cancer Audit might be employed directly by the Ministry. However, the University wished to maintain its independence.

5.8 For a number of reasons, the University of Otago is no longer participating in the evaluation. The NSU is seeking to appoint another evaluation team against a background of limited expertise in New Zealand for this kind of work.

5.9 Without reliable results from these two phases of the national evaluation, no-one can provide assurance about the effectiveness of the Programme. This is especially worrying, given that:

- there were regions other than Gisborne with a high incidence of cervical cancer at the time of the Inquiry;

- the Ministry accepted that the presence of other unacceptable under-reporting over the past decade could not be ruled out; and

- the Committee of Inquiry decided against recommending a specific examination of these regions on the basis that the national evaluation would be undertaken, and would identify under-reporting if it had occurred.

## Access to Medical Records

**The issue of enabling those undertaking audit and evaluation of the Programme to gain access to sufficient medical records of relevant women to support effective monitoring, evaluation, and audit remains unresolved.**

5.10 For the evaluation to be effective, those undertaking it need access to the cytology slides of all women who have developed cervical cancer,[23] and the records of any treatment they have received in relation to possible cervical cancer. Without this information, there is a risk that the evaluation will be a pointless exercise.

[23] The final section of Appendix 3 – which outlines the national evaluation – provides details of the women selected for the purpose of the Cancer Audit. The audit is currently planned to involve looking at the screening histories and clinical management of 429 women diagnosed with invasive cervical cancer. We refer to these women as the "relevant" women.

5.11 The Committee of Inquiry felt strongly that audit and evaluation was an integral part of women's treatment in the Programme, and that clinical reviewers engaged to evaluate the Programme required access to protected information relevant to the Programme without the need to obtain consent. The Committee of Inquiry emphasised that:

> *By far the most important change which is required to make the National Cervical Screening Programme fully effective is the removal of legal barriers which are preventing the comprehensive evaluation of the Programme from proceeding.*[24]

5.12 For each relevant woman, the Cancer Audit will need to answer the question "Why did this woman develop invasive cervical cancer?" The clinical reviewers will therefore require information about the women from five sources:

- the Cancer Register – held by the Cancer Registry within the Ministry and used to identify people who have or have had cancer;
- the National Cervical Screening Register – a register of cytology and histology results held by the NSU and used to help manage the Programme (for example, by providing for women to be reminded when their next smear is due, by following up the treatment of women with detected abnormalities, and for compilation of statistics that do not identify individual women);
- slides taken as part of cervical screening procedures – which have to be considered separately from the data on the National Cervical Screening Register because they are bodily substances obtained in the course of a health care procedure;
- individual women's medical records held by hospitals or individual medical practitioners (such as GPs); and
- interviews with the women.

We explain below the legal constraints on making health information from these sources available to the clinical reviewers.

[24] Page 232 of the Committee of Inquiry's report.

## *The Cancer Register*

5.13 The Ministry may disclose data entries in the Cancer Register to the clinical reviewers engaged to evaluate the Programme to enable them to identify women relevant to the Cancer Audit. This disclosure is permitted by the Health Information Privacy Code[25] because the Cancer Audit is one of the purposes in connection with which the information was obtained.

## *The National Cervical Screening Register*

5.14 Disclosure of data on the National Cervical Screening Register is relevant only to women actually on the Register – a proportion of the women identified from the Cancer Register as relevant to the Cancer Audit will either:

- have never had a smear test; or
- have had a smear test (or tests) but elected not to be included on the National Cervical Screening Register.

5.15 As things currently stand under the Health Act 1956, the consent of the relevant women identified from the Cancer Register must be obtained to allow disclosure of the women's data on the National Cervical Screening Register to the clinical reviewers. Regulations may be made under the Health Act 1956 to give access for persons studying cancer, but an amendment to the Act itself is proposed in order to address the issues raised by the Committee of Inquiry and explicitly allow access to the National Cervical Screening Register for monitoring, evaluation, and audit purposes. However:

- the legislation is yet to be introduced:
- the amendment is not likely to come into effect until at least mid-2002; and
- the Cancer Audit must therefore be designed to meet the current legislative arrangements.

## *Cytology Slides*

5.16 Re-reading of slides is a key component of any screening audit. The tests to be conducted are the same as those routinely conducted as part of laboratories' in-house quality assurance procedures.

5.17 The storage of, and access to, cytology slides is subject to the Code of Health and Disability Consumers' Rights (also known as the Code of Rights) which requires informed consent for their use. The consent can be express or

[25] The Health Information Privacy Code 1994 (revised in 2000) applies to health information about identifiable individuals. The rules of the Code are enforceable by complaining to the Privacy Commissioner, and there may be financial and other consequences for agencies that breach these rules.

implied, and it could be argued that (because the Cancer Audit is to subject the slides to the same tests that form part of routine quality assurance) women enrolled on the National Cervical Screening Register have already implied their consent.

5.18 The information derived from reading a slide (for example, a written report on a slide) may be health information and therefore subject to the Health Information Privacy Code. Routine disclosures of such information would be be permitted under the Health Information Privacy Code if there were a reliable system (whether by law or merely practice) for informing the woman about the use of the information at the time it was obtained from her. However, before any such system was introduced, a change to the Health Act (as discussed in paragraph 5.15) would be necessary to ensure that such disclosures (without seeking the woman's consent) were permissible.

5.19 In view of the uncertainty and debate surrounding these issues, the Government proposes to further amend the Health Act to require cervical cytology and histology slides of all women who have results recorded on the National Cervical Screening Register (and/or who have cervical cancer) to be made available for the purpose of routine monitoring, evaluation, and audit of the Programme. Such an amendment would displace any contrary provision of the Health Information Privacy Code.

## *Medical Records*

**The continuing requirement for consent to disclose medical records to clinical reviewers engaged to monitor, evaluate, or audit the Programme is inconsistent with the Committee of Inquiry's recommendation that they should have "ready access to all medical files recording the treatment of the cervical cancer by all health providers who had a role in such treatment".**

5.20 The clinical reviewer undertaking monitoring, evaluation, and audit may need access to women's medical records – for example, to establish the timing and nature of any treatment the women had. The source of the records will generally be a health agency who has been involved in the woman's treatment – usually either a hospital doctor, a GP, or both.

5.21 The Health Information Privacy Code only permits the disclosure of the health information (i.e. the medical record) by the health agency in particular circumstances. For example, where the disclosure is:

- authorised by the woman or her representative; or
- one of the purposes in connection with which the information was obtained; or

- where the health agency believes on reasonable grounds that it is either not desirable or not practicable to obtain authorisation from the woman or her representative *and* the disclosure is *directly related to* one of the purposes in connection with which the information was obtained; or

- to provide information for statistical or (ethics committee-approved) research purposes, which will not be published in a form that could be reasonably expected to identify an individual.

5.22 Given the more general nature of medical records (as opposed to the specific screening histories on the National Cervical Screening Register and the cytology slides), health agencies are unlikely to view disclosure of the records to the clinical reviewer as *one of the purposes in connection with which the information was obtained*. They are therefore likely to interpret these provisions as requiring them to obtain consent from individual women, at least in cases where they can be contacted.

5.23 Generally, therefore, consent will be required for disclosure of the women's medical records to the clinical reviewers, and there are only limited plans to legislate to change this position (which are described in paragraphs 5.25 to 5.28 below).

### *Interviews*

5.24 Arranging interviews with the women will necessarily require their consent.

## Proposed Legislative Changes on Disclosure of Health Information

**The Government is proposing more limited changes, and recognises that if high numbers of women decline access to their medical records, this could compromise the results of the monitoring, evaluation, and audit.**

5.25 In June 2001, the Ministry issued a discussion document on the Government's intentions to put legislation before Parliament which would have provided for disclosure of data on the National Cervical Screening Register and medical records, in line with the Committee of Inquiry's recommendation. (We explain the background to the discussion document in paragraphs 8.4 to 8.11 on pages 57-59).

5.26 The Ministry subsequently confirmed its intention to seek an amendment to the Health Act 1956 to explicitly allow access to data on the National Cervical Screening Register for the purpose of monitoring, evaluation, and audit. As explained above (paragraph 5.15), the legislation has yet to be introduced and the amendment is not likely to come into effect until at least mid-2002.

5.27 Responses to the discussion document were predominantly against the notion of access to women's medical records without their specific consent. Respondents were concerned that medical records could contain personal and sensitive information that had nothing to do with cervical screening. Therefore, the following more limited changes are planned to the provision for access to medical records:

- efforts will be made to seek women's consent and, where a woman gives consent, the person who holds her medical records will be required to make them available;
- efforts may be made to obtain consent prospectively – for example, when the woman is treated or when her details are placed on the Cancer Register; and
- when consent cannot be sought – for example, because the woman cannot be traced – the Director-General of Health will be empowered to require the person who holds her medical records to provide the relevant information.

5.28 The Cabinet Paper that set out this proposal noted that these more limited changes meant that high numbers of women declining access to their medical records could compromise the results of the monitoring, evaluation, and audit.

## Cultural Issues Affecting Access to Medical Records

**The issues affecting access to the medical data and records of Maori women are even more complex, and progress in addressing the Committee of Inquiry's concerns is slow.**

5.29 Maori women experience a relatively high rate of cervical cancer. In the period 1989 to 1993, the age-standardised incidence rate of cervical cancer was 29.8 per 100,000 Maori women compared to 12.0 per 100,000 for all women.

5.30 In order to gain access to Maori women's data on the National Cervical Screening Register, an application must be made to the Kaitiaki Group for permission. The Kaitiaki Group was established under the Health (Cervical Screening (Kaitiaki)) Regulations 1999 – "the Kaitiaki Regulations" – that were developed to encourage Maori participation in the Programme by recognising the cultural importance of, and the need to maintain confidentiality of, Maori women's data.

5.31 The Kaitiaki Regulations apply to Maori women's data on the National Cervical Screening Register where that data:

- is for the purpose of enabling the compilation and publication of statistics that do not enable the identification of the women to whom those statistics relate; or

- is protected information – i.e. it does not enable the identification of the woman or women to whom the information relates.

5.32 The Kaitiaki Group acts as guardian of Maori women's data on the National Cervical Screening Register and the data must not be disclosed, used or published without the approval of the Group. Pacific Island women have been seeking similar protection.

5.33 The Committee of Inquiry found that the Kaitiaki Regulations had delayed or obstructed gaining access to Maori women's data for the purpose of monitoring, evaluating, and auditing the Programme. It recommended that the Kaitiaki Regulations be reconsidered to allow independent clinical reviewers to have access to the information.

5.34 The Government has since committed to undertaking consultation before any changes to the Kaitiaki Regulations. A meeting has been held between the Kaitiaki Group and the Ministry, which has agreed to draft a discussion document that acknowledges the history of the Group and sets out the recommendations and the proposals that will be consulted on. The draft discussion document is planned for release in February 2002, to be followed by a series of regional Hui.

5.35 In the meantime, a wider evaluation of the Programme for Maori and Pacific Island women is planned but not due to begin until at least December 2002. The evaluation will include aspects such as involvement of women in the development and operation of the Programme, availability of culturally appropriate information, and access to high-quality treatment and services.

## Part Six

# Role and Involvement of Ethics Committees

## National Ethics Committee and National Standards

**A National Ethics Committee is being established and the Operational Standards for ethics committees have been revised.**

6.1 Section 16 of the New Zealand Public Health and Disability Act 2000 requires the establishment of a National Ethics Committee. This Committee will have a broad role in relation to health and disability ethics.

6.2 A *National Standard for Ethics Committees* was published in June 1996. The Committee of Inquiry considered that there were two areas of ethics committee operations that needed clarification:

- First, *when* ethical review is required. The Committee of Inquiry considered that the guidelines should make it clear that any monitoring, evaluation, and audit of past and current medical treatment does not require ethics committee approval.

- Secondly, the processes used by Regional Ethics Committees for considering national or multi-centre trials. Different processes could lead to conflicting decisions by Regional Ethics Committees, and cause researchers problems when their research covers more than one region.

6.3 Ethics committee approval has been a factor contributing to the delay in starting the Cancer Audit. However, we understand that ethics committee approval is not required for the use of health information for monitoring or internal audit undertaken by staff involved in a health institution or service such as the Programme – although approval would be required for other research into the effectiveness of the Programme.

## Ethics Committee Approval

6.4 Because the Cancer Audit is to be undertaken by external clinical reviewers, irrespective of rules for ethical approval, the Ministry takes the view that ethical approval is an important quality assurance mechanism in relation to the design of the Cancer Audit. In reaching this view, the Ministry also cites the fact that the clinical reviewers will be interviewing the women and have access to sensitive personal and health information.

6.5 In this context, the Committee of Inquiry's recommendations on work required of the National Ethics Committee assume particular importance. The terms of reference for the National Ethics Committee give it a second opinion role in relation to decisions of Regional Ethics Committees (recently renamed Health and Disability Ethics Committees). This role is intended to address the Committee of Inquiry's recommendation that *consideration should be given to*

*processes to allow [*ethics committees'*] decisions to be appealed to an independent body.*[26]

## Future Work of the National Ethics Committee

6.6 The Minister has also asked the National Ethics Committee to address the following three recommendations of the Committee of Inquiry:

- to review the operation of ethics committees and the impact that their decisions are having on independently funded evaluation exercises and on medical research;
- to provide guidance to ethics committees regarding the weighing up of harms and benefits in assessing the ethics of observational studies; and
- to consider the issue of multi-centre and national studies.[27]

6.7 Although the Ministry funds ethics committees to provide independent ethical review of proposals for health research and innovative practice, it has no jurisdiction over them. They are by nature independent. However, we consider that the NSU will need to continue to monitor the work undertaken by the National Ethics Committee and report to the Minister on whether the Committee of Inquiry's recommendations in relation to ethics committees are being implemented.

[26] Recommendation 23, set out in full on page 67.
[27] Respectively recommendations 19, 21 and 22 on page 67.

## Part Seven

# Capability of People Undertaking the Programme

# People Working in Laboratories

**The Ministry has made some progress in addressing the Committee of Inquiry's recommendations on training and development of the technical laboratory staff who undertake cervical screening. However, there has been little change in relation to medical practitioners.**

7.1 The Committee of Inquiry was concerned about the qualifications of smear readers. It recommended that the Medical Laboratory Technologists Regulations 1989 be amended to permit cervical smears to be read only by:

- registered medical practitioners with specialist qualifications in pathology and appropriate training in cytopathology; or
- appropriately trained cytoscreeners.

7.2 In response, the Ministry has prepared a draft Cabinet Paper for consultation on proposals to amend the Regulations to ensure that laboratory technologists who intend to read smears are appropriately trained.

7.3 The proposals do not enable the regulation of smear readers who are medical practitioners (rather than laboratory technologists) registered under the Medical Practitioners Act 1995 – although this Act does (of course) contain a broader requirement for practitioners to be competent to practise.

7.4 We understand from the Ministry that there are now no pathologists (i.e. medical practitioners) carrying out primary screening – this is entirely undertaken by cytoscreeners and cytotechnologists. And to ensure a degree of competence for all new anatomical pathologists, from 2001 trainees are required to successfully complete a cytology component as part of their qualification. In addition, a practical examination in cytology will be required from 2002.

7.5 The Committee of Inquiry also considered that there needed to be a strategy in place to ensure that:

- there are sufficient trained cytotechnologists and cytopathologists;
- there are appropriate training sites for them; and
- the training requirements and maintenance of competence of smear readers and cytopathologists is reviewed.

7.6 The Ministry has almost completed a workforce survey of laboratories, and has had discussions with training agencies, colleges, professional bodies and education providers. The results from the survey – which indicate likely future problems in sustaining the workforce and the skill base for the Programme in New Zealand – will inform the *Workforce Development Strategy*. This Strategy has been prepared in draft and includes consideration of issues related

to the employment of cytoscreeners, cytotechnologists, and pathologists undertaking cytopathology. It also addresses recruitment, competence, and ongoing training and education.

## People Taking Smears

**The NSU does not contract with smear takers, but has some influence over the quality of this crucial element of the screening process.**

7.7 For cervical screening to be effective, the smear taker must take a sufficient quantity and quality of cells from the cervix. However, District Health Boards (not the NSU) contract with the primary health care providers who actually take the smears – who are usually GPs and Practice Nurses.

7.8 In practice, regular monitoring, audit, and evaluation of the quality of smear taking is through the laboratories, which should request repeat smears to be taken where a smear is unsatisfactory – i.e. insufficient quantity and quality of cells have been taken to allow a reliable reading. In these cases, the woman is inconvenienced by the need to return for another smear.

7.9 The NSU's regional staff have access to data on unsatisfactory smears by smear takers. Though there are no set procedures, the Ministry told us that the staff monitor the quality of smear takers in order to identify GPs and practice nurses with a high rate of unsatisfactory smears who might need retraining.

7.10 We also noted that the standard for determining unsatisfactory smears currently being applied by laboratories in New Zealand is the same as the US standard that is based on women returning for tests once a year. The UK cervical screening programme has a longer interval – as in New Zealand – but its standard for determining unsatisfactory smears is higher than the US standard,[28] reflecting the higher risk inherent in the longer interval.

[28] The US requires 10% coverage of the slide with cells from the cervix, whereas the UK standard is 33%. In the US, 33% visibility of the cells is required, whereas the UK standard is 50%. In the UK 8-10% of smears result in a request from the laboratory for a repeat smear; in New Zealand the rate is 1%.

## Part Eight

# Communication with Women

## Communication About the Programme

**Women are more likely to access the Programme if they understand and have confidence in it. Effective, timely communication with women about the Programme, its objectives, and how it is conducted, is therefore crucial.**

8.1 The NSU has developed a web site – www.healthywomen.org.nz – to provide information to women about both the breast and cervical screening programmes. It has developed pamphlets for women and health professionals about the Programme.

8.2 As explained in paragraph 7.7 on page 54, the NSU does not contract with smear takers. It therefore has no control over smear taking and is not able to direct what information smear takers provide to patients. However, it provides training for health promotion workers, with 9 regional and 3 national training events having been provided over the last two years.

8.3 The Committee of Inquiry wanted women to be given more information to enable them to make informed decisions about screening, and to provide them with information regarding potential risks and benefits of cervical screening. The NSU has contracted with a women's organisation to develop a brochure for this purpose. The brochure was due for completion in December 2001. It will now not be ready until June 2002, partly due to the wish to include legislative changes that have not yet been made.

## June 2001 Discussion Document

**Confusion over the intention of the Ministry's June 2001 discussion document was an example of poor communication about the Programme.**

8.4 As noted in paragraph 5.27 on page 45, responses to the Ministry's discussion document on provisions for disclosure of health information for the purpose of monitoring, evaluating and auditing the Programme were predominantly against the notion of giving access to women's medical records without their specific consent.

8.5 A number of submissions also commented on the poor quality of the discussion document. We reviewed the document and concluded that it was an inadequate communication with women, for the following reasons:

- Although it was entitled "discussion document" it communicated intentions rather than proposals.
- It did not explain these intentions clearly or in sufficient detail to enable a sensible response.
- It provided no details of the Cancer Audit or precisely what women's health information would be used for.

- In parts, the document gave the impression that the health information might be provided more widely than only to clinical reviewers employed by or in contact with the Ministry to evaluate the Programme.

- The document relied largely on quotations from the Committee of Inquiry's report to emphasise the value and importance of monitoring, evaluating and auditing the Programme.

8.6 The Privacy Commissioner's submission on the discussion document had expressed similar concerns:

> *The "Discussion Document" states that its "aim…is to inform [the reader] of the legislative changes relating to audit and research of cervical cancer." Although here and there in the document there are references to.. "proposed changes", the general tenor of the document is that this is a done deal, and that the real point of the communication is to reassure people that "auditors and researchers given access to personal information will be required to keep this information confidential and secure." That statement, and another variant of it, is the only part of this document which was seen as meriting bold type.*

8.7 The Privacy Commissioner then went on to state that:

> *I would have expected that the "Discussion Document" would specify what the problem with the present law is thought to be, and some alternative means of dealing with that problem. Neither of these features is present. I do not consider that the government has any basis to claim, on the basis of distribution of this document, that there has been meaningful public informed debate about whatever the proposed law changes are.*

8.8 A private individual in making her submission eloquently summed up the shortcomings of the document with the words:

> *After I have read a section of the proposed changes in the discussion document I find I am asking the questions – who, when, how, what and why.*

8.9 Ministry staff acknowledged the shortcomings of the discussion document. However, they explained to us that the tenor of the document had reflected the Government's already stated intention to implement the Committee of Inquiry's recommendations in full. The main intentions of the document were therefore to inform women of the changes the Government proposed to make, and to seek public input on their implementation.

8.10 A further difficulty was that the protocol for the Cancer Audit was still being developed. Since decisions on the protocol effectively determined the detail of

the legislative changes, the Ministry had felt that it was not possible to be more specific about the detailed use of the information. The document had therefore focused on assuring women that their information would be protected.

8.11 In future, to improve communication, we consider that the Ministry needs to more clearly specify the intention of its documents. By using the term "discussion document" the Ministry set up an expectation with the reader that the proposed changes were by no means final. In addition, communicating with women's groups, and with professionals with expertise in clinical reviews, before issuing the document for comment would have encouraged a more informed debate.

## Use of Terminology

**Careful thought also needs to be given to the terminology used in communicating the Programme to women.**

8.12 Examples of what we mean are the words "audit" (un-prefixed by the word "cancer") and "auditor", which are extensively used in documents about the Programme. To many people the word "auditor" readily conjures up images of the traditional auditors of financial records and accounts.

8.13 In our view, there is a need to find an alternative term for use in published documents relating to the Programme that will more faithfully reflect the work undertaken by medically-trained reviewers (clinical reviewer is the term we have consciously used in this report), who are essentially required to provide:

- a second *medical* opinion on the diagnosis and treatment provided to the women relevant to the Cancer Audit; and
- a *medical* view on the reasons why the disease progressed to invasive cancer.

8.14 In order to ensure that in future all major communications about the Programme contain clear messages, we recommend that they are "piloted" with a number of women's groups before they are published in final form.

# Appendices

## Appendix 1

# Terms of Reference of the Committee of Inquiry

The terms of reference of the Inquiry were contained in the Minister of Health's letter of appointment. The Minister directed Ailsa Patricia Duffy QC, Druiscilla Kapu Barrett CNZM, and Máire Angela Duggan MD, FRCPC to conduct an Inquiry into the reading of abnormalities in cervical smears in the Gisborne region prior to March 1996 (taking into account the results of the reviews of cervical cytology and histology samples carried out by the Health Funding Authority) on the following terms:

(i) To determine whether there has been an unacceptable level of under-reporting in consequence of misreading and/or mis-reporting of abnormalities in cervical smears in the Gisborne region.

(ii) If you determine that there has been an unacceptable level of under-reporting, to identify the factors that are likely to have led to that under-reporting.

(iii) If you determine that there has been an unacceptable level of under-reporting, to satisfy yourselves whether or not this was an isolated case rather than evidence of a systemic issue for the National Cervical Screening Programme.

(iv) To identify changes already made to legislation, to laboratory or other processes or to professional practices to address the risks of under-reporting of abnormalities in cervical smears.

(v) To identify other changes agreed to be implemented, either by the Government or by professional organisations, that will further address any risks of under-reporting of abnormalities in cervical smears.

(vi) To consider all relevant proposals that could ameliorate any risks of under-reporting of abnormalities in cervical smears and identify whether these are covered by 4 or 5 above and whether further changes are needed.

(vii) To comment on any other issue the Inquiry Team believes to be of particular relevance.

(viii) To make recommendations, consistent with section 4(a) of the Health and Disability Services Act 1993, as to any further action the Government or its agencies should consider taking.

## Appendix 2

# The Committee of Inquiry's Recommendations

**Term of Reference Eight required the Committee of Inquiry –**

*To make recommendations, consistent with section 4(a) of the Health and Disability Services Act 1993, as to any further action the Government or its agencies should consider taking.*

**The following paragraphs are the Committee of Inquiry's response to this term of reference, and all material is directly taken from the Committee of Inquiry's report (section 11, pages 255 to 263).**

1. The remaining two phases of the national evaluation designed by the Otago University team must proceed. Until those phases are completed the Programme's safety for women cannot be known. It is imperative that this exercise is completed within the next six months. Particular attention should be given to the discrepancy between the average reporting rate of high-grade abnormalities of Douglass Hanly Moir Pathology (2.5%-3.7%) for the re-read of the Gisborne women's smear tests and the current New Zealand national average for reporting high-grade abnormalities (0.8%). Unless this exercise is carried out the possibility that the national average is flawed and that there is a systemic problem of under-reporting in New Zealand laboratories cannot be excluded.

2. If the national evaluation throws doubt on the accuracy of the current national average, then the Committee recommends that all women who are or who have participated in the Programme should be invited to re-enrol on the register as new entrants and they should be offered two smear tests 12 months apart. Women who have never enrolled on the Register or who have had their names removed from the Register should be invited through notices in the print media to also go through the process of having two smear tests twelve months apart.

3. A comprehensive evaluation of all aspects of the National Cervical Screening Programme which reflects the 1997 Draft Evaluation Plan developed by Doctors Cox and Richardson should be commenced within 18 months. This exercise should build upon the three-phase evaluation referred to in recommendation 1.

4. The *Policy And Quality Standards For The National Cervical Screening Programme* and the *Evaluation and Monitoring Plan For The National Cervical Screening Programme* prepared by Dr Julia Peters and her team must be implemented fully within the next 12 months.

5. There needs to be a full legal assessment of the *Policy and Quality Standards for the National Cervical Screening Programme* and the *Evaluation and*

*Monitoring Plan for the National Cervical Screening Programme* to ensure that the requisite legal authority to carry out these plans is in place.

6. The National Cervical Screening Programme should be thoroughly evaluated by lawyers to determine whether or not those persons charged with tasks under the Programme have the necessary legal authority to discharge them.

7. The National Cervical Screening Programme should issue annual statistical reports. These reports should provide statistical analysis to indicate the quality of laboratory performance. They should also provide statistical analysis of all other aspects of the Programme. They must be critically evaluated to identify areas of deficiency or weakness in the Programme. These must be remedied in a timely manner.

8. Meaningful statistical information should be generated from both the National Cervical Screening Register and the Cancer Register on a regular basis. Attention must be paid not only to laboratory reporting rates but also to trends and the incidence of the disease, assessed by regions that are meaningful to allow some correlation between reporting profiles of laboratories and the incidence of cancer. Because cervical smear tests may be read outside the region in which the smear test is taken, a recording system needs to be devised which identifies the region where smears are taken.

9. The compulsory setting of a minimum number of smears that should be read by laboratories each year must be put in place. The proposal to impose three minimum volume standards on laboratories must be implemented. These are: each fixed laboratory site will process a minimum of 15,000 gynaecological cytology cases; each pathologist will report at least 500 abnormal gynaecological cytology cases, cytotechnical staff must primary screen a minimum of 3,000 gynaecological cytology cases per annum. This should be implemented within 12 months.

10. There needs to be a balanced approach, which recognises the importance of all aspects of the National Cervical Screening Programme. The emphasis on smear taking and increasing the numbers of women enrolled on the Programme needs to be adjusted.

11. The culture which was developing in the Health Funding Authority regarding the management of the National Cervical Screening Programme under the management of Dr Julia Peters needs to be preserved and encouraged now that the Health Funding Authority has merged into the new Ministry of Health.

12. The National Cervical Screening Programme must be managed within the Ministry of Health as a separate unit by a manager who has the power to contract directly with the providers of the Programme on behalf of the Ministry. The Programme's delivery should not be reliant on the generic funding agreements the Ministry makes with providers of health services. For this purpose the unit will require its own budget.

13. The National Cervical Screening Programme should be under the control of a second or third tier manager within the Ministry. The Manager of the unit should as a minimum hold specialist medical qualifications in public health or epidemiology. As a consequence of the Programme's link with the Cartwright Report it has always had a female national co-ordinator. While there are understandable reasons for having the Programme managed by a woman it is not necessary for cervical screening programmes to have female managers. The cervical screening programme in New South Wales is managed by a male medical practitioner. The time has arrived for the National Screening Programme to be treated as a medical programme which is part of a national cancer control strategy. In the past its link with the Cartwright Report has at times resulted in its purpose as a cancer control strategy being compromised for non-medical reasons.

14. The Health Act 1956 should be amended to permit the National Cervical Screening Programme to be effectively audited, monitored and evaluated by any appropriately qualified persons irrespective of their legal relationship with the Ministry of Health. This requires an amendment to S.74A of the Health Act to permit such persons to have ready access to all information on the National Cervical Screening Register.

15. There needs to be a reconsideration of the Kaitiaki Regulations, and the manner in which those regulations currently affect the Ministry of Health gaining access to aggregate data of Maori women enrolled on the National Cervical Screening Register. The Ministry of Health and any appropriately qualified persons engaged by it (be they independent contractors, agents or employees) require ready access to the information currently protected by the Kaitiaki Regulations in order to carry out any audit, monitoring or evaluation of the Programme.

16. The present legal rights of access to information held on the Cancer Registry need to be clarified. The Ministry and any appropriately qualified persons it engages to carry out (external or internal) audits, monitoring or evaluation of cervical cancer incidence and mortality require ready access to all information stored on the Cancer Registry about persons registered as having cervical cancer.

17. The Health Act 1956 requires amendment to enable the Ministry of Health and any appropriately qualified persons it engages to carry out (external or internal) audits, monitoring or evaluation of cervical cancer incidence and mortality to have ready access to all medical files recording the treatment of the cervical cancer by all health providers who had a role in such treatment.

18. There needs to be change to guidelines under which ethics committees operate to make it clear that any (external and internal) audit, monitoring and evaluation of past and current medical treatment does not require the approval of ethics committees.

19. There should also be a review of the operation of ethics committees and the impact their decisions are having on independently funded evaluation exercises and on medical research generally in New Zealand.

20. Ethics committees require guidance regarding the application of the Privacy Act and the Privacy Health Information Code. Ethics committees need to be informed that the interpretation of legislation relating to personal privacy is for the agency holding a patient's data to decide. They would, therefore, benefit from having at least one legally qualified person on each regional committee.

21. Ethics committees require guidance regarding the weighing up of harms and benefits in assessing the ethics of observational studies.

22. A national ethics committee should be established for the assessment of multi-centre or national studies.

23. The procedures under which ethics committees operate need to be re-examined. Consideration should be given to processes to allow their decisions to be appealed to an independent body.

24. The National Cervical Screening Programme requires its own system to deal with complaints regarding the Programme's delivery. It also needs to have in place a user-friendly system which can respond to complaints of Programme failures, such as under-reporting. The difficulty that witness A experienced in having her medical misadventure recognised as a failure of the Programme and a failure of Gisborne Laboratories must be avoided in the future.

25. The National Cervical Screening Register needs to be electronically linked with the Cancer Register.

26. Performance standards should be put in place for the National Cervical Screening Register and the Cancer Registry. The currency of the data on both Registers needs to be improved. The Cancer Registry should be funded in a way that enables it to provide timely and accurate data that is meaningful.

27. Standards for the National Cervical Screening Programme should be reviewed every two years and more frequently if monitoring indicates that some of the standards are inappropriate.

28. The Government in consultation with other bodies or agencies needs to ensure that there are sufficient trained cytotechnologists and cytopathologists and that there are appropriate training sites for them. There should also be a review of the training requirements and maintenance of competence of smear test readers and cytopathologists.

29. The Medical Laboratory Technologists Regulations 1989 should be amended to permit only registered medical practitioners with specialist qualifications in pathology and appropriate training in cytopathology or appropriately trained cytoscreeners to read cervical smear tests.

30. Legal obligations in addition to those mandated by IANZ must be imposed on all laboratories reading cervical cytology requiring them to retain records of patients' cytology and histology results (including slides, reports and any other material relating to the patient) in safe storage for a period of no less than five years from the date on which the results were reported. Secondly all laboratory owners must made legally responsible for ensuring that a patient's records are readily accessible and properly archived during the five year storage period irrespective of changes in the laboratory's ownership through a sale of shares or a sale of the laboratory's business. The vendor of the shares or the laboratory's business should carry a primary legal responsibility to store the records, though the option to transfer this legal responsibility as a condition of the sale to the purchaser should be permitted. Similar provisions should apply to laboratory amalgamations. In this case the newly merged entity should be responsible for storing the records.

31. The cervical smear test and histology histories of women enrolled on the National Cervical Screening Register should be made electronically available online to all laboratories reading cervical cytology.

32. Standards must be developed for ensuring the accuracy of laboratory coding and this aspect of the National Cervical Screening Register must be subject to an appropriate quality assurance process.

33. The National Cervical Screening Programme should work towards developing a population based register and move away from being the utility based register that it now is.

34. There should be a legal obligation on the Accident Compensation Corporation, the Medical Council and the Health and Disability Commissioner to advise the National Cervical Screening Programme's manager of complaints about the professional performance of providers to the Programme when complaints are made to those various organisations about the treatment of a patient in relation to the Programme.

35. Consideration should be given to the addition of an express requirement in the provisions governing medical disciplinary proceedings which would oblige the Tribunal seized of the facts of any given case specifically to consider whether there are any grounds for concern that there may be a public health risk involved. If that concern is present the Tribunal should be required to inform the Minister of Health.

36. There should be an exchange of information between the Accident Compensation Corporation and Medical Council regarding claims for medical misadventure and disciplinary actions against medical practitioners.

37. It is recommended that the Programme liaise with the Royal College of Pathologists of Australia. In its submissions the Royal College advised that it believed that the collaborative relationship the college had with the Federal Government in Australia might be a model worth consideration by the Inquiry. It was suggested that it was appropriate to use medical colleges as an over-

arching body to provide advice on issues. The benefit of this is, if the College is asked to provide an opinion on issues such as professional practice, quality or standards, it has access to the views from multiple professionals and also a critical evaluation of current literature in contemporary standard practices. It is suggested that the National Cervical Screening Programme, which has achieved a great deal, would benefit from greater professional input at a College level. In particular, it is suggested that a National Cervical Cancer Register and a Cervical Cancer Mortality Review process be a means of continually evaluating the Programme's effectiveness. The Committee supports the College's submission and recommends that it be acted upon.

38. The Programme must provide women with information to enable them to make informed decisions about screening and provide them with information regarding potential risks and benefits. Until the Programme has been monitored and evaluated in accordance with the current three phase national evaluation the Programme has an obligation to inform women that the quality of the performance of some of its parts has not been tested. Women should also be informed that screening will not necessarily detect cervical cancer.

39. Medical practitioners need to be reminded that cervical smear tests are not a means of diagnosing cervical cancer. They need to be alert to signs of cervical cancer, and they should not place too much reliance on a patient's smear test results to discount the possibility of cervical cancer being present.

40. Primary screening of cervical smears should only be performed by individuals who are appropriately trained for that task. Consideration should be given to requiring pathologists to train as cytoscreeners if they want to function as primary screeners.

41. If cytology is a significant component of a pathologist's practice then he or she must participate in continuing medical education in that subject.

42. If cytology is a major component of a pathologist's practice, it is desirable that he or she should have added qualifications in cytopathology; either a fellowship slanted towards cytopathology or a diploma in cytopathology. Consideration should be given to making this a mandatory requirement.

43. Pathologists should be more open minded and critical of laboratory performance. They should be alert to the possibility that their practice or the practice of their colleagues may be sub-optimal.

44. The Medical Council should ensure that systems are in place whereby medical practitioners are not deterred from reporting to it their concerns about the practice of an individual medical practitioner. Complainants should be assured that their reports will not result in them being penalised in any way.

45. The screening programme should have in place a system over and above the audit and monitoring reports, to identify deficiencies in its process. A form of survey of users so that they can be proactive rather than reactive in the delivery of the programme would be useful.

46. A process to ensure that the recommendations made by the Committee are implemented should be put in place.

## Appendix 3

# Evaluation of the National Cervical Screening Programme

The Ministry called for tenders for an evaluation of the Programme in 1996. A team of medical experts from the University of Otago submitted a tender in June 1997, which proposed an evaluation of the Programme in terms of its effectiveness, acceptability, and cost effectiveness. The Ministry rejected the tender on cost grounds. However, the Committee of Inquiry recommended that a comprehensive evaluation of all aspects of the programme, along the lines of the tender, proceed within 18 months.

In addition to the elements set out below, this wider evaluation is now to be addressed as part of the regular monitoring and statistical reporting outlined in paragraphs 4.8 to 4.14 on pages 34-35. It will also cover:

- an assessment of the organisational features and recruitment strategies of the Programme;
- economic analysis; and
- evaluation of the effectiveness of the Programme for Maori and Pacific Island women.

After the Ministry rejected the original tender, it called for tenders for a more limited, three-part evaluation of the Programme. In May 1999, the team from the University of Otago was contracted to undertake a national evaluation of the Programme, consisting of the following three phases:

1. To establish the data required for monitoring and audit.
2. To examine the follow-up treatment of women with abnormal smears. The aim of this phase was to assess:
    - whether the treatment offered to women with abnormal smears met the Programme's guidelines for the management of abnormal smears, and whether all women with abnormal smears were followed up;
    - the proportion of women who continued to have abnormal smears after treatment of low-grade abnormalities and high-grade abnormalities;
    - the timeliness of follow-up for women who have had abnormal smears; and
    - the specificity of cervical screening in New Zealand.

3. To undertake an audit of invasive cervical cancer – a cancer audit.

The second and third phases of the evaluation had not been undertaken at the time the Committee of Inquiry reported, and it concluded that they must proceed. The NSU considers the Cancer Audit to be the largest and most complex project to implement in response to the Committee of Inquiry's recommendations.

The Cancer Audit will involve looking at the screening histories and management of 429 women diagnosed with invasive cervical cancer.[29] It will require the medical experts undertaking the Cancer Audit (whom we refer to as clinical reviewers) to have access to and examine:

- data on the Cancer Register, if available;
- the cytology histories and slides of the 429 women; and
- in many cases, their medical records – it currently appears that 49% of the women have no cytology history on the screening Register, and their records will be needed to establish (among other things) whether they have had smear tests taken.

The clinical reviewers may also need to interview the women.

[29] For Maori and Pacific Island women the period covered is 1 January 1998 to 30 June 2001. For other women the period covered is 1 January 2000 to 30 June 2001. A longer period for Maori and Pacific Island women was needed to obtain large enough numbers of women for the sample to be statistically significant and for the women not to be individually identifiable.